



**FINAL RANDOMIZED BLINDED PHASE (PART A) CLINICAL STUDY
REPORT ADDENDUM 1 (SAFETY FROM OPEN-LABEL PHASE
[PART B])**

**A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled
Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273
SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older**

PROTOCOL NUMBER

mRNA-1273-P301

Name of Test Product:	mRNA-1273
Indication:	COVID-19
ClinicalTrials.gov Identifier:	NCT04470427
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Drug Development Phase:	3
Study Initiation Date:	First participant first visit for Part A: 27 Jul 2020 First patient decision visit for Part B: Dec 2020
Part B Analysis Cutoff Date:	Data cutoff for Part B: 26 Mar 2021 The analyses presented in this report are based on a database lock date of 04 May 2021
Sponsor Medical Officer:	Allison August, MD
Date of Original Report:	05 Aug 2021
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The study was conducted according to the International Council for Harmonisation
harmonised tripartite guideline E6(R2): Good Clinical Practice.

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Synopsis

Title of Study: A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older

Investigator(s): This was a multicenter study.

Study Center(s): This study was conducted at 99 study sites in the United States.

Publication(s) (Reference): Refer to the mRNA-1273-P301 Part A clinical study report (CSR) for relevant publications describing Part A results. No publications reporting Part B data have been submitted.

Study Period (Years): 27 Jul 2020 (First participant first visit-Part A)

Dec 2020 (First participant decision visit)

26 Mar 2021 (data cutoff date)

Drug Development Phase: 3

Background and Rationale: On 18 Dec 2020, the US FDA granted emergency use authorization (EUA) for the mRNA-1273 vaccine for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. This was the second EUA for COVID-19 vaccines after the EUA granted for the Pfizer-BioNTech vaccine on 11 Dec 2020. Following EUA approval of COVID-19 vaccines, there was a substantial increase in withdrawals of EUA-eligible participants who opted to be immunized with authorized vaccines, given that all participants in this study had to meet the inclusion criterion for increased risk of COVID-19 disease based on circumstances or geography. To preserve the remaining participants in the study while still enabling them to be vaccinated against SARS-CoV-2, the clinical protocol for this study was subsequently amended to adapt the study design to a 2-part Phase 3 study: Part A and Part B. Part A, the Blinded Phase was a randomized, stratified, observer-blind, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine compared to placebo in adults 18 years of age and older who have no known history of SARS-CoV-2 infection but

whose occupation or location and living circumstances put them at increased risk of acquiring COVID-19 and/or SARS-CoV-2 infection.

Given that the primary efficacy endpoint for mRNA-1273 against COVID-19 was met per the protocol-defined interim analysis (IA), Part B, the Open-Label Observational Phase was designed to offer participants who received placebo in Part A of this study and who met EUA eligibility an option to request 2 doses of mRNA-1273 vaccine and remain on study. After the EUA was granted for COVID-19 vaccines, and prior to the mRNA-1273 P301 protocol amendment, which allowed unblinding, there were several hundred participants who unblinded early or discontinued the study to receive vaccine under EUA. Part B was prompted by the EUA and permitted all ongoing study participants to (a) be informed of the availability and eligibility criteria of any COVID-19 vaccine made available under EUA and (b) the option to offer all ongoing study participants who request unblinding an opportunity to schedule a participant decision visit (PDV) to know their original group assignment (placebo vs. mRNA-1273 vaccine). All participants in Part A were to proceed to Part B, starting with a PDV, at which time participants were given the option to be unblinded to their original group assignment.

The results of Part A (database lock was performed on 04 May 2021 and includes data for each individual participant up to early unblinding, study discontinuation, the Part B PDV, or data cutoff date [26 Mar 2021], whichever was earlier) are presented in the Part A CSR.

The purpose of this addendum is to present data (descriptive summaries) from the Open-Label Observational Phase (Part B) of the study based on the database lock on 04 May 2021 and includes safety (unsolicited adverse events [AEs], serious adverse events [SAEs], medically-attended AEs [MAAEs], and AEs leading to discontinuation) and efficacy (case counts) data from early unblinding or the Part B PDV to the data cutoff date (26 Mar 2021). Part A (Blinded Phase, randomization to early unblinding or PDV) of the study provides a median of 148 days of follow-up. Part B (Open-Label Observational Phase, early unblinding or PDV to data cutoff date) of the study provides additional follow-up of a median of 67 days. The total median follow-up period was 7.6 months from randomization or 6.5 months after Dose 2 across Part A and Part B up to database lock for the analysis, aligned with published regulatory guidance regarding the necessary data package for the evaluation of COVID-19 vaccines.

Objectives: The study objectives and endpoints for this study are presented in the final randomized blinded phase (Part A) CSR.

Methodology: Study mRNA-1273-P301 has two parts: Part A, the Blinded Phase and Part B, the Open-Label Observational Phase.

Part A was a randomized, stratified, observer-blind, placebo-controlled evaluation of the efficacy, safety, and immunogenicity of mRNA-1273 SARS CoV-2 vaccine compared to placebo in adults 18 years of age or older. A total of 30,415 participants were randomly assigned to receive doses of either 100 µg of mRNA-1273 vaccine or placebo in a 1:1 randomization ratio. Given that the primary efficacy endpoint for mRNA-1273 against COVID-19 was met per the protocol-defined IA, Part B, the Open-Label Observational Phase of this study, was designed to offer participants who received placebo in Part A of this study and who met EUA eligibility an option to request open-label mRNA-1273. All participants in Part A were to proceed to Part B, starting with a PDV, at which time participants were given the option to be unblinded to their original group assignment. At the initiation of Part B, site personnel who were blinded during Part A were unblinded at the participant level at the PDV.

This CSR addendum provides the safety and efficacy results of Part B from early unblinding or the PDV through data cutoff date (26 Mar 2021).

Participants who requested to not be unblinded, who requested to be unblinded but received mRNA-1273 in Part A, and who requested to be unblinded and received placebo in Part A and chose to remain on placebo were to continue the original study schedule of events (SoE).

Participants who were unblinded, received placebo in Part A, were EUA eligible, and requested to receive mRNA-1273 were planned to have the following additional clinic visits as shown the Supplemental SoE ([mRNA-1273-P301 Clinical Study Protocol](#) Table 21 [[Appendix 16.1.1](#)]).

- Open-label Dose 1 (OL-D1): occurred at the PDV or at a scheduled subsequent visit.
- Open-label Dose 2 (OL-D29): occurred 28 days after Dose 1 on OL-D1.
- Open-label Clinic Visit (OL-D57): occurred 1 month after Dose 2 on OL-D29.
- Participants were to continue to comply with the original study SoE ([mRNA-1273-P301 Clinical Study Protocol](#) Table 16, Table 17, Table 18, and Table 19) as applicable.

Participants who were unblinded, received only 1 dose of mRNA-1273 in Part A, were EUA eligible, and requested to receive mRNA-1273 were planned to have the following additional clinic visits as shown in the Modified Supplemental SoE ([mRNA-1273-P301 Clinical Study Protocol](#) Table 22 [[Appendix 16.1.1](#)]).

- Their second dose on OL-D1: occurred at the PDV or at a scheduled subsequent visit.
- Open-label Clinic Visit (OL-D29): occurred 1 month after Dose 2 on OL-D1.

Participants receiving only 1 dose of mRNA-1273 in Part A were eligible to receive the second dose of mRNA-1273 under the following circumstances:

- They had a dosing error in Part A of the study that resulted in 1 dose of mRNA-1273 and 1 dose of placebo being administered.
- They did not have an AE that contraindicated the second dose of mRNA-1273 in Part A of the study.
- They did not withdraw consent in Part A of the study.
- They did not complete their second dose in Part A of the study for reasons other than the above.

All participants are expected to complete 24 months of follow-up after the second injection; study participants who entered the Supplemental or Modified Supplemental SoE did so in addition to their original SoE. Accordingly, all study participants are planned to complete the full study follow-up to 24 months after the second injection in Part A (mRNA-1273 or placebo).

Efficacy endpoints included COVID-19 cases, severe COVID-19 cases, COVID-19 cases using the secondary definition of COVID-19, cases of SARS-CoV-2 infection regardless of symptomatology and severity, and cases of asymptomatic SARS-CoV-2 infection.

Safety assessments included unsolicited AEs, MAAEs, SAEs, AEs leading to discontinuation from injection and/or study participation, pregnancy and accompanying outcomes, and concomitant medications and non-study vaccinations.

Number of Subjects (Planned and Analyzed): Approximately 30,000 participants were planned to receive doses of either 100 µg of mRNA-1273 vaccine or placebo in a 1:1 randomization ratio in Part A.

In Part A, a total of 30,415 participants were randomized: 15,206 in the placebo group and 15,209 in the mRNA-1273 group.

A total of 28,964 participants started Part B. Of these, 14,618 participants received mRNA-1273 in Part A (referred as mRNA-1273 group); 1698 participants received placebo in Part A and chose to remain in the placebo group; 12,648 participants received placebo in Part A and chose to receive mRNA-1273 in Part B (referred as placebo–mRNA-1273 group).

Diagnosis and Main Criteria for Inclusion and Exclusion: Refer to the Part A CSR for the inclusion and exclusion criteria for the study.

Test Product, Dose and Mode of Administration, Batch Number(s): In Part B, participants who were unblinded, received placebo in Part A, and requested to receive mRNA-1273, were administered an 0.5 mL intramuscular (IM) injection containing 100 µg of mRNA-1273 (Lot Numbers: 7006121001, 7006320002, 7006320003, 7006320005, 7006320006, 7006320008, 7006320010, 7007421001, 7007421002) into the deltoid muscle on a 2-dose injection schedule on Open Label Day 1 and Day 29.

Participants who were unblinded, received only 1 dose of mRNA-1273 in Part A, and requested to receive mRNA-1273 were administered a single dose of 0.5 mL IM injection containing 100 µg of mRNA-1273 (Lot Numbers: 7006121001, 7006320002, 7006320003, 7006320005, 7006320006, 7006320008, 7006320010, 7007421001, 7007421002) into the deltoid muscle on Open Label Day 1.

Control Product, Dose and Mode of Administration, Batch Number(s): Placebo; participants who requested to be unblinded in Part B and received placebo in Part A and chose to remain on placebo. These participants had received placebo (0.9% sodium chloride) as an 0.5 mL IM injection into the deltoid muscle on an identical schedule as mRNA-1273 during Part A of the study only, and they did not receive any additional placebo injections.

Duration of Treatment: Two doses of mRNA-1273 28 days apart (Day 1 and Day 29) for participants who were unblinded, received placebo in Part A, and requested to receive mRNA-1273 in Part B. A single dose on Day 1 for participants who were unblinded, received only 1 dose of mRNA-1273 in Part A, and requested to receive mRNA-1273 in Part B.

Estimands and Intercurrent Events: Refer to the Part A CSR for estimands and intercurrent events.

Statistical Methods: The following analysis periods and treatment groups were used for efficacy analyses for Part B:

Part B Group	Per-Protocol Set Sample Size	Description	Part B Analysis Period for Efficacy
mRNA-1273	14,287	Participants randomized to mRNA-1273 in Part A	From PDV/early unblinding to the earlier of 2 potential dates: data cutoff date for efficacy (26 Mar 2021) or the last observed in study date, where last observed was defined as the earliest of the following possibilities: study discontinuation, study completion, or death.
Placebo	2104	Participants randomized to placebo in Part A and did not receive mRNA-1273 in Part B	

The following analysis period and treatment groups were used for safety analyses for Part B:

Part B Group	Safety Set Sample Size	Description	Part B Analysis Period for Safety
mRNA-1273	15,184	Participants received at least 1 dose of mRNA-1273 in Part A	From PDV/early unblinding to the earlier of 2 dates: the data cutoff date for safety (26 Mar 2021) or the date last observed in the study. If a participant received mRNA-1273 in Part B, from the first date of study vaccine in Part B to the earlier of 2 dates: data cutoff date for safety (26 Mar 2021) or the date last observed in the study. Last observed was defined as the earliest of the following possibilities: study discontinuation, study completion, or death.
Placebo	2514	Participants only received Placebo in Part A and did not receive mRNA-1273 in Part B	From PDV/early unblinding to the earlier of 2 dates: data cutoff date for safety (26 Mar 2021) or the date last observed in study. Last observed was defined as the earliest of the following possibilities: study discontinuation, study completion, or death.
Placebo-mRNA-1273	12,648	Participants only received Placebo in Part A and received mRNA-1273 in Part B	From first dose of mRNA-1273 in Part B to earlier of 2 dates: data cutoff date for safety (26 Mar 2021) or the date last observed in the study. Last observed was defined as the earliest of the following possibilities: study discontinuation, study completion, or death.

Summary of Results:

Subject Disposition: A total of 28,964 participants started Part B (participants who had PDV or early unblinding). Of these, 14,618 participants received mRNA-1273 in Part A (referred as mRNA-1273 group); 1698 participants received placebo in Part A and chose to remain in the placebo group; 12,648 participants received placebo in Part A and chose to receive mRNA-1273 in Part B (referred as placebo–mRNA-1273 group) and received at least 1 dose of the vaccine.

Of 12,648 participants in the placebo-mRNA-1273 group, 19 participants discontinued the study vaccine.

There were 195 participants who received 1 dose of mRNA-1273 during Part A and received the second dose of mRNA-1273 in Part B in the Safety Set.

A total of 1698/30,346 (5.6%) participants discontinued the study in Part B; 290/15,184 (1.9%) participants in the mRNA-1273 group, 1357/2514 (54.0%) participants in the placebo group, and 51/12,648 (0.4%) participants in the placebo-mRNA-1273 group. The most common reasons for study discontinuations were protocol deviations, withdrawal of consent by participant, and other reasons.

Efficacy

The purpose of this CSR addendum is to provide the efficacy results of Part B based on the median follow-up of 67 days. For the purpose of this CSR addendum, efficacy results are provided for mRNA-1273 and placebo group in text and in summary tables (case counts and incidence rate). For the placebo-mRNA-1273 group, incidence rates are not reported as this group had a relative short duration of follow-up after the second dose of mRNA-1273 in Part B, therefore, efficacy results for the placebo-mRNA-1273 group are not described in this CSR addendum.

For efficacy analyses in Part B, participants at risk were defined as participants who started the open-label phase before or on the efficacy data cutoff date, had no prior SARS-CoV-2 infection (defined by positive postbaseline RT-PCR or Elecsys results) and were not a COVID-19 case up to PDV or early unblinding, whichever was earlier.

Primary endpoint:

In the mRNA-1273 group, of 13,704 participants at risk, 19 (0.1%) adjudicated COVID-19

cases were detected in the per-protocol (PP) Set during the Part B of the study. The corresponding incidence rate for the mRNA-1273 group remained low (7.961 cases per 1000 person-years; 95% confidence interval [CI]: 4.793, 12.432). The results in Part B are consistent with Part A, where the incidence rate in the mRNA-1273 group was 9.599 cases per 1000 person-years (95% CI: 7.231, 12.494) which confirms the persistence of efficacy in the mRNA-1273 group. In the placebo group, of 1,175 participants at risk, 3 (0.3%) adjudicated COVID-19 cases were detected. The incidence rate for the placebo group was 77.378 cases per 1000 person-years; (95% CI: 15.957, 226.131), which was 10-fold higher than in the mRNA-1273 group.

	Part A final analysis (Median follow-up from randomization to early unblinding or PDV: 148 days)		Part B (Median follow-up from early unblinding or PDV to data cutoff: 67 days)		
	mRNA-1273 (N=14287)	Placebo (N=14164)	mRNA-1273 (N=14287)	Placebo (N=2104)	Placebo-mRNA-1273 (N=12060)
Number of subjects at risk ^a	–	–	13704	1175	11234
Number of subjects with COVID-19* n (%) ^b	55 (0.4)	744 (5.3)	19 (0.1)	3 (0.3)	56 (0.5)
Before first injection of mRNA-1273 in open-label phase	–	–	–	–	17 (0.2)
Between first injection and second injection of mRNA-1273 in open-label phase	–	–	–	–	37 (0.3)
After second injection of mRNA-1273 in open-label phase	–	–	–	–	2 (<0.1)
Number of subjects censored, n (%) ^b	14232 (99.6)	13420 (94.7)	13685 (99.9)	1172 (99.7)	11178 (99.5)
Person-years ^c	5729.9	5445.2	2386.6	38.8	–
Incidence rate per 1,000 person-years (95% CI) ^d	9.599 (7.231, 12.494)	136.633 (126.991, 146.814)	7.961 (4.793, 12.432)	77.378 (15.957, 226.131)	–

Abbreviations: CI = confidence intervals; COVID-19 = coronavirus disease 2019; PDV = participant decision visit; RT-PCR = reverse transcription polymerase chain reaction

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at scheduled visits without eligible symptoms within 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

^a. Subjects at risk are defined as subjects who started the open-label phase before or on efficacy data cutoff date, had no prior SARS-CoV-2 infection (defined by positive postbaseline RT-PCR or Elecsys results) and were not a disease COVID-19 case up to PDV or early unblinding, whichever is earlier.

^b. Percentages in Part B are based on number of subjects at risk.

- c. Person-years is defined as the total years from randomization date (Part A) or PDV/early unblinding date (Part B) to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- d. Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

Secondary endpoints:

Severe COVID-19: The number of severe COVID-19 cases in Part B were too low in the PP Set for any meaningful comparison.

Secondary Definition of COVID-19: In the mRNA-1273 group, of 13,704 participants at risk, 39 (0.3%) COVID-19 cases using the secondary definition for COVID-19 in the PP set were detected. The incidence rate in Part B was 16.357 cases per 1000 person-years; (95% CI: 11.631, 22.360). The results are consistent with Part A (10.124 cases per 1000 person-years; 95% CI: 7.688, 13.088) and supported the persistence of efficacy of mRNA-1273. In the placebo group, of 1,175 participants at risk, 4 (0.3%) COVID-19 cases using the secondary definition for COVID-19 in the PP set were detected. The incidence rate in Part B was 103.713 cases per 1000 person-years; (95% CI: 28.258, 265.546), and the incidence rate in Part A was 148.525 cases per 1000 person-years; (95% CI: 138.453, 159.136).

The RT-PCR results and anti-nucleocapsid bAb as measured by Elecsys assay at PDV were included in the analyses of SARS-CoV-2 infection regardless of symptomatology and severity and asymptomatic infection in Part A CSR. No further analyses are provided for the open-label phase.

Safety

The safety assessments included unsolicited AEs MAAEs, SAEs, and AEs leading to withdrawal from study vaccine and/or study from early unblinding or PDV to data cutoff date.

The purpose of this CSR addendum is to provide additional safety follow-up data based on median follow-up of 67 days in Part B for those remaining in the original randomized groups (mRNA-1273 and placebo groups) beyond early unblinding or the PDV up to the data cutoff date (26 Mar 2021), which yielded a total observation period of 7.6 months from randomization or 6.5 months after Dose 2 across Part A and Part B. In addition, data from the placebo group participants who were vaccinated with mRNA-1273 (placebo-mRNA-1273

group) in Part B were collected to further expand the safety evaluation of mRNA-1273 from this newly vaccinated group.

Overall, no new safety concerns were identified in Part B.

Unsolicited treatment-emergent AEs (TEAEs)

In the mRNA-1273 group, 1729/15,184 (11.4%) participants experienced 2557 TEAEs in the Safety Set. Of these, 22/15,184 (0.1%) participants experienced TEAEs related to the study vaccine. No unsolicited TEAE (preferred term [PT]) occurred in $\geq 1\%$ of participants. No unexpected findings or new trend appeared in unsolicited TEAEs in the mRNA-1273 group.

In the placebo group, 41/2514 (1.6%) participants experienced 66 TEAEs in the Safety Set. No participants had TEAEs considered related to the study vaccine. No unsolicited TEAE (PT) occurred in $\geq 1\%$ of participants.

In the placebo-mRNA-1273 group, 2446/12,648 (19.3%) participants experienced 4814 TEAEs in the Safety Set. Of these, 758/12,648 (6.0%) participants experienced TEAEs related to study vaccine. The most common unsolicited TEAEs (at least 1% of participants) were injection site pain (451 [3.6%] participants), headache (233 [1.8%] participants), fatigue (211 [1.7%] participants), pain (175 [1.4%] participants), pyrexia (167 [1.3%] participants), chills (136 [1.1%] participants), and hypertension (129 [1.0%] participants). The commonly reported events were generally consistent with reactogenicity and the unsolicited adverse events reported within the 28-day follow-up period after vaccination in the mRNA-1273 group observed in Part A.

Deaths

As of the data cutoff date of this CSR addendum, 12 participants died in Part B.

A total of 8/15,184 ($<0.1\%$) participants in the mRNA-1273 group died (median time from PDV: 46.5 days) during Part B: cardiac TEAEs in 3 participants (cardiac arrest, myocardial infarction, and acute myocardial infarction in 1 participant each); head injury in 1 participant; pulmonary embolism, gastrointestinal hemorrhage, and pulseless electrical activity in 1 participant; cerebrovascular accident in 1 participant; and sudden death (unknown cause) for 1 participant. One participant experienced an SAE of pulmonary mass before PDV (during Part A) and died during Part B.

In the placebo group, 1/2514 (<0.1%) participant (age 84 years) died 9 days after the PDV due to ventricular arrhythmia.

A total of 3/12,648 (<0.1%) participants in the placebo–mRNA-1273 group died (median time from PDV: 54 days) during Part B: congestive cardiac failure, gastrointestinal hemorrhage, and anticoagulation drug level above therapeutic range in 1 participant; accidental drug overdose in 1 participant; and cerebrovascular accident in 1 participant.

None of the participants died due to COVID-19. None of the deaths was considered related to the study vaccine.

SAEs

In the mRNA-1273 group, 141/15,184 (0.9%) participants reported 181 SAEs. All individual SAEs (PT) were reported in <0.1% of participants. No SAEs were considered related to the study vaccine. Overall, no new safety concern was identified.

In the placebo group, 7/2514 (0.3%) participants reported 8 SAEs. No SAEs were considered related to the study vaccine.

In the placebo-mRNA-1273 group, 148/12,648 (1.2%) participants reported 190 SAEs. All individual SAEs (PT) were reported in <0.1% of participants. Serious AEs considered by the investigator to be related to the study vaccine were reported in 4 participants: paraesthesia, muscular weakness, spontaneous abortion, and autoimmune thyroiditis. All events resolved within 2 days except autoimmune thyroiditis which was ongoing at the time of data cutoff. In addition, 1 participant experienced an SAE (considered as related to the study vaccine by the investigator) of pericardial effusion in Part B before data cutoff but was reported by site after the database lock.

Unsolicited TEAEs leading to discontinuation from the study vaccine and the study

The participant incidence of TEAEs leading to study discontinuation was low (7/15,184 participants in the mRNA-1273 group, 1/2514 participant in the placebo group, and 4/12,648 participants in the placebo–mRNA-1273 group); none of the events was considered related to study vaccine by the investigator.

In the placebo–mRNA-1273 group, 12/12,648 (<0.1%) participants discontinued the study vaccine due to TEAEs. Of these 12 participants, 4 participants discontinued the vaccine because of nonserious TEAEs that were considered by the investigator to be vaccine-related.

One participant discontinued the vaccine because of Grade 1 chills. The participant experienced the event 34 days after receiving the first dose. The event resolved after 2 days.

One participant discontinued the vaccine because of Grade 2 urticaria. The participant experienced the event 1 day after receiving the first dose. The event resolved after 3 days.

One participant discontinued the vaccine because of Grade 3 parotitis. The participant experienced the event 11 days after receiving the first dose. The event was ongoing at the time of data cutoff.

One participant (64-year-old) discontinued the vaccine because of Grade 2 unilateral deafness. The participant experienced the event 5 days after receiving the first dose of mRNA-1273 in Part B. The event was resolving at the time of data cutoff.

MAAEs

In the mRNA-1273 group, 1457/15,184 (9.6%) participants experienced 2067 MAAEs. Of these, 9 (<0.1%) participants experienced MAAEs related to the study vaccine. All MAAEs (PT) were reported in <1% of participants. The most common MAAEs ($\geq 0.4\%$ of participants) were hypertension (69/15,184 [0.5%] participants), urinary tract infection (65/15,184 [0.4%] participants), and COVID-19 (32/15,184 [0.2%] participants). Overall, no new safety concern was identified related to MAAEs.

In the placebo group, 37/2514 (1.5%) participants experienced 51 MAAEs. All MAAEs (PT) were reported in $\leq 0.1\%$ of participants.

In the placebo–mRNA-1273 group, 1509/12,648 (11.9%) participants experienced 2202 MAAEs. Of these, 74 (0.6%) participants experienced MAAEs related to the study vaccine. All MAAEs (PT) were reported in <1% of participants. The most common MAAEs ($\geq 0.4\%$ of participants) were hypertension (98/12,648 [0.8%] participants) and urinary tract infection (59/12,648 [0.5%] participants), and COVID-19 (51/12,648 [0.4%] participants).

Pregnancies

According to the safety database, a total of 37 pregnancies were reported (19 in the placebo-mRNA-1273 group and 18 in the mRNA-1273 group) during Part B of the study. Of the outcomes known as of 04 May 2021, 4 participants (3 in the placebo-mRNA-1273 group and 1 in the mRNA-1273 group) experienced spontaneous abortion; of these, the event in 1 participant in the placebo-mRNA-1273 group was considered related to the study vaccine by the investigator.

One participant in the placebo-mRNA-1273 group underwent elective termination of pregnancy; there were no reported pregnancy complications for this participant.

Conclusions: In conclusion, efficacy of mRNA-1273 to prevent COVID-19 persisted in Part B. The safety profile of mRNA-1273 remained acceptable, similar to that observed in Part A, and no new safety concerns were noted. The benefit/risk profile of mRNA-1273 remains strongly favorable through 6.5 months median follow-up after Dose 2.

Original Report Date (Part A CSR): 05 Aug 2021

Report Addendum Date: 05 Aug 2021

List of Abbreviations and Definition of Terms

Abbreviation	Definition
AE	adverse event
AR	adverse reaction
bAb	binding antibodies
CDC	Centers for Disease Control and Prevention
CI	confidence interval
COVID-19	coronavirus disease 2019
CSR	clinical study report
EUA	emergency use authorization
HCP	healthcare practitioner
IA	interim analysis
IM	intramuscular
INR	international normalized ratio
LLOQ	lower limit of quantification
MAAE	medically-attended AE
mITT	modified intent-to-treat
OL	open-label
PDV	participant decision visit
PP	per-protocol
PT	preferred term
SAE	serious adverse event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SOC	system organ class
SoE	schedule of events
TEAE	treatment-emergent AE

1 Introduction

1.1 Background

Refer the Part A Clinical Study Report (CSR) (Section 1.1).

1.2 Nonclinical Studies

A summary of the nonclinical studies conducted for mRNA-1273 is provided in the Part A CSR (Section 1.2).

1.3 Clinical Studies

A summary of the clinical studies conducted for mRNA-1273 is provided in the Part A CSR (Section 1.3).

1.4 Study Rationale

On 18 Dec 2020, the US FDA granted emergency use authorization (EUA) for the mRNA-1273 vaccine for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. This was the second EUA for COVID-19 vaccines after the EUA granted for the Pfizer-BioNTech vaccine on 11 Dec 2020. Following EUA approval of COVID-19 vaccines, there was a substantial increase in withdrawals of EUA-eligible participants who opted to be immunized with authorized vaccines, given that all participants in this study had to meet the inclusion criterion for increased risk of COVID-19 disease based on circumstances or geography. To preserve the remaining participants in the study while still enabling them to be vaccinated against SARS-CoV-2, the clinical protocol for this study was subsequently amended to adapt the study design to a 2-part Phase 3 study: Part A and Part B. Part A, the Blinded Phase was a randomized, stratified, observer-blind, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine compared to placebo in adults 18 years of age and older who have no known history of SARS-CoV-2 infection but whose occupation or location and living circumstances put them at increased risk of acquiring COVID-19 and/or SARS-CoV-2 infection.

Given that the primary efficacy endpoint for mRNA-1273 against COVID-19 was met per the protocol-defined interim analysis (IA), Part B, the Open-Label Observational Phase was designed to offer participants who received placebo in Part A of this study and who met EUA

eligibility an option to request 2 doses of mRNA-1273 vaccine and remain on study. After the EUA was granted for COVID-19 vaccines, and prior to the mRNA-1273 P301 protocol amendment, which allowed unblinding, there were several hundred participants who unblinded early or discontinued the study to receive vaccine under EUA. Part B was prompted by the EUA and permitted all ongoing study participants to (a) be informed of the availability and eligibility criteria of any COVID-19 vaccine made available under EUA and (b) the option to offer all ongoing study participants who request unblinding an opportunity to schedule a Participant Decision Visit (PDV) to know their original group assignment (placebo vs. mRNA-1273 vaccine). All participants in Part A were to proceed to Part B, starting with a PDV, at which time participants were given the option to be unblinded to their original group assignment.

The results of Part A (database lock was performed on 04 May 2021 and includes data for each individual participant up to early unblinding, study discontinuation, the Part B PDV, or data cutoff date [26 Mar 2021], whichever was earlier) are presented in the Part A CSR. This CSR addendum presents the data from Part B (from PDV or early unblinding) up to the data cutoff date of 26 Mar 2021.

2 Study Objectives and Endpoints

The study objectives and endpoints for this study are presented in the final randomized blinded phase (Part A) CSR.

The purpose of this addendum is to present data (descriptive summaries) from the Open-Label Observational Phase (Part B) of the study based on the database lock on 04 May 2021 and includes safety (unsolicited AEs, serious adverse events [SAEs], medically-attended AEs [MAAEs], and AEs leading to discontinuation) and efficacy (case counts) data from early unblinding or the Part B PDV to the data cutoff date (26 Mar 2021). Part A (Blinded Phase, randomization to early unblinding or PDV) of the study provides a median of 148 days of follow-up. Part B (Open-Label Observational Phase, early unblinding or PDV to data cutoff date) of the study provides additional follow-up of a median of 67 days. The total median follow-up period was 7.6 months from randomization or 6.5 months after Dose 2 across Part A and Part B up to database lock for the analysis, aligned with published regulatory guidance regarding the necessary data package for the evaluation of COVID-19 vaccines.

3 Investigational Plan

3.1 Overall Study Design and Plan

Study mRNA-1273-P301 has two parts: Part A, the Blinded Phase and Part B, the Open-Label Observational Phase.

Part A was a randomized, stratified, observer-blind, placebo-controlled evaluation of the efficacy, safety, and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine compared to placebo in adults 18 years of age or older. A total of 30,415 participants were randomly assigned to receive doses of either 100 µg of mRNA-1273 vaccine or placebo in a 1:1 randomization ratio. Given that the primary efficacy endpoint for mRNA-1273 against COVID-19 was met per the protocol-defined IA, Part B, the Open-Label Observational Phase of this study, was designed to offer participants who received placebo in Part A of this study and who met EUA eligibility an option to request open-label mRNA-1273. All participants in Part A were to proceed to Part B, starting with a PDV, at which time participants were given the option to be unblinded to their original group assignment. At the initiation of Part B, site personnel who were blinded during Part A were unblinded at the participant level at the PDV.

All participants may have attended up to 8 scheduled clinic visits, including Screening Day 1, Day 29, Day 57, Day 209, Day 394, Day 759, and the PDV as specified in the Schedule of Events (SoE; [mRNA-1273-P301 Clinical Study Protocol](#) Table 16 [Vaccination Phase, Day 1 - Day 57], Table 17 [Surveillance Phase, Day 64 - Day 394], Table 18 [Surveillance Phase, Day 401 - Day 759], Table 19 [Convalescent Period, Starting with the Illness Visit], and Table 20 [Part B: Participant Decision Clinic Visit]; [Appendix 16.1.1](#)). Participants eligible for Part B dosing may have had up to 3 additional scheduled clinic visits as specified in the SoE ([mRNA-1273-P301 Clinical Study Protocol](#) Table 21 [Open-Label Observational Phase - Placebo Participants who request to receive mRNA-1273] and Table 22 [Open-Label Observational Phase – mRNA-1273 Participants who ONLY received 1 dose of mRNA-1273]; [Appendix 16.1.1](#)).

This CSR addendum provides the safety and efficacy results of Part B from early unblinding or the PDV through data cutoff date (26 Mar 2021). A schematic diagram of Part B is provided in [Figure 3-1](#).

Participants who requested to not be unblinded, who requested to be unblinded but received mRNA-1273 in Part A, and who requested to be unblinded and received placebo in Part A and chose to remain on placebo were to continue the original study SoEs.

Participants who were unblinded, received placebo in Part A, were EUA eligible, and requested to receive mRNA-1273 were planned to have the following additional clinic visits as shown the Supplemental SoE ([mRNA-1273-P301 Clinical Study Protocol](#) Table 21 [[Appendix 16.1.1](#)]).

- Open-label Dose 1 (OL-D1): occurred at the PDV or at a scheduled subsequent visit.
- Open-label Dose 2 (OL-D29): occurred 28 days after Dose 1 on OL-D1.
- Open-label Clinic Visit (OL-D57): occurred 1 month after Dose 2 on OL-D29.
- Participants were to continue to comply with the original study SoE ([mRNA-1273-P301 Clinical Study Protocol](#) Table 16, Table 17, Table 18, and Table 19) as applicable.

Participants who were unblinded, received only 1 dose of mRNA-1273 in Part A, were EUA eligible, and requested to receive mRNA-1273 were planned to have the following additional clinic visits as shown in the Modified Supplemental SoE ([mRNA-1273-P301 Clinical Study Protocol](#) Table 22 [[Appendix 16.1.1](#)]).

- Their second dose on OL-D1: occurred at the PDV or at a scheduled subsequent visit.
- Open-label Clinic Visit (OL-D29): occurred 1 month after Dose 2 on OL-D1.

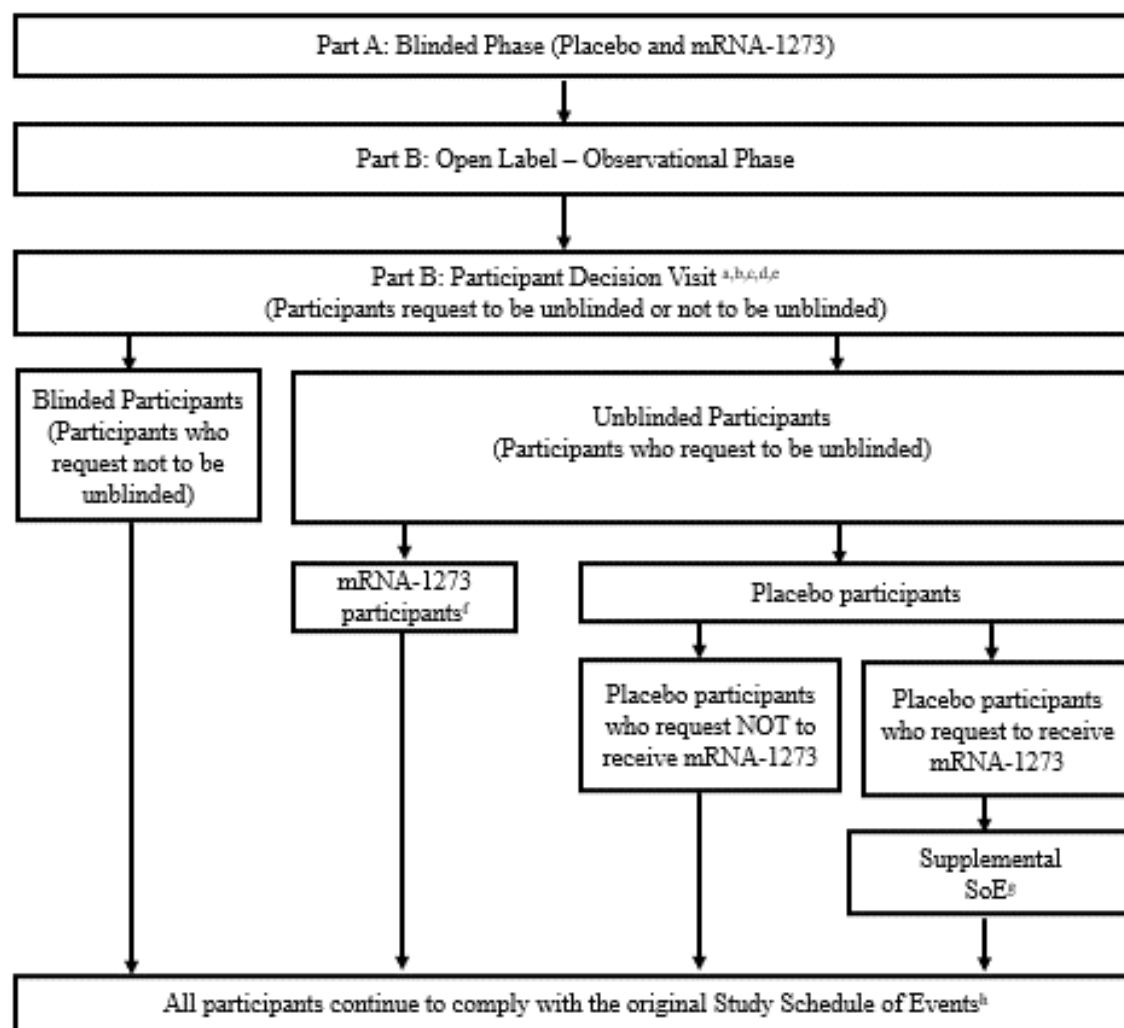
Participants receiving only 1 dose of mRNA-1273 in Part A were eligible to receive the second dose of mRNA-1273 under the following circumstances:

- They had a dosing error in Part A of the study that resulted in 1 dose of mRNA-1273 and 1 dose of placebo being administered.
- They did not have an AE that contraindicated the second dose of mRNA-1273 in Part A of the study.
- They did not withdraw consent in Part A of the study.
- They did not complete their second dose in Part A of the study for reasons other than the above.

All participants are expected to complete 24 months of follow-up after the second injection; study participants who entered the Supplemental or Modified Supplemental SoE did so in addition to their original SoE. Accordingly, all study participants are planned to complete the full study follow-up to 24 months after the second injection in Part A (mRNA-1273 or placebo).

Full details of the investigational plan are presented in the Part A CSR (Section 3).

Figure 3-1 Part B, the Open-Label Observational Phase



^a All participants were encouraged to remain in the study.

^b All participants were given the option to be unblinded to treatment received in Part A: Blinded Phase.

^c All participants were counselled about the importance of continuing other public health measures to limit the spread of disease including physical-social distancing, wearing a mask, and hand-washing.

^d All participants signed a revised informed consent form.

^e All participants consented to provide a nasopharyngeal swab and a blood sample for immunologic analysis.

^f mRNA-1273 recipients who only received 1 dose of the mRNA-1273 vaccine received the second dose of mRNA-1273 vaccine. Additional details provided in the [mRNA-1273 P301 Clinical Study Protocol Supplemental SoE Table 22](#).

^g Placebo recipients who requested to receive mRNA-1273 and met EUA eligibility were to comply with a [mRNA-1273 P301 Clinical Study Protocol Supplemental SoE Table 21](#) in addition to the Original Study Schedule of Events.

^h Original Study SoE are provided in [mRNA-1273 P301 Clinical Study Protocol](#) (Table 16, Table 17, Table 18, and Table 19).

3.2 Study Assessments and Procedures

3.2.1 Efficacy Assessments

This CSR addendum include following efficacy endpoints:

- COVID-19 cases
- Severe COVID-19 cases
- SARS-CoV-2 infection regardless of symptomatology and severity
- Secondary definition of COVID-19
- Asymptomatic SARS-CoV-2 infection

COVID-19 cases were defined as participants meeting clinical criteria based both on symptoms for COVID-19 ([Section 3.2.1.1](#)) and on RT-PCR detection of SARS-CoV-2 ([Section 3.2.1.2](#)) from samples collected within 72 hours of the study participant reporting symptoms that met the definition of COVID-19. The surveillance for COVID-19 symptoms, including signs of severe systemic illness and the corresponding clinical pathways for data collection, is presented graphically in [mRNA-1273-P301 Clinical Study Protocol](#) Figure 4 ([Appendix 16.1.1](#)). An adjudication committee was assembled for the purpose of reviewing potential cases to determine if the criteria for the primary and secondary endpoints were met.

3.2.1.1 Surveillance for COVID-19 Symptoms

In Part B, surveillance for signs and symptoms of COVID-19 is ongoing from PDV and/or open-label (OL) Day 1 through the Open-Label Observational Phase.

According to the Centers for Disease Control and Prevention (CDC) as of 10 Jun 2020 ([CDC 2020](#)), patients with COVID-19 have reported a wide range of symptoms ranging from mild symptoms to severe illness. Throughout the study, to surveil for COVID-19, the following prespecified symptoms that met the criteria for suspicion of COVID-19 were elicited weekly from the participant, and the presence of any one of these symptoms lasting at least 48 hours (except for fever and/or respiratory symptoms) resulted in the site arranging an Illness Visit to collect a nasopharyngeal swab within 72 hours:

- Fever (temperature $\geq 38^{\circ}\text{C}$) or chills (of any duration, including ≤ 48 hours)

- Shortness of breath or difficulty breathing (of any duration, including ≤ 48 hours)
- Cough (of any duration, including ≤ 48 hours)
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

3.2.1.2 Testing for SARS-CoV-2 Infection

For the assessment of asymptomatic cases, SARS-CoV-2 infection was defined by seroconversion due to infection measured by binding antibody (bAb) levels against SARS-CoV-2 nucleocapsid or by positive RT-PCR at predefined timepoints. Seroconversion was defined by the participant's serostatus at baseline:

- Participants seronegative at baseline: bAb levels against SARS-CoV-2 nucleocapsid below the lower limit of quantification (LLOQ) at Study Day 1 and RT-PCR negative that increased to above or equal to LLOQ starting at Study Day 57 or later

Further details about surveillance for COVID-19 symptoms, assessments during the convalescence period, and SARS-CoV-2 infection testing are provided in the Part A CSR (Sections 3.7.2.1, 3.7.2.2, and 3.7.2.3, respectively).

3.2.2 Safety Assessments

Safety assessments included monitoring and recording of the following for each participant in Part B:

- Unsolicited AEs
- AEs leading to discontinuation from injection and/or study participation

- MAAEs, SAEs, pregnancy and accompanying outcomes, and concomitant medications and non-study vaccinations

The AE and SAE definitions are provided in the [mRNA-1273-P301 Clinical Study Protocol](#) Section 8.3.1 and Section 8.3.3, respectively ([Appendix 16.1.1](#)).

An unsolicited AE was any AE reported by the participant that was not specified as a solicited adverse reaction (AR) in the protocol or was specified as a solicited AR in the protocol but started outside the protocol-defined, post-injection period for reporting solicited ARs. In Part A, the solicited ARs were recorded by the participant in the eDiary within 7 days after the injection; however, no solicited ARs were collected separately in Part B. This was true even for the placebo group participants who chose to be unblinded and received two doses of 100 µg of mRNA-1273. Solicited ARs were not captured because sufficient data on these common events had already been captured and analyzed in Part A of this study.

An MAAE was an AE that led to an unscheduled visit to a healthcare practitioner (HCP). This included visits to a study site for unscheduled assessments (eg, rash assessment, abnormal laboratory follow-up, SARS-CoV-2 infection) and visits to HCPs external to the study site (eg, urgent care, primary care physician). Investigators reviewed unsolicited AEs for the occurrence of any MAAEs. All MAAEs were fully reported on the MAAE page of the eCRF.

Any suspected cases of anaphylaxis were to be recorded as MAAEs and reported as an SAE.

At every study site visit or telephone contact, participants were asked a standard question to elicit any medically related changes in their well-being according to the scripts provided. Participants were also asked if they had been hospitalized, had any accidents, used any new medications, changed concomitant medication regimens (both prescription and over-the-counter medications), or had any non-study vaccinations.

4 Statistical Analysis Methods

For efficacy in Part B, summaries of COVID-19 cases, severe COVID-19 cases, and COVID-19 cases using the secondary definition of COVID-19 infection were analyzed. For the placebo-mRNA-1273 group, incidence rates were not reported because this group had a relative short duration of follow-up after the second dose of mRNA-1273 in Part B; thus, this group did not represent a meaningful control. The following analysis periods and treatment groups were used for efficacy analyses for Part B:

Part B Group	Per-Protocol Set Sample Size	Description	Part B Analysis Period for Efficacy
mRNA-1273	14,287	Participants randomized to mRNA-1273 in Part A	From PDV/early unblinding to the earlier of 2 potential dates: data cutoff date for efficacy (26 Mar 2021) or the last observed in study date, where last observed was defined as the earliest of the following possibilities: study discontinuation, study completion, or death.
Placebo	2104	Participants randomized to placebo in Part A and did not receive mRNA-1273 in Part B	

Unsolicited AEs, SAE, MAAEs, and AEs leading to withdrawal were collected throughout Part B. Solicited ARs collected in Part A through an eDiary with prompts for 7 days and longer in case of persistent ARs on Day 7 were not collected in Part B. At the time of the final analysis of blinded data, in addition to the planned analysis of safety for the blinded phase (Part A), summaries of SAEs, MAAEs, and AEs leading to withdrawal in Part B were also provided. The summary was provided using the Part B groups during the Part B analysis period for safety as described in the table below:

Part B Group	Safety Set Sample Size	Description	Part B Analysis Period for Safety
mRNA-1273	15,184	Participants received at least 1 dose of mRNA-1273 in Part A	From PDV/early unblinding to the earlier of 2 dates: the data cutoff date for safety (26 Mar 2021) or the date last observed in the study. If a participant received mRNA-1273 in Part B, from the first date of study vaccine in Part B to the earlier of 2 dates: data cutoff date for safety (26 Mar 2021) or the date last observed in the study. Last observed was defined as the earliest of the following possibilities: study discontinuation, study completion, or death.
Placebo	2514	Participants only received Placebo in Part A and did not receive mRNA-1273 in Part B	From PDV/early unblinding to the earlier of 2 dates: data cutoff date for safety (26 Mar 2021) or the date last observed in study. Last observed was defined as the earliest of the following possibilities: study discontinuation, study completion, or death.
Placebo-mRNA-1273	12,648	Participants only received Placebo in Part A and received mRNA-1273 in Part B	From first dose of mRNA-1273 in Part B to earlier of 2 dates: data cutoff date for safety (26 Mar 2021) or the date last observed in the study. Last observed was defined as the earliest of the following possibilities: study discontinuation, study completion, or death.

5 Study Populations

5.1 Disposition of Subjects

A total of 28,964 participants started Part B (participants who had PDV or early unblinding; [Table 14.1.1.1.5.5](#)). Of these, 14,618 participants received mRNA-1273 in Part A (referred as mRNA-1273 group); 1698 participants received placebo in Part A and chose to remain in the placebo group; 12,648 participants received placebo in Part A and chose to receive mRNA-1273 in Part B (referred as placebo-mRNA-1273 group) and received at least 1 dose of the vaccine. A total of 21,598 participants were ≥ 18 and < 65 years and 7366 were ≥ 65 years ([Table 14.1.1.1.5.2.2](#)).

Of 12,648 participants in the placebo-mRNA-1273 group, 19 participants discontinued the study vaccine.

There were 195 participants who received 1 dose of mRNA-1273 during Part A and received the second dose of mRNA-1273 in Part B in the Safety Set.

A total of 1698/30,346 (5.6%) participants discontinued the study in Part B; 290/15,184 (1.9%) participants in the mRNA-1273 group, 1357/2514 (54.0%) participants in the placebo group, and 51/12,648 (0.4%) participants in the placebo-mRNA-1273 group. The most common reasons for study discontinuations were protocol deviations, withdrawal of consent by participant, and other reasons. It should be noted that vaccine became available under EUA in some cases, even mandatory to a large proportion of the study participants during early Part B and late Part A.

5.2 Demographics and Other Baseline Characteristics

Demographics and other baseline characteristics at the time of study entry are provided in the Part A CSR.

In the mRNA-1273 group (Part B), of 15,184 participants in the safety set, 52.1% participants were male, and 47.9% participants were female ([Table 14.1.3.2.5](#)). The mean age was 51.4 years (range 18 to 95 years); 75.2% of participants were ≥ 18 to < 65 years of age and 24.8% were ≥ 65 years. The majority of participants were White (79.3%) and not Hispanic or Latino (78.5%). The majority of participants (82.3%) had a specified occupational risk for acquisition of SARS-CoV-2 infection; the most common occupational

risks included other (31.9%) and health care workers (25.1%). A total of 83.9% of participants had a location and living circumstances risk for acquisition of SARS-CoV-2.

In the placebo group (Part B), of 2514 participants in the safety set, 55.4% participants were male, and 44.6% participants were female ([Table 14.1.3.2.5](#)). The mean age was 47.1 years (range 18 to 90 years); 85.7% of participants were ≥ 18 to < 65 years of age and 14.3% were ≥ 65 years. The majority of participants were White (76.0%) and not Hispanic or Latino (74.7%). The majority of participants (91.9%) had a specified occupational risk for acquisition of SARS-CoV-2 infection; the most common occupational risks included health care workers (55.1%) and other (19.5%). A total of 82.5% of participants had a location and living circumstances risk for acquisition of SARS-CoV-2.

In the placebo-mRNA-1273 group, of 12,648 participants in the safety set, 52.7% participants were male, and 47.3% participants were female ([Table 14.1.3.2.5](#)). The mean age was 52.2 years (range 18 to 95 years); 73.2% of participants were ≥ 18 to < 65 years of age and 26.8% were ≥ 65 years. The majority of participants were White (79.8%) and not Hispanic or Latino (79.4%). The majority of participants (80.9%) had a specified occupational risk for acquisition of SARS-CoV-2 infection; the most common occupational risks included other (34.3%) and health care workers (19.4%). A total of 83.9% of participants had a location and living circumstances risk for acquisition of SARS-CoV-2.

The baseline demographics and characteristics at the time of study entry by age group for the safety population are provided in [Table 14.1.3.2.2.2](#).

5.3 Duration of Follow-up

The median duration of follow-up from early unblinding or PDV to data cutoff date was 67 days (Part A CSR [Table 14.1.6.2.1](#)).

6 Efficacy Results

The primary efficacy endpoint was adjudicated symptomatic COVID-19 cases starting 14 days after the second injection. There have been 3 analyses of efficacy – an IA (based on a data snapshot on 11 Nov 2020) at which vaccine efficacy of mRNA-1273 was demonstrated based on pre-specified statistical criterion, primary analysis (based on a data snapshot on 25 Nov 2020), and the final analysis of blinded phase (Part A) data based on database lock of 04 May 2021 which included data up to early unblinding, study discontinuation, the Part B PDV or data cutoff date (26 Mar 2021), whichever was earlier. The results from the final efficacy analysis of the blinded phase are provided in the Part A CSR.

This section summarizes the symptomatic COVID-19 cases, severe COVID-19 cases, and COVID-19 cases using the secondary definition of COVID-19 from Part B and includes data from the early unblinding or PDV through data cutoff date (26 Mar 2021).

The purpose of this CSR addendum is to provide the efficacy results of Part B based on the median follow-up of 67 days. For the purpose of this CSR addendum, efficacy results are provided for mRNA-1273 and placebo group in text and in summary tables (case counts and incidence rate). For the placebo-mRNA-1273 group, incidence rates are not reported as this group had a relative short duration of follow-up after the second dose of mRNA-1273 in Part B, therefore, efficacy results for the placebo-mRNA-1273 group are not described in this CSR addendum.

For efficacy analyses in Part B, participants at risk were defined as participants who started the open-label phase before or on the efficacy data cutoff date, had no prior SARS-CoV-2 infection (defined by positive postbaseline RT-PCR or Elecsys results) and were not a COVID-19 case up to PDV or early unblinding, whichever was earlier.

6.1 Primary Endpoint

6.1.1 Symptomatic COVID-19

In the mRNA-1273 group, of 13,704 participants at risk, 19 (0.1%) adjudicated COVID-19 cases were detected in the per-protocol (PP) Set during the Part B of the study. The corresponding incidence rate for the mRNA-1273 group remained low (7.961 cases per 1000 person-years; 95% confidence interval [CI]: 4.793, 12.432). The results in Part B are consistent with Part A, where the incidence rate in the mRNA-1273 group was 9.599 cases per 1000 person-years (95% CI: 7.231, 12.494) which confirms the persistence of efficacy in

the mRNA-1273 group ([Table 6-1](#)). In the placebo group, of 1,175 participants at risk, 3 (0.3%) adjudicated COVID-19 cases were detected. The incidence rate for the placebo group was 77.378 cases per 1000 person-years; (95% CI: 15.957, 226.131), which was 10-fold higher than in the mRNA-1273 group.

The results of COVID-19 cases regardless of adjudication were consistent with adjudicated COVID-19 cases ([Table 14.2.2.1.4.8.1](#)).

The results of adjudicated COVID-19 cases and COVID-19 cases regardless of adjudication committee assessments in the open-label phase for the modified intent-to-treat (mITT) Set are provided in [Table 14.2.2.1.3.8.2](#) and [Table 14.2.2.1.4.8.2](#), respectively.

Table 6-1: Summary of COVID-19* Based on Adjudication Committee Assessments in Blinded Phase (Part A) and Open-Label Phase (Part B) (Per-Protocol Set)

	Part A final analysis (Median follow-up from randomization to early unblinding or PDV: 148 days)		Part B (Median follow-up from early unblinding or PDV to data cutoff: 67 days)		
	mRNA-1273 (N=14287)	Placebo (N=14164)	mRNA-1273 (N=14287)	Placebo (N=2104)	Placebo-mRNA-1273 (N=12060)
Number of subjects at risk ^a	–	–	13704	1175	11234
Number of subjects with COVID-19*, n (%) ^b	55 (0.4)	744 (5.3)	19 (0.1)	3 (0.3)	56 (0.5)
Before first injection of mRNA-1273 in open-label phase	–	–	–	–	17 (0.2)
Between first injection and second injection of mRNA-1273 in open-label phase	–	–	–	–	37 (0.3)
After second injection of mRNA-1273 in open-label phase	–	–	–	–	2 (<0.1)
Number of subjects censored, n (%) ^b	14232 (99.6)	13420 (94.7)	13685 (99.9)	1172 (99.7)	11178 (99.5)
Person-years ^c	5729.9	5445.2	2386.6	38.8	–
Incidence rate per 1,000 person-years (95% CI) ^d	9.599 (7.231, 12.494)	136.633 (126.991, 146.814)	7.961 (4.793, 12.432)	77.378 (15.957, 226.131)	–

Abbreviations: CI = confidence intervals; COVID-19 = coronavirus disease 2019; PDV = participant decision visit; RT-PCR = reverse transcription polymerase chain reaction

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at scheduled visits without eligible symptoms within 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

^a Subjects at risk are defined as subjects who started the open-label phase before or on efficacy data cutoff date, had no prior SARS-CoV-2 infection (defined by positive postbaseline RT-PCR or Elecsys results) and were not a disease COVID-19 case up to PDV or early unblinding, whichever is earlier.

^b Percentages in Part B are based on number of participants at risk.

^c Person-years is defined as the total years from randomization date (Part A) or PDV/early unblinding date (Part B) to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

^d Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

Source: [Table 14.2.2.1.3.8.1](#) and Part A [Table 14.2.2.1.3.1.1](#).

6.2 Secondary Endpoints

6.2.1 Severe COVID-19

The number of severe COVID-19 cases in Part B were too low in the PP Set for any meaningful comparison ([Table 14.2.2.2.3.8.1](#) [based on Adjudication Committee Assessments] and [Table 14.2.2.2.4.8.1](#) [regardless of Adjudication Committee Assessments]).

The adjudicated severe COVID-19 cases and COVID-19 cases regardless of adjudication committee assessments in the open-label phase for the mITT Set are provided in [Table 14.2.2.2.3.8.2](#) and [Table 14.2.2.2.4.8.2](#), respectively.

6.2.2 SARS-CoV-2 Infection Regardless of Symptomatology and Severity

The RT-PCR results and anti-nucleocapsid bAb as measured by Elecsys assay at PDV were included in the analysis of SARS-CoV-2 infection regardless of symptomatology and severity, in Part A CSR (Section 6.2.2). No further analysis is provided for the open-label phase.

6.2.3 Secondary Definition of COVID-19

The secondary case definition of COVID-19 was defined as the presence of at least 1 of the following systemic symptoms: fever (temperature $\geq 38^{\circ}\text{C}$), or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle aches or body aches, headache, new loss of taste or smell, sore throat, nasal congestion or rhinorrhea, nausea or vomiting, or diarrhea AND a positive NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) for SARS CoV-2 by RT-PCR.

In the mRNA-1273 group, of 13,704 participants at risk, 39 (0.3%) COVID-19 cases using the secondary definition for COVID-19 in the PP set were detected ([Table 14.2.2.4.2.7.1](#)). The incidence rate in Part B was 16.357 cases per 1000 person-years; (95% CI: 11.631, 22.360). The results are consistent with Part A (10.124 cases per 1000 person-years; 95% CI: 7.688, 13.088) and supported the persistence of efficacy of mRNA-1273. In the placebo group, of 1,175 participants at risk, 4 (0.3%) COVID-19 cases using the secondary definition for COVID-19 in the PP set were detected ([Table 14.2.2.4.2.7.1](#)). The incidence rate in Part B was 103.713 cases per 1000 person-years; (95% CI: 28.258, 265.546), and the incidence rate in Part A was 148.525 cases per 1000 person-years; (95% CI: 138.453, 159.136).

The COVID-19 cases using the secondary definition for COVID-19 in the mITT Set are provided in [Table 14.2.2.4.2.7.2](#).

6.2.4 Asymptomatic SARS-CoV-2 Infection

The RT-PCR results and anti-nucleocapsid bAb as measured by Elecsys assay at PDV were included in the analysis of asymptomatic infection in Part A CSR (Section 6.2.6). No further analysis is provided for the open-label phase.

7 Safety Results

Safety results from the final analysis of Part A (double blind randomized study period) based on a median follow-up of 5.3 months (data up to the Part B PDV, early unblinding, or data cutoff date of 26 Mar 2021, whichever was earlier) are provided in the Part A CSR. mRNA-1273 demonstrated an acceptable safety profile during Part A in the participant population enrolled in this study.

The purpose of this CSR addendum is to provide additional safety follow-up data based on median follow-up of 67 days in Part B for those remaining in the original randomized groups (mRNA-1273 and placebo groups) beyond early unblinding or the PDV up to the data cutoff date (26 Mar 2021), which yielded a total observation period of 7.6 months from randomization or 6.5 months after Dose 2 across Part A and Part B. In addition, data from the placebo group participants who were vaccinated with mRNA-1273 (placebo-mRNA-1273 group) in Part B were collected to further expand the safety evaluation of mRNA-1273 from this newly vaccinated group.

7.1 Solicited Adverse Reactions

Solicited ARs were collected in Part A of the study and are presented in the Part A CSR. Solicited ARs were not collected in Part B.

7.2 Unsolicited Adverse Events

7.2.1 Overview of Unsolicited Adverse Events

In Part B, of 15,184 participants in the Safety Set who received mRNA-1273 in Part A, 1729 (11.4%) participants experienced at least 1 unsolicited TEAE regardless of relationship to the study vaccine in the mRNA-1273 group including 141 (0.9%) participants with SAEs, 1457 (9.6%) participants with MAAEs, and 147 (1.0%) participants with severe treatment-emergent AE (TEAEs; [Table 7-1](#)). Seven deaths were reported in the mRNA-1273 group in Part B. Additionally, 1 participant had a TEAE in Part A and died in Part B. Seven (<0.1%) participants experienced TEAEs leading to discontinuation from the study. The incidence of unsolicited TEAEs which were assessed by the investigator as related to the study vaccine was low. Of 15,184 participants, 22 (0.1%) participants experienced TEAEs which were assessed by the investigator as related to the study vaccine including 9 (<0.1%) participants with MAAEs and 1 (<0.1%) participant with a severe TEAE. No SAE, fatal AE,

and AEs leading to withdrawal from injection or study were considered by the investigator as related to the study vaccine.

Two participants in the mRNA-1273 group listed as participants with TEAEs leading to discontinuation from study vaccine received both doses of mRNA-1273 in Part A.

In the placebo group, of 2514 participants in the Safety Set, 41 (1.6%) participants experienced at least 1 unsolicited TEAE including 7 (0.3%) SAEs and 37 (1.5%) MAAEs. One (<0.1%) fatal TEAE was reported. Of 2514 participants, 1 participant experienced a TEAE leading to withdrawal from the study. No participants had TEAEs considered by the investigator to be related to the study vaccine.

In the placebo–mRNA-1273 group, of 12,648 participants in the Safety Set, 2446 (19.3%) participants experienced at least 1 unsolicited TEAE including 148 participants with SAEs and 1509 participants with MAAEs. Three deaths were reported. Twelve (<0.1%) participants experienced TEAEs leading to discontinuation from the study vaccine and 4 (<0.1%) participants experienced TEAEs leading to discontinuation from the study. Of 12,648 participants in the Safety Set, 758 (6.0%) participants experienced TEAEs which were considered by the investigator to be related to study vaccine including 74 (0.6%) participants with MAAEs, 4 (<0.1%) participants with SAEs, and 24 (0.2%) participants with severe TEAEs. In addition, 1 participant experienced an SAE (considered related to the study vaccine by the investigator) of pericardial effusion in Part B before data cutoff but was reported after the database lock. Overall, 4/12,648 (<0.1%) participants discontinued the study vaccine due to TEAEs that were considered as related to the study vaccine by the investigator. No fatal AE and AEs leading to withdrawal from study were considered by the investigator as related to the study vaccine.

Table 7-1: Summary of Unsolicited Treatment-Emergent Adverse Events in the Open-Label Phase (Safety Set)

	Placebo (N=2514) n (%)	mRNA-1273 (N=15184) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	Total (N=30346) n (%)
Unsolicited TEAEs regardless of relationship to study vaccination				
All	41 (1.6)	1729 (11.4)	2446 (19.3)	4216 (13.9)
Serious	7 (0.3)	141 (0.9)	148 (1.2)	296 (1.0)
Fatal	1 (<0.1)	7 (<0.1)	3 (<0.1)	11 (<0.1)
Medically-attended	37 (1.5)	1457 (9.6)	1509 (11.9)	3003 (9.9)
Leading to discontinuation from study vaccine	0	2 (<0.1)	12 (<0.1)	14 (<0.1)
Leading to discontinuation from participation in the study	1 (<0.1)	7 (<0.1)	4 (<0.1)	12 (<0.1)
Severe	4 (0.2)	147 (1.0)	179 (1.4)	330 (1.1)
Unsolicited TEAEs related to study vaccination				
All	0	22 (0.1)	758 (6.0)	780 (2.6)
Serious	0	0	4 (<0.1)	4 (<0.1)
Fatal	0	0	0	0
Medically-attended	0	9 (<0.1)	74 (0.6)	83 (0.3)
Leading to discontinuation from study vaccine	0	0	4 (<0.1)	4 (<0.1)
Leading to discontinuation from participation in the study	0	0	0	0
Severe	0	1 (<0.1)	24 (0.2)	25 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

Source: [Table 14.3.1.30.1.1](#).

7.2.2 Analysis of Unsolicited Adverse Events

In the mRNA-1273 group, 1729/15,184 (11.4%) participants experienced 2557 TEAEs in the Safety Set ([Table 14.3.1.31.1.1](#)). No unsolicited TEAE (preferred term [PT]) occurred in $\geq 1\%$ of participants. No unexpected findings or new trend appeared in unsolicited TEAEs in the mRNA-1273 group.

In the placebo group, 41/2514 (1.6%) participants experienced 66 TEAEs in the Safety Set. No unsolicited TEAE (PT) occurred in $\geq 1\%$ of participants.

In the placebo–mRNA-1273 group, 2446/12,648 (19.3%) participants experienced 4814 TEAEs in the Safety Set. The most common unsolicited TEAEs (occurring in at least 1% of participants) in the placebo–mRNA-1273 group were injection site pain (451 [3.6%] participants), headache (233 [1.8%] participants), fatigue (211 [1.7%] participants), pain (175 [1.4%] participants), pyrexia (167 [1.3%] participants), chills (136 [1.1%] participants), and hypertension (129 [1.0%] participants). The commonly reported events were generally consistent with reactogenicity and the unsolicited adverse events reported within the 28-day follow-up period after vaccination in the mRNA-1273 group observed in Part A.

7.2.3 Subgroup Analysis of Unsolicited Adverse Events

7.2.3.1 Age Group

In Part B, within the mRNA-1273 group, the overall incidence of TEAEs, SAEs, MAAEs, and severe TEAEs were generally higher in the older age (≥ 65 years) group (14.2%, 1.6%, 12.5%, and 1.6%, respectively) than the younger (≥ 18 to < 65 years) age group (10.5%, 0.7%, 8.6%, and 0.8%, respectively; [Table 14.3.1.30.1.2](#)); however, no difference was apparent for TEAEs assessed as vaccine-related by the investigator between the age groups.

The participant incidence of unsolicited TEAEs (PTs) in the mRNA-1273 group was generally similar between the younger (≥ 18 to < 65 years) age group and the older (≥ 65 years) age group ([Table 14.3.1.31.1.2](#)). With respect to system organ class (SOC), the following imbalance was noted between the younger age group (≥ 18 to < 65 years) and older age group (≥ 65 years): metabolism and nutrition disorders (0.5% vs 1.0%, respectively), cardiac disorders (0.2% vs 0.8%, respectively), vascular disorders (0.5% vs 1.3%, respectively), and musculoskeletal and connective tissue disorders (1.1% vs 2.4%, respectively).

In the placebo–mRNA-1273 group, no difference between the age groups was noted in the most common unsolicited TEAEs (headache, hypertension, injection site pain, fatigue, pain, pyrexia, and chills; [Table 14.3.1.31.1.2](#)).

7.3 Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

7.3.1 Deaths

As of the data cutoff date of this CSR addendum, 12 participants died in Part B ([Table 7-2](#) and [Table 7-3](#)).

In the mRNA-1273 group, 8/15,184 (<0.1%) participants died (median time from PDV: 46.5 days) during Part B. Of these 8 participants, 5 participants were >60 years. One participant (56-year-old female) died (sudden death) 182 days after receiving the second dose of mRNA-1273 in Part A. According to the medical examiner, cause of death was combined drug intoxication (methamphetamine, diphenhydramine). One participant (72-year-old female) experienced cardiac arrest 155 days after receiving the second dose of mRNA-1273 in Part A. The participant had a history of coronary artery disease, stent placement, and non-alcoholic fatty liver disease.

In the placebo group, 1/2514 (<0.1%) participant (age 84 years) died 9 days after the PDV due to ventricular arrhythmia.

In the placebo–mRNA-1273 group, 3/12,648 (<0.1%) participants died (median time from PDV: 54 days) during Part B. One participant (79-year-old male) died 27 days after receiving the second dose of mRNA-1273 in Part B. The participant had a medical history of multiple comorbidities including cardiovascular diseases (coronary artery disease, pacemaker placement, atrial fibrillation, hypertension, angina, pacemaker infection), chronic kidney disease stage 3, renal carcinoma, and coagulopathy. The participant was also taking concomitant medications for comorbidities including antihypertensive, antianginal, and warfarin. The participant experienced chest pain with a slightly elevated troponin 16 days after the second dose and was admitted to the hospital. The 12-lead electrocardiogram showed the participant had a ventricular paced rhythm. An echocardiogram showed mild concentric ventricular hypertrophy with an ejection fraction of 55-60% and mild valvular abnormalities. Laboratory tests shows elevated coagulation parameters with international normalized ratio (INR) 2.7 (normal range: 0.8-1.2). Two days later the participant was discharged but INR remained elevated (1.7). The subject died because of supra therapeutic INR, congestive heart failure, and gastrointestinal bleeding.

None of the participants died due to COVID-19 ([Listing 16.2.7.9.3](#)). None of deaths was considered related to the study vaccine.

A listing of the deaths is presented in [Listing 16.2.12.3](#).

Case narratives for the participants who experienced a fatal TEAE are provided in [Section 15](#).

Table 7-2: Summary of Death in Open-Label Phase (Safety Set)

	Placebo (N=2514)	mRNA-1273 (N=15184)	Placebo- mRNA-1273 (N=12648)	Total (N=30346)
Total number of deaths due to any cause, n (%)	1 (<0.1)	8 (<0.1)	3 (<0.1)	12 (<0.1)
Time of death from first injection (days) ^a				
Mean (SD)	127.0 (NA)	184.4 (40.83)	204.7 (18.15)	184.7 (39.14)
Median	127.0	193.5	202.0	195.0
Min, Max	127, 127	122, 239	188, 224	122, 239
Time of death from first injection (days) ^a , n (%)				
< 28 days	0	0	0	0
>= 28 and < 57 days	0	0	0	0
>= 57 and < 168 days	1 (<0.1)	3 (<0.1)	0	4 (<0.1)
>= 168 days	0	5 (<0.1)	3 (<0.1)	8 (<0.1)
Time of death from PDV (days) ^b				
Mean (SD)	9.0 (NA)	44.5 (26.32)	56.3 (19.60)	44.5 (25.76)
Median	9.0	46.5	54.0	46.5
Min, Max	9, 9	7, 88	38, 77	7, 88
Time of death from PDV (days) ^b , n (%)				
< 28 days	1 (<0.1)	2 (<0.1)	0	3 (<0.1)
>= 28 and < 57 days	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
>= 57 and < 168 days	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
>= 168 days	0	0	0	0

Abbreviation: PDV = Participant Decision Visit.

^a Time of death from first injection is calculated as: date of death – date of first injection in the study.

^b Time of death from PDV is calculated as: date of death – date of PDV.

Source: [Table 14.3.1.36.1.1.](#)

Table 7-3: Participants With Serious Adverse Events Resulting in Death in Open-Label Phase (Safety Set)

Treatment Assignment	Age	Sex	Preferred Term	Study Day of Death	Relationship to Study Vaccine ^a
mRNA-1273	56	Female	Sudden death (unknown cause)	Day 182	Not related
mRNA-1273	72	Female	Cardiac arrest	Day 155	Not related
mRNA-1273	69	Male	Myocardial infarction	Day 95	Not related
mRNA-1273	62	Male	Acute myocardial infarction	Day 184	Not related
mRNA-1273	71	Male	Cerebrovascular accident	Day 212	Not related
mRNA-1273	41	Male	Head injury	Day 180	Not related
mRNA-1273	49	Male	Pulmonary embolism	Day 138	Not related
			Pulseless electrical activity		Not related
			Gastrointestinal haemorrhage		Not related
mRNA-1273	75	Female	Pulmonary mass	Day 136	Not related
Placebo	84	Female	Ventricular arrhythmia	Day 128	Not related
Placebo – mRNA-1273	79	Male	Cardiac failure congestive	Day 27	Not related
			Gastrointestinal haemorrhage		Not related
			Anticoagulation drug level above therapeutic		Not related
Placebo – mRNA-1273	30	Female	Accidental overdose ^b	Day 10	Not related
Placebo-mRNA-1273	61	Female	Cerebrovascular accident	Day 44	Not related

^a. Relationship is based on investigator assessment.

^b. Inadvertent drug overdose on fentanyl, xylazine, and cocaine

Source: [Listing 16.2.12.3](#) and [Listing 16.2.7.9.3](#).

7.3.2 Other Serious Adverse Events

The overall incidence of SAEs was low in Part B. In the mRNA-1273 group, 141/15,184 (0.9%) participants reported 181 SAEs ([Table 14.3.1.32.1.1](#)). All individual SAEs (PT) were reported in <0.1% of participants. COVID-19 was reported as an SAE in 1 participant. No SAEs were considered related to the study vaccine in this group. Overall, no new safety concern was identified.

In the placebo group, 7/2514 (0.3%) participants reported 8 SAEs. No SAEs were considered related to the study vaccine.

In the placebo–mRNA-1273 group, 148/12,648 (1.2%) participants reported 190 SAEs. All individual SAEs (PT) were reported in <0.1% of participants. COVID-19 was reported as an SAE in 3 participants. Serious AEs considered by the investigator to be related to the study vaccine were reported in 4 participants ([Listing 16.2.7.10.3](#)). In addition, 1 participant experienced an SAE (considered as related to the study vaccine by the investigator) of pericardial effusion in Part B before data cutoff but was reported by site after the database lock.

A 41-year-old female participant experienced an SAE of Grade 3 paraesthesia (left arm) 9 days after the first dose of mRNA-1273 in the left arm in Part B. The participant presented for an unscheduled visit due to swelling, redness, and tenderness at the injection site. The participant was not hospitalized overnight and was discharged from the hospital the same day; however, the event was considered as medically significant. The event resolved within 2 days. The vaccine dose was delayed because of the SAE. The subject received the second dose of mRNA-1273 37 days after the first dose and was treated prophylactically with antihistamines prior to dosing.

A 74-year-old male participant experienced an SAE of muscular weakness in lower extremities along with fever of 102°F and urinary retention 1 day after receiving the second dose of mRNA-1273 in Part B. Treatment included paracetamol for fever. The event resolved within 1 day after onset.

A 28-year-old female participant experienced an SAE of spontaneous abortion. The details are provided in [Section 7.4](#) (Pregnancies).

A 39-year-old male participant with a family history of Hashimoto disease experienced an SAE of autoimmune thyroiditis 27 days after the first dose of mRNA-1273 in Part B. The event was ongoing at the time of data cutoff date.

A 23-year-old male participant experienced an SAE of pericardial effusion 19 days after the second dose of mRNA-1273 in Part B. The participant had also been experiencing a nonserious event of bradycardia relative to baseline. This event was reported by the site after data cutoff date and was considered as resolving.

Case narratives for the participants who experienced SAEs are provided in [Section 15](#).

The details about notable SAEs are provided below.

Anaphylaxis

Amongst the SAEs, a grade 3 anaphylaxis was reported in 2 participants in the placebo-mRNA-1273 group, both of which were considered unrelated to mRNA-1273. These 2 participants had history of asthma. The first participant was a 51-year-old female who experienced anaphylaxis 19 days after the first injection which resolved the same day; the participant did not receive the second dose. The second participant was a 57-year-old female who experienced anaphylaxis a few months after receiving the second dose of vaccine; however, it was not temporally related to mRNA-1273 and considered associated to a steroid injection per the investigator. In the placebo group, no anaphylaxis was reported. In the mRNA-1273 group, 1 participant experienced anaphylaxis due to antigen challenge allergy testing.

Facial Paralysis

In any group, no participant experienced an SAE of Bell's palsy or demyelination, eg, Guillain Barre syndrome.

Seizure

There was 1 SAE of unrelated seizure in the mRNA-1273 group. This SAE was reported in a 56-year-old male with history of seizures within a context of non-compliance to antiepileptic medication. The participant experienced the event 30 days after the initial dose in Part A. The participant experienced worsening of seizure in Part B 6 months 4 days after the initial dose. No cases of seizure in the placebo or placebo-mRNA-1273 groups were noted.

Cerebrovascular accident

In the mRNA-1273 group, 3 participants experienced an SAE of strokes (including 1 fatal event) and 1 serious transient ischemic attack. All occurred approximately 6 months after the vaccination and were unrelated to the vaccine and occurred in participants with risk factors for cerebrovascular accident, ie, metabolic disease like hyperlipidemia, type 2 diabetes, atherosclerosis, or aortic stenosis. In the placebo-mRNA group, 7 participants experienced an SAE of stroke. Four of these were >65 years old (68 to 84 years of age). Time to onset was between 1 day to approximately 2 months after vaccination. There was 1 male participant of 84-years-old with pancytopenia due to myelodysplastic syndrome who experienced a

subarachnoid hemorrhage and subdural hematoma in the context of an orthostatic hypotension and fall during the night following the second dose of mRNA-1273. All participants had risk factors for cerebrovascular accident and cases were considered unrelated to vaccination. No cerebrovascular accident was reported in the placebo group.

Pericarditis and myocarditis

No cases of myocarditis were reported in any groups.

One case of acute pericarditis (verbatim: “acute infective pericarditis”) was reported as an SAE in a 63-year-old male in the placebo group; the event occurred 24 days after a COVID-19 diagnosis. In addition, one case of pericardial effusion was reported as an SAE (resolving) in a 23-year-old male in the placebo–mRNA-1273 group. No participant in the mRNA-1273 group experienced pericarditis.

Because myocarditis and pericarditis are typically rare events, Moderna assessed the clinical database for evidence of individual clinical symptoms that have been associated with these events. The Part B data were assessed for TEAEs potentially associated with myocarditis or pericarditis. The TEAE data were assessed for any events mapping to PT in the CDC working case definition diagnostic algorithm for acute myocarditis and pericarditis. Using this approach, TEAEs were identified for the following seven PTs: angina pectoris, chest discomfort, chest pain, musculoskeletal chest pain, dyspnea, palpitations, and syncope.

The TEAE database (collected for the 28 days after any injection) was assessed for the identified PTs, and the assessment further narrowed for those TEAEs occurring in temporal proximity to injection (within 7 days of any injection) based on the observed epidemiology of cases of myocarditis and pericarditis characterized from post-authorization data. As part of the study, the collection of unsolicited TEAEs that are nonserious do not include narrative information but rather the verbatim entries regarding the event. All TEAEs were reviewed regardless of severity or causality (as per investigator). Finally, the listing of participants reporting any of these PTs within 7 days of any injection was cross-checked to identify any participants reporting more than 1 of the targeted PTs, reflecting constellations more suggestive of a possible diagnosis of myocarditis or pericarditis.

Only 1 participant reported more than one of the target PTs: a 66-year-old male experienced 2 nonserious, moderate, and considered unrelated TEAEs of chest discomfort and dyspnea on Day 5 after the second dose. Both TEAEs resolved, the chest discomfort within 6 days and

the dyspnea within 2 days. Other potentially relevant TEAEs reported for this participant within 7 days of these events were unrelated nonserious TEAEs of rhinorrhea, cough, fatigue, decreased appetite, and headache.

In this assessment of the targeted PTs, 1 participant manifested more than 1 of the identified PTs within 7 days of any injection. Other TEAEs identified in this analysis were predominantly short in duration, resolved, and did not cluster with other relevant TEAEs to suggest cases of myocarditis or pericarditis.

7.3.3 Other Clinically Meaningful Adverse Events

7.3.3.1 Unsolicited Adverse Events leading to Discontinuation From the Study Vaccine or From the Study

The participant incidence of TEAEs leading to study discontinuation was low (7/15,184 participants in the mRNA-1273 group, 1/2514 participant in the placebo group, and 4/12,648 participants in the placebo–mRNA-1273 group; [Table 14.3.1.35.1.1](#)); none of the events was considered related to the study vaccine by the investigator ([Table 7-1](#)).

In the placebo–mRNA-1273 group, the overall number of participants who discontinued the study vaccine due to TEAEs was low (12/12,648 [$<0.1\%$] participants; [Table 14.3.1.34.1.1](#)). Of these 12 participants, 4 participants discontinued the vaccine because of nonserious TEAEs that were considered by the investigator to be vaccine-related ([Table 7-1](#)).

One participant discontinued the vaccine because of Grade 1 chills. The participant experienced the event 34 days after receiving the first dose. The event resolved after 2 days.

One participant discontinued the vaccine because of Grade 2 urticaria. The participant experienced the event 1 day after receiving the first dose. The event resolved after 3 days.

One participant discontinued the vaccine because of Grade 3 parotitis. The participant experienced the event 11 days after receiving the first dose. The event was ongoing at the time of data cutoff.

One participant (64-year-old) discontinued the vaccine because of Grade 2 unilateral deafness. The participant experienced the event 5 days after receiving the first dose of mRNA-1273 in Part B. The event was resolving at the time of data cutoff.

Overall, 6 participants in the placebo–mRNA-1273 group discontinued the study vaccine due to a serious TEAE (arthritis bacterial, pancreatic carcinoma metastatic, prostate cancer, anaphylactic reaction (time to onset of 18 days after the first dose and resolved the same day), brain stem infarction, and spontaneous abortion); none of the events were considered related to study vaccine by the investigator ([Listing 16.2.7.9.3](#)).

Case narratives for participants with AEs leading to discontinuation from the study or study vaccine are provided in [Section 15](#).

7.3.3.2 Medically-Attended Treatment-Emergent Adverse Events

In the mRNA-1273 group, 1457/15,184 (9.6%) participants experienced 2067 MAAEs ([Table 14.3.1.33.1.1](#)). All individual MAAEs (PT) were reported in <1% of participants. The most common MAAEs ($\geq 0.4\%$ of participants) were hypertension (69/15,184 [0.5%] participants), urinary tract infection (65/15,184 [0.4%] participants), and COVID-19 (32/15,184 [0.2%] participants). Overall, no new safety concern was identified related to MAAEs.

In the placebo group, 37/2514 (1.5%) participants experienced 51 MAAEs. All MAAEs (PT) were reported in $\leq 0.1\%$ of participants.

In the placebo–mRNA-1273 group, 1509/12,648 (11.9%) participants experienced 2202 MAAEs. All MAAEs (PT) were reported in <1% of participants. The most common MAAEs ($\geq 0.4\%$ of participants) were hypertension (98/12,648 [0.8%] participants) and urinary tract infection (59/12,648 [0.5%] participants), and COVID-19 (51/12,648 [0.4%] participants).

7.3.4 Subgroup Analysis of Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

7.3.4.1 Age Group

In the mRNA-1273 group, the overall participant incidence of SAEs in Part B was higher in the older (≥ 65 years) age group (60/3769 [1.6%] participants) than in the younger (≥ 18 years to <65 years) age group (81/11,415 [0.7%] participants; [Table 14.3.1.32.1.2](#)). This is consistent with the safety findings observed in Part A. No notable difference was observed in the individual SAEs (PT) between the age groups. Similarly, the overall participant incidence of MAAEs in Part B was higher in older (≥ 65 years) age group (471/3769 [12.5%]

participants) than in the younger (≥ 18 years to < 65 years) age group (986/11,415 [8.6%] participants; [Table 14.3.1.33.1.2](#)), but no notable difference was observed in the individual MAAEs (PT) between the age groups.

A summary of death by age group is provided in [Table 14.3.1.36.1.2](#). Summaries of participant incidence of TEAE leading to discontinuation from study vaccine and TEAE leading to discontinuation from study by SOC and PT by age group are provided in [Table 14.3.1.34.1.2](#) and [Table 14.3.1.35.1.2](#), respectively.

7.4 Pregnancies

As of the date of the data cutoff for this CSR addendum, 10 participants (9 in the placebo-mRNA-1273 group and 1 in the mRNA-1273 group) had positive results for urine pregnancy tests performed at the site during Part B ([Listing 16.2.8.3](#)).

According to the safety database, a total of 37 pregnancies were reported (19 in the placebo-mRNA-1273 group and 18 in the mRNA-1273 group) during Part B of the study ([Table 7-4](#)). Of the outcomes known as of 04 May 2021, 4 participants (3 in the placebo-mRNA-1273 group and 1 in the mRNA-1273 group) experienced spontaneous abortion; of these, the event in 1 participant in the placebo-mRNA-1273 group was considered related to the study vaccine by the investigator.

A 28-year-old participant in the placebo-mRNA-1273 group, had a positive pregnancy test at home 8 days after the first dose of mRNA-1273 in Part B. Two-days later (10 days after the first dose of mRNA-1273 in Part B) the participant started bleeding, which continued for the next 6 days. The participant had not taken any additional pregnancy tests but believed that she had a miscarriage and was no longer pregnant. The investigator assessed the event, spontaneous abortion, as related to the study vaccine due to a temporal relationship between the spontaneous abortion and the vaccination.

One participant in the placebo-mRNA-1273 group underwent elective termination of pregnancy; there were no reported pregnancy complications for this participant.

Case narratives for the participants who experienced pregnancies are provided in [Section 15](#).

Table 7-4: Incidence of Pregnancies Reported in Part B and Outcomes (Safety Set)

	Frequency
Participants who received placebo in Part A and mRNA-1273 in Part B	
Number of pregnancies reported in Part B	19
Known pregnancy outcomes	5
Spontaneous abortion/miscarriage	3
Elective termination ^a	1
Outcome unknown/lost to follow-up	1
Participants who received mRNA-1273 in Part A	
Number of pregnancies reported in Part B	18
Known pregnancy outcomes	5
Spontaneous abortion/miscarriage	1
Elective termination	0
Outcome unknown/lost to follow-up	1
Participants who received placebo in Part A and did not receive mRNA-1273 in Part B	
Number of pregnancies reported in Part B	0
Known pregnancy outcomes	0
Outcome unknown/lost to follow-up	0

^a There were no reported pregnancy complications.

8 Conclusions

This CSR addendum provides efficacy and safety results based on median follow-up of 67 days in Part B, which yielded a total observation period of 7.6 months from randomization or 6.5 months after Dose 2 across Part A and Part B.

Efficacy

The efficacy analysis in Part B confirmed persistence of efficacy of mRNA-1273 to prevent COVID-19. The incidence rate of adjudicated symptomatic COVID-19 cases (primary endpoint) in participants who received 2 doses of mRNA-1273 in Part A remained low in Part B; the results are consistent with those observed in Part A. The results of the secondary endpoint, COVID-19 cases using the secondary definition of COVID-19, were also consistent with those observed in Part A.

Safety

Overall, no new safety concerns were identified in Part B.

In the mRNA-1273 group, the participant incidence of unsolicited TEAEs related to the study vaccine was low (22/15,184 [0.1%] participants); no unsolicited TEAE (PT) occurred in $\geq 1\%$ of participants. No unexpected findings or new trend appeared in unsolicited TEAEs. All individual SAEs (PT) were reported in $<0.1\%$ of participants, and no SAEs were considered related to the study vaccine. All individual MAAEs (PT) were reported in $<1\%$ of participants and no new safety concern with respect to MAAEs was observed. Of 15,184 participants, 7 participants discontinued the study due to TEAEs; none of the events was related to study vaccine.

In the mRNA-1273 group, 8 participants died during Part B. None of the participants died due to COVID-19. None of deaths was considered related to the study vaccine.

In the mRNA-1273 group, 18 pregnancies were reported during Part B of the study. One participant experienced a spontaneous abortion. The investigator assessed the event as not related to study vaccine.

In the placebo–mRNA-1273 group, the most commonly reported unsolicited TEAEs were headache, hypertension, injection site pain, fatigue, pain, pyrexia, and chills. This is

consistent with the reactogenicity and the unsolicited adverse events reported within the 28-day follow-up period after vaccination in the mRNA-1273 group observed in Part A.

In the placebo–mRNA-1273 group, individual SAEs (PT) were reported in <0.1% of participants. Serious AEs considered by the investigator to be related to the study vaccine were reported in 5 participants (paraesthesia, muscular weakness, spontaneous abortion, autoimmune thyroiditis, and pericardial effusion). All events resolved within 2 days except autoimmune thyroiditis which was ongoing at the time of data cutoff and pericardial effusion which was resolving.

In the placebo–mRNA-1273 group, individual MAAEs (PT) were reported in <1% of participants.

In the placebo–mRNA-1273 group, 4 participants discontinued the vaccine because of nonserious TEAEs which were considered to be vaccine-related (chills, urticaria, parotitis, and unilateral deafness). Four participants discontinued the study due to TEAEs; none of the events were related to study vaccine.

In the placebo–mRNA-1273 group, 3 participants died during Part B. None of the participants died due to COVID-19. None of deaths was considered related to the study vaccine.

In the placebo–mRNA-1273 group, 19 pregnancies were reported during Part B. Three participants experienced spontaneous abortion; of these, the event in 1 participant was considered related to study vaccine by the investigator.

In conclusion, efficacy of mRNA-1273 to prevent COVID-19 persisted in Part B. The safety profile of mRNA-1273 remained acceptable, similar to that observed in Part A, and no new safety concerns were noted. The benefit/risk profile of mRNA-1273 remains strongly favorable through 6.5 months median follow-up after Dose 2.

9 References

Centers for Disease Control and Prevention (CDC). 2020. Coronavirus Disease 2019 (COVID-19). Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>. (accessed 2020 Jun 11).

14 Tables and Figures

14.1 Demographic, Background, and Disposition Data

Number	Title
Table 14.1.1.1.5.5	Subject Disposition in Open-Label Phase
Table 14.1.1.1.5.2.2	Subject Disposition by Age Group in Open-Label Phase
Table 14.1.3.2.5	Baseline Demographics and Characteristics in Open-Label Phase
Table 14.1.3.2.2.2	Baseline Demographics and Characteristics by Age Group in Open-Label Phase

14.2 Efficacy Data

Number	Title
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Table 14.2.2.1.3.8.2	Summary of COVID-19* Based on Adjudication Committee Assessments in Open-Label Phase mITT Set
Table 14.2.2.1.4.8.1	Summary of COVID-19* in Open-Label Phase Per-Protocol Set
Table 14.2.2.1.4.8.2	Summary of COVID-19* in Open-Label Phase mITT Set
Table 14.2.2.2.3.8.1	Summary of Severe COVID-19* Based on Adjudication Committee Assessments in Open-Label Phase Per-Protocol Set
Table 14.2.2.2.3.8.2	Summary of Severe COVID-19* Based on Adjudication Committee Assessments in Open-Label Phase mITT Set
Table 14.2.2.2.4.8.1	Summary of Severe COVID-19* in Open-Label Phase Per-Protocol Set
Table 14.2.2.2.4.8.2	Summary of Severe COVID-19* in Open-Label Phase mITT Set
Table 14.2.2.4.2.7.1	Summary of Secondary Definition of COVID-19* in Open-Label Phase Per-Protocol Set
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14.3 Safety Data

14.3.1 Displays of Adverse Events

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Table 14.3.1.30.1.1	Summary of Unsolicited TEAE in Open-Label Phase Safety Set
Table 14.3.1.30.1.2	Summary of Unsolicited TEAE by Age Group in Open-Label Phase Safety Set
Table 14.3.1.31.1.1	Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set
Table 14.3.1.31.1.2	Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

14.3.2 Displays of Deaths, Other Serious and Clinically Meaningful Adverse Events

Number	Title
Table 14.3.1.32.1.1	Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set
Table 14.3.1.32.1.2	Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set
Table 14.3.1.33.1.1	Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set
Table 14.3.1.33.1.2	Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set
Table 14.3.1.34.1.1	Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term in Open-Label Phase Safety Set
Table 14.3.1.34.1.2	Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

Number	Title
Table 14.3.1.35.1.1	Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term in Open-Label Phase Safety Set
Table 14.3.1.35.1.2	Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set
Table 14.3.1.36.1.1	Summary of Death in Open-Label Phase Safety Set
Table 14.3.1.36.1.2	Summary of Death by Age Group in Open-Label Phase Safety Set

Table 14.1.1.1.5.5
Subject Disposition in Open-Label Phase
Safety Set

	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects				
Started Open-Label Phase [1]	1698 (67.5)	12648 (100)	14618 (96.3)	28964 (95.4)
Received First Injection in Open-Label Phase		12648 (100)		
Received Second Injection in Open-Label Phase		11757 (93.0)		
Discontinued Study Vaccine in Open-Label Phase		19 (0.2)		
Reason for Discontinuation of Study Vaccine				
Adverse Event		0		
Serious Adverse Event		0		
Death		0		
Lost to Follow-Up		1 (<0.1)		
Physician Decision		0		
Pregnancy		0		
Protocol Deviation		0		
Study Terminated by Sponsor		0		
Withdrawal of Consent by Participant		0		
Due to SARS-CoV-2		0		
Other		0		

Percentages are based on the number of safety subjects.

[1] Subjects who started open-label phase include subjects who had participant decision visit or unblinding date.

[2] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.5.5
Subject Disposition in Open-Label Phase
Safety Set

	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Completed Study [2]	0	0	0	0
Discontinued from Study	1357 (54.0)	51 (0.4)	290 (1.9)	1698 (5.6)
Reason for Discontinuation of Study				
Adverse Event	0	0	1 (<0.1)	1 (<0.1)
Serious Adverse Event	0	1 (<0.1)	0	1 (<0.1)
Death	1 (<0.1)	3 (<0.1)	8 (<0.1)	12 (<0.1)
Lost to Follow-Up	7 (0.3)	3 (<0.1)	11 (<0.1)	21 (<0.1)
Physician Decision	7 (0.3)	3 (<0.1)	5 (<0.1)	15 (<0.1)
Pregnancy	1 (<0.1)	0	1 (<0.1)	2 (<0.1)
Protocol Deviation	493 (19.6)	11 (<0.1)	106 (0.7)	610 (2.0)
Study Terminated by Sponsor	0	0	0	0
Withdrawal of Consent by Participant	175 (7.0)	23 (0.2)	124 (0.8)	322 (1.1)
Due to SARS-CoV-2	0	0	0	0
Other	673 (26.8)	7 (<0.1)	34 (0.2)	714 (2.4)

Percentages are based on the number of safety subjects.

[1] Subjects who started open-label phase include subjects who had participant decision visit or unblinding date.

[2] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.5.2.2
Subject Disposition by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects								
Started Open-Label Phase [1]	1443 (67.0)	9256 (100)	10899 (95.5)	21598 (94.6)	255 (71.0)	3392 (100)	3719 (98.7)	7366 (98.0)
Received First Injection in Open-Label Phase		9256 (100)				3392 (100)		
Received Second Injection in Open-Label Phase		8448 (91.3)				3309 (97.6)		
Discontinued Study Vaccine in Open-Label Phase		15 (0.2)				4 (0.1)		
Reason for Discontinuation of Study Vaccine								
Adverse Event		0				0		
Serious Adverse Event		0				0		
Death		0				0		
Lost to Follow-Up		1 (<0.1)				0		

Percentages are based on the number of safety subjects.

[1] Subjects who started open-label phase include subjects who had participant decision visit or unblinding date.

[2] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.5.2.2
Subject Disposition by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Reason for Discontinuation of Study Vaccine (Cont.)								
Physician Decision		0				0		
Pregnancy		0				0		
Protocol Deviation		0				0		
Study Terminated by Sponsor		0				0		
Withdrawal of Consent by Participant		0				0		
Due to SARS-CoV-2		0				0		
Other		0				0		
Completed Study [2]	0	0	0	0	0	0	0	0
Discontinued from Study	1135 (52.7)	40 (0.4)	221 (1.9)	1396 (6.1)	222 (61.8)	11 (0.3)	69 (1.8)	302 (4.0)

Percentages are based on the number of safety subjects.

[1] Subjects who started open-label phase include subjects who had participant decision visit or unblinding date.

[2] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.5.2.2
Subject Disposition by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Reason for Discontinuation of Study								
Adverse Event	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Serious Adverse Event	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Death	0	2 (<0.1)	4 (<0.1)	6 (<0.1)	1 (0.3)	1 (<0.1)	4 (0.1)	6 (<0.1)
Lost to Follow-Up	7 (0.3)	2 (<0.1)	11 (<0.1)	20 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Physician Decision	6 (0.3)	3 (<0.1)	4 (<0.1)	13 (<0.1)	1 (0.3)	0	1 (<0.1)	2 (<0.1)
Pregnancy	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	0	0	0	0
Protocol Deviation	397 (18.4)	9 (<0.1)	78 (0.7)	484 (2.1)	96 (26.7)	2 (<0.1)	28 (0.7)	126 (1.7)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	142 (6.6)	19 (0.2)	98 (0.9)	259 (1.1)	33 (9.2)	4 (0.1)	26 (0.7)	63 (0.8)
Due to SARS-CoV-2	0	0	0	0	0	0	0	0
Other	582 (27.0)	5 (<0.1)	24 (0.2)	611 (2.7)	91 (25.3)	2 (<0.1)	10 (0.3)	103 (1.4)

Percentages are based on the number of safety subjects.

[1] Subjects who started open-label phase include subjects who had participant decision visit or unblinding date.

[2] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.3.2.5
Baseline Demographics and Characteristics in Open-Label Phase
Safety Set

	Placebo (N=2514)	Placebo- mRNA-1273 (N=12648)	mRNA-1273 (N=15184)	Total (N=30346)
Age at Screening (Years)				
n	2514	12648	15184	30346
Mean (SD)	47.1 (14.72)	52.2 (15.64)	51.4 (15.51)	51.4 (15.55)
Median	46.0	53.0	53.0	52.0
Min, Max	18, 90	18, 95	18, 95	18, 95
Age Group at Screening, n (%)				
>=18 and <65 Years	2155 (85.7)	9256 (73.2)	11415 (75.2)	22826 (75.2)
Mean (SD)	43.3 (12.01)	45.4 (12.33)	45.1 (12.35)	45.0 (12.33)
Median	44.0	47.0	46.0	46.0
Min, Max	18, 64	18, 64	18, 64	18, 64
>=65 Years	359 (14.3)	3392 (26.8)	3769 (24.8)	7520 (24.8)
Mean (SD)	70.3 (5.11)	70.8 (4.85)	70.4 (4.66)	70.6 (4.77)
Median	69.0	70.0	69.0	70.0
Min, Max	65, 90	65, 95	65, 95	65, 95
Age Subgroup at Screening, n (%)				
>=18 and <65 Years	2155 (85.7)	9256 (73.2)	11415 (75.2)	22826 (75.2)
>=65 and <70 Years	197 (7.8)	1620 (12.8)	1906 (12.6)	3723 (12.3)
>=70 and <75 Years	101 (4.0)	1092 (8.6)	1206 (7.9)	2399 (7.9)
>=75 and <80 Years	38 (1.5)	469 (3.7)	466 (3.1)	973 (3.2)
>=80 Years	23 (0.9)	211 (1.7)	191 (1.3)	425 (1.4)

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Table 14.1.3.2.5
Baseline Demographics and Characteristics in Open-Label Phase
Safety Set

	Placebo (N=2514)	Placebo- mRNA-1273 (N=12648)	mRNA-1273 (N=15184)	Total (N=30346)
Age Subgroup at Screening, n (%)				
>=18 and <65 Years	2155 (85.7)	9256 (73.2)	11415 (75.2)	22826 (75.2)
>=65 and <75 Years	298 (11.9)	2712 (21.4)	3112 (20.5)	6122 (20.2)
>=75 and <85 Years	54 (2.1)	638 (5.0)	616 (4.1)	1308 (4.3)
>=85 Years	7 (0.3)	42 (0.3)	41 (0.3)	90 (0.3)
Age and Health Risk for Severe COVID-19, n (%) [1]				
>=18 and <65 Years and Not at Risk	1796 (71.4)	7084 (56.0)	8890 (58.5)	17770 (58.6)
>=18 and <65 Years and at Risk	359 (14.3)	2176 (17.2)	2530 (16.7)	5065 (16.7)
>=65 Years	359 (14.3)	3388 (26.8)	3764 (24.8)	7511 (24.8)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]				
Chronic Lung Disease	91 (3.6)	658 (5.2)	712 (4.7)	1461 (4.8)
Significant Cardiac Disease	67 (2.7)	675 (5.3)	762 (5.0)	1504 (5.0)
Severe Obesity	133 (5.3)	925 (7.3)	1070 (7.0)	2128 (7.0)
Diabetes	178 (7.1)	1279 (10.1)	1460 (9.6)	2917 (9.6)
Liver Disease	13 (0.5)	83 (0.7)	104 (0.7)	200 (0.7)
Human Immunodeficiency Virus Infection	10 (0.4)	81 (0.6)	94 (0.6)	185 (0.6)
At Risk for Severe COVID-19 at Screening, n (%)				
Yes	425 (16.9)	3032 (24.0)	3448 (22.7)	6905 (22.8)
One Risk Factor for Severe COVID-19	366 (14.6)	2449 (19.4)	2791 (18.4)	5606 (18.5)
Two or More Risk Factors for Severe COVID-19	59 (2.3)	583 (4.6)	657 (4.3)	1299 (4.3)
No	2089 (83.1)	9616 (76.0)	11736 (77.3)	23441 (77.2)

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Table 14.1.3.2.5
Baseline Demographics and Characteristics in Open-Label Phase
Safety Set

	Placebo (N=2514)	Placebo- mRNA-1273 (N=12648)	mRNA-1273 (N=15184)	Total (N=30346)
Age and Risk for Severe COVID-19, n (%) [3]				
>=18 and <65 Years and Not at Risk	1837 (73.1)	7252 (57.3)	9095 (59.9)	18184 (59.9)
>=18 and <65 Years and at Risk	318 (12.6)	2004 (15.8)	2320 (15.3)	4642 (15.3)
>=65 Years and Not at Risk	252 (10.0)	2364 (18.7)	2641 (17.4)	5257 (17.3)
>=65 Years and at Risk	107 (4.3)	1028 (8.1)	1128 (7.4)	2263 (7.5)
Baseline RT-PCR Results, n (%)				
Negative	2478 (98.6)	12513 (98.9)	15017 (98.9)	30008 (98.9)
Positive	28 (1.1)	67 (0.5)	88 (0.6)	183 (0.6)
Missing	8 (0.3)	68 (0.5)	79 (0.5)	155 (0.5)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)				
Negative	2432 (96.7)	12408 (98.1)	14851 (97.8)	29691 (97.8)
Positive	80 (3.2)	223 (1.8)	309 (2.0)	612 (2.0)
Missing	2 (<0.1)	17 (0.1)	24 (0.2)	43 (0.1)
Baseline SARS-CoV-2 Status, n (%) [4]				
Negative	2414 (96.0)	12327 (97.5)	14750 (97.1)	29491 (97.2)
Positive	93 (3.7)	244 (1.9)	347 (2.3)	684 (2.3)
Missing	7 (0.3)	77 (0.6)	87 (0.6)	171 (0.6)
Sex, n (%)				
Male	1393 (55.4)	6663 (52.7)	7918 (52.1)	15974 (52.6)
Female	1121 (44.6)	5985 (47.3)	7266 (47.9)	14372 (47.4)

Note: Footnotes are listed on the last page.

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Table 14.1.3.2.5
Baseline Demographics and Characteristics in Open-Label Phase
Safety Set

	Placebo (N=2514)	Placebo- mRNA-1273 (N=12648)	mRNA-1273 (N=15184)	Total (N=30346)
Race, n (%)				
White	1910 (76.0)	10088 (79.8)	12034 (79.3)	24032 (79.2)
Black or African American	252 (10.0)	1279 (10.1)	1567 (10.3)	3098 (10.2)
Asian	213 (8.5)	526 (4.2)	656 (4.3)	1395 (4.6)
American Indian or Alaska Native	21 (0.8)	100 (0.8)	113 (0.7)	234 (0.8)
Native Hawaiian or Other Pacific Islander	10 (0.4)	22 (0.2)	36 (0.2)	68 (0.2)
Multiracial	41 (1.6)	277 (2.2)	320 (2.1)	638 (2.1)
Other	49 (1.9)	245 (1.9)	299 (2.0)	593 (2.0)
Not Reported	11 (0.4)	63 (0.5)	97 (0.6)	171 (0.6)
Unknown	7 (0.3)	48 (0.4)	62 (0.4)	117 (0.4)
Ethnicity, n (%)				
Hispanic or Latino	611 (24.3)	2497 (19.7)	3122 (20.6)	6230 (20.5)
Not Hispanic or Latino	1878 (74.7)	10040 (79.4)	11920 (78.5)	23838 (78.6)
Not Reported	15 (0.6)	68 (0.5)	105 (0.7)	188 (0.6)
Unknown	10 (0.4)	43 (0.3)	37 (0.2)	90 (0.3)
Race and Ethnicity Group, n (%) [5]				
Minority	847 (33.7)	3783 (29.9)	4654 (30.7)	9284 (30.6)
Non-minority	1662 (66.1)	8844 (69.9)	10504 (69.2)	21010 (69.2)
Missing	5 (0.2)	21 (0.2)	26 (0.2)	52 (0.2)
Race and Ethnicity Group, n (%) [6]				
White	1407 (56.0)	8059 (63.7)	9535 (62.8)	19001 (62.6)
Communities of Color	1102 (43.8)	4568 (36.1)	5623 (37.0)	11293 (37.2)
Missing	5 (0.2)	21 (0.2)	26 (0.2)	52 (0.2)

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Table 14.1.3.2.5
Baseline Demographics and Characteristics in Open-Label Phase
Safety Set

	Placebo (N=2514)	Placebo- mRNA-1273 (N=12648)	mRNA-1273 (N=15184)	Total (N=30346)
Weight (kg)				
n	2503	12576	15099	30178
Mean (SD)	84.35 (20.548)	86.19 (21.825)	85.70 (21.951)	85.79 (21.790)
Median	81.82	83.18	83.00	83.00
Min, Max	35.9, 193.0	30.7, 223.0	30.3, 236.4	30.3, 236.4
Height (cm)				
n	2503	12574	15100	30177
Mean (SD)	171.27 (9.851)	170.81 (10.075)	170.73 (9.937)	170.81 (9.988)
Median	171.45	170.20	170.18	170.20
Min, Max	118.0, 205.7	122.3, 223.5	104.1, 221.0	104.1, 223.5
Body Mass Index (kg/m ²)				
n	2503	12574	15096	30173
Mean (SD)	28.69 (6.378)	29.45 (6.728)	29.32 (6.837)	29.32 (6.757)
Median	27.50	28.25	28.13	28.13
Min, Max	13.9, 62.5	10.3, 72.7	9.8, 86.1	9.8, 86.1
Body Mass Index Subgroup, n (%)				
< 30 kg/m ²	1661 (66.1)	7639 (60.4)	9276 (61.1)	18576 (61.2)
>=30 kg/m ²	842 (33.5)	4935 (39.0)	5820 (38.3)	11597 (38.2)
Missing	11 (0.4)	74 (0.6)	88 (0.6)	173 (0.6)

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Table 14.1.3.2.5
Baseline Demographics and Characteristics in Open-Label Phase
Safety Set

	Placebo (N=2514)	Placebo- mRNA-1273 (N=12648)	mRNA-1273 (N=15184)	Total (N=30346)
Occupational Risk, n (%) [2]	2310 (91.9)	10237 (80.9)	12500 (82.3)	25047 (82.5)
Healthcare Workers	1385 (55.1)	2455 (19.4)	3809 (25.1)	7649 (25.2)
Emergency Response	80 (3.2)	216 (1.7)	302 (2.0)	598 (2.0)
Retail or Restaurant Operations	118 (4.7)	862 (6.8)	958 (6.3)	1938 (6.4)
Manufacturing and Production Operations	58 (2.3)	363 (2.9)	426 (2.8)	847 (2.8)
Warehouse Shipping and Fulfillment Centers	24 (1.0)	151 (1.2)	190 (1.3)	365 (1.2)
Transportation and Delivery Services	68 (2.7)	412 (3.3)	484 (3.2)	964 (3.2)
Border Protection and Military Personnel	16 (0.6)	53 (0.4)	68 (0.4)	137 (0.5)
Personal Care and In-Home Services	82 (3.3)	386 (3.1)	472 (3.1)	940 (3.1)
Hospitality and Tourism Workers	16 (0.6)	211 (1.7)	238 (1.6)	465 (1.5)
Pastoral, Social or Public Health Workers	42 (1.7)	462 (3.7)	535 (3.5)	1039 (3.4)
Educators and Students	158 (6.3)	1399 (11.1)	1551 (10.2)	3108 (10.2)
Other	491 (19.5)	4339 (34.3)	4850 (31.9)	9680 (31.9)
Location and Living Circumstances Risk, n (%) [2]	2074 (82.5)	10611 (83.9)	12736 (83.9)	25421 (83.8)
Resides in Nursing Home or Assisted Living Facility	3 (0.1)	26 (0.2)	35 (0.2)	64 (0.2)
Resides in Multi-Family Dwelling	65 (2.6)	348 (2.8)	463 (3.0)	876 (2.9)
Resides in High Density Housing	218 (8.7)	1095 (8.7)	1291 (8.5)	2604 (8.6)
Resides in Low Density, Multi-Family Setting	219 (8.7)	1273 (10.1)	1492 (9.8)	2984 (9.8)
Resides in a Single Family Home	1446 (57.5)	6960 (55.0)	8402 (55.3)	16808 (55.4)
Other	295 (11.7)	1880 (14.9)	2198 (14.5)	4373 (14.4)

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Table 14.1.3.2.5
Baseline Demographics and Characteristics in Open-Label Phase
Safety Set

Baseline refers to the baseline in blinded phase.

Percentages are based on the number of safety subjects.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
- [4] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [5] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [6] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Table 14.1.3.2.2.2
Baseline Demographics and Characteristics by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
Age at Screening (Years)								
n	2155	9256	11415	22826	359	3392	3769	7520
Mean	43.3	45.4	45.1	45.0	70.3	70.8	70.4	70.6
(SD)	(12.01)	(12.33)	(12.35)	(12.33)	(5.11)	(4.85)	(4.66)	(4.77)
Median	44.0	47.0	46.0	46.0	69.0	70.0	69.0	70.0
Min, Max	18, 64	18, 64	18, 64	18, 64	65, 90	65, 95	65, 95	65, 95
Age Group at Screening, n (%)								
>=18 and <65 Years	2155 (100)	9256 (100)	11415 (100)	22826 (100)	0	0	0	0
Mean	43.3	45.4	45.1	45.0				
(SD)	(12.01)	(12.33)	(12.35)	(12.33)				
Median	44.0	47.0	46.0	46.0				
Min, Max	18, 64	18, 64	18, 64	18, 64				
>=65 Years	0	0	0	0	359 (100)	3392 (100)	3769 (100)	7520 (100)
Mean					70.3	70.8	70.4	70.6
(SD)					(5.11)	(4.85)	(4.66)	(4.77)
Median					69.0	70.0	69.0	70.0
Min, Max					65, 90	65, 95	65, 95	65, 95

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Table 14.1.3.2.2.2
Baseline Demographics and Characteristics by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
Age Subgroup at Screening, n (%)								
>=18 and <65 Years	2155 (100)	9256 (100)	11415 (100)	22826 (100)	0	0	0	0
>=65 and <70 Years	0	0	0	0	197 (54.9)	1620 (47.8)	1906 (50.6)	3723 (49.5)
>=70 and <75 Years	0	0	0	0	101 (28.1)	1092 (32.2)	1206 (32.0)	2399 (31.9)
>=75 and <80 Years	0	0	0	0	38 (10.6)	469 (13.8)	466 (12.4)	973 (12.9)
>=80 Years	0	0	0	0	23 (6.4)	211 (6.2)	191 (5.1)	425 (5.7)
Age Subgroup at Screening, n (%)								
>=18 and <65 Years	2155 (100)	9256 (100)	11415 (100)	22826 (100)	0	0	0	0
>=65 and <75 Years	0	0	0	0	298 (83.0)	2712 (80.0)	3112 (82.6)	6122 (81.4)
>=75 and <85 Years	0	0	0	0	54 (15.0)	638 (18.8)	616 (16.3)	1308 (17.4)
>=85 Years	0	0	0	0	7 (1.9)	42 (1.2)	41 (1.1)	90 (1.2)

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Table 14.1.3.2.2.2
Baseline Demographics and Characteristics by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
Age and Health Risk for Severe COVID-19, n (%) [1]								
>=18 and <65 Years and Not at Risk	1796 (83.3)	7082 (76.5)	8890 (77.9)	17768 (77.8)	0	2 (<0.1)	0	2 (<0.1)
>=18 and <65 Years and at Risk	359 (16.7)	2173 (23.5)	2524 (22.1)	5056 (22.2)	0	3 (<0.1)	6 (0.2)	9 (0.1)
>=65 Years	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	359 (100)	3387 (99.9)	3763 (99.8)	7509 (99.9)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]								
Chronic Lung Disease	69 (3.2)	435 (4.7)	473 (4.1)	977 (4.3)	22 (6.1)	223 (6.6)	239 (6.3)	484 (6.4)
Significant Cardiac Disease	26 (1.2)	266 (2.9)	321 (2.8)	613 (2.7)	41 (11.4)	409 (12.1)	441 (11.7)	891 (11.8)
Severe Obesity	119 (5.5)	786 (8.5)	896 (7.8)	1801 (7.9)	14 (3.9)	139 (4.1)	174 (4.6)	327 (4.3)
Diabetes	132 (6.1)	780 (8.4)	919 (8.1)	1831 (8.0)	46 (12.8)	499 (14.7)	541 (14.4)	1086 (14.4)
Liver Disease	10 (0.5)	60 (0.6)	84 (0.7)	154 (0.7)	3 (0.8)	23 (0.7)	20 (0.5)	46 (0.6)
Human Immunodeficiency Virus Infection	8 (0.4)	67 (0.7)	77 (0.7)	152 (0.7)	2 (0.6)	14 (0.4)	17 (0.5)	33 (0.4)

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Table 14.1.3.2.2.2
Baseline Demographics and Characteristics by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
At Risk for Severe COVID-19 at Screening, n (%)								
Yes	318 (14.8)	2004 (21.7)	2320 (20.3)	4642 (20.3)	107 (29.8)	1028 (30.3)	1128 (29.9)	2263 (30.1)
One Risk Factor for Severe COVID-19	278 (12.9)	1659 (17.9)	1925 (16.9)	3862 (16.9)	88 (24.5)	790 (23.3)	866 (23.0)	1744 (23.2)
Two or More Risk Factors for Severe COVID-19	40 (1.9)	345 (3.7)	395 (3.5)	780 (3.4)	19 (5.3)	238 (7.0)	262 (7.0)	519 (6.9)
No	1837 (85.2)	7252 (78.3)	9095 (79.7)	18184 (79.7)	252 (70.2)	2364 (69.7)	2641 (70.1)	5257 (69.9)
Age and Risk for Severe COVID-19, n (%) [3]								
>=18 and <65 Years and Not at Risk	1837 (85.2)	7252 (78.3)	9095 (79.7)	18184 (79.7)	0	0	0	0
>=18 and <65 Years and at Risk	318 (14.8)	2004 (21.7)	2320 (20.3)	4642 (20.3)	0	0	0	0
>=65 Years and Not at Risk	0	0	0	0	252 (70.2)	2364 (69.7)	2641 (70.1)	5257 (69.9)
>=65 Years and at Risk	0	0	0	0	107 (29.8)	1028 (30.3)	1128 (29.9)	2263 (30.1)

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Table 14.1.3.2.2.2
Baseline Demographics and Characteristics by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
Baseline RT-PCR Results, n (%)								
Negative	2121 (98.4)	9148 (98.8)	11270 (98.7)	22539 (98.7)	357 (99.4)	3365 (99.2)	3747 (99.4)	7469 (99.3)
Positive	27 (1.3)	58 (0.6)	81 (0.7)	166 (0.7)	1 (0.3)	9 (0.3)	7 (0.2)	17 (0.2)
Missing	7 (0.3)	50 (0.5)	64 (0.6)	121 (0.5)	1 (0.3)	18 (0.5)	15 (0.4)	34 (0.5)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)								
Negative	2077 (96.4)	9045 (97.7)	11126 (97.5)	22248 (97.5)	355 (98.9)	3363 (99.1)	3725 (98.8)	7443 (99.0)
Positive	76 (3.5)	198 (2.1)	276 (2.4)	550 (2.4)	4 (1.1)	25 (0.7)	33 (0.9)	62 (0.8)
Missing	2 (<0.1)	13 (0.1)	13 (0.1)	28 (0.1)	0	4 (0.1)	11 (0.3)	15 (0.2)
Baseline SARS-CoV-2 Status, n (%) [4]								
Negative	2060 (95.6)	8984 (97.1)	11039 (96.7)	22083 (96.7)	354 (98.6)	3343 (98.6)	3711 (98.5)	7408 (98.5)
Positive	89 (4.1)	214 (2.3)	311 (2.7)	614 (2.7)	4 (1.1)	30 (0.9)	36 (1.0)	70 (0.9)
Missing	6 (0.3)	58 (0.6)	65 (0.6)	129 (0.6)	1 (0.3)	19 (0.6)	22 (0.6)	42 (0.6)

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Table 14.1.3.2.2.2
Baseline Demographics and Characteristics by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
Sex, n (%)								
Male	1156 (53.6)	4799 (51.8)	5841 (51.2)	11796 (51.7)	237 (66.0)	1864 (55.0)	2077 (55.1)	4178 (55.6)
Female	999 (46.4)	4457 (48.2)	5574 (48.8)	11030 (48.3)	122 (34.0)	1528 (45.0)	1692 (44.9)	3342 (44.4)
Race, n (%)								
White	1599 (74.2)	7057 (76.2)	8654 (75.8)	17310 (75.8)	311 (86.6)	3031 (89.4)	3380 (89.7)	6722 (89.4)
Black or African American	241 (11.2)	1075 (11.6)	1345 (11.8)	2661 (11.7)	11 (3.1)	204 (6.0)	222 (5.9)	437 (5.8)
Asian	195 (9.0)	467 (5.0)	589 (5.2)	1251 (5.5)	18 (5.0)	59 (1.7)	67 (1.8)	144 (1.9)
American Indian or Alaska Native	19 (0.9)	76 (0.8)	92 (0.8)	187 (0.8)	2 (0.6)	24 (0.7)	21 (0.6)	47 (0.6)
Native Hawaiian or Other Pacific Islander	10 (0.5)	19 (0.2)	33 (0.3)	62 (0.3)	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Multiracial	33 (1.5)	250 (2.7)	288 (2.5)	571 (2.5)	8 (2.2)	27 (0.8)	32 (0.8)	67 (0.9)
Other	44 (2.0)	218 (2.4)	276 (2.4)	538 (2.4)	5 (1.4)	27 (0.8)	23 (0.6)	55 (0.7)
Not Reported	9 (0.4)	51 (0.6)	84 (0.7)	144 (0.6)	2 (0.6)	12 (0.4)	13 (0.3)	27 (0.4)
Unknown	5 (0.2)	43 (0.5)	54 (0.5)	102 (0.4)	2 (0.6)	5 (0.1)	8 (0.2)	15 (0.2)

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Table 14.1.3.2.2.2
Baseline Demographics and Characteristics by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
Ethnicity, n (%)								
Hispanic or Latino	551 (25.6)	2222 (24.0)	2768 (24.2)	5541 (24.3)	60 (16.7)	275 (8.1)	354 (9.4)	689 (9.2)
Not Hispanic or Latino	1582 (73.4)	6961 (75.2)	8549 (74.9)	17092 (74.9)	296 (82.5)	3079 (90.8)	3371 (89.4)	6746 (89.7)
Not Reported	14 (0.6)	43 (0.5)	72 (0.6)	129 (0.6)	1 (0.3)	25 (0.7)	33 (0.9)	59 (0.8)
Unknown	8 (0.4)	30 (0.3)	26 (0.2)	64 (0.3)	2 (0.6)	13 (0.4)	11 (0.3)	26 (0.3)
Race and Ethnicity Group, n (%)								
[5]								
Minority	775 (36.0)	3294 (35.6)	4076 (35.7)	8145 (35.7)	72 (20.1)	489 (14.4)	578 (15.3)	1139 (15.1)
Non-minority	1377 (63.9)	5952 (64.3)	7319 (64.1)	14648 (64.2)	285 (79.4)	2892 (85.3)	3185 (84.5)	6362 (84.6)
Missing	3 (0.1)	10 (0.1)	20 (0.2)	33 (0.1)	2 (0.6)	11 (0.3)	6 (0.2)	19 (0.3)
Race and Ethnicity Group, n (%)								
[6]								
White	1148 (53.3)	5253 (56.8)	6459 (56.6)	12860 (56.3)	259 (72.1)	2806 (82.7)	3076 (81.6)	6141 (81.7)
Communities of Color	1004 (46.6)	3993 (43.1)	4936 (43.2)	9933 (43.5)	98 (27.3)	575 (17.0)	687 (18.2)	1360 (18.1)
Missing	3 (0.1)	10 (0.1)	20 (0.2)	33 (0.1)	2 (0.6)	11 (0.3)	6 (0.2)	19 (0.3)

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Table 14.1.3.2.2.2
Baseline Demographics and Characteristics by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
Weight (kg)								
n	2144	9207	11359	22710	359	3369	3740	7468
Mean	84.43	87.30	86.56	86.66	83.90	83.17	83.10	83.17
(SD)	(20.794)	(22.665)	(22.683)	(22.518)	(19.030)	(19.021)	(19.333)	(19.176)
Median	81.82	84.09	83.64	83.64	82.73	81.36	81.20	81.40
Min, Max	35.9, 193.0	30.7, 223.0	30.3, 236.4	30.3, 236.4	46.0, 172.0	34.8, 184.5	37.2, 165.0	34.8, 184.5
Height (cm)								
n	2144	9206	11359	22709	359	3368	3741	7468
Mean	171.22	171.15	170.98	171.07	171.57	169.89	169.97	170.01
(SD)	(9.902)	(9.978)	(9.902)	(9.933)	(9.545)	(10.281)	(10.005)	(10.114)
Median	171.45	170.94	170.20	170.50	172.70	170.18	170.18	170.18
Min, Max	118.0, 205.7	122.3, 204.5	104.1, 221.0	104.1, 221.0	142.2, 195.6	124.5, 223.5	123.0, 208.3	123.0, 223.5
Body Mass Index (kg/m ²)								
n	2144	9206	11356	22706	359	3368	3740	7467
Mean	28.74	29.71	29.53	29.53	28.39	28.75	28.67	28.69
(SD)	(6.496)	(6.983)	(7.120)	(7.012)	(5.622)	(5.919)	(5.850)	(5.870)
Median	27.51	28.43	28.25	28.26	27.46	27.76	27.86	27.79
Min, Max	13.9, 62.5	10.3, 72.7	9.8, 86.1	9.8, 86.1	17.4, 56.0	12.1, 71.1	11.2, 62.9	11.2, 71.1

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Table 14.1.3.2.2.2
Baseline Demographics and Characteristics by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
Body Mass Index Subgroup, n (%)								
< 30 kg/m ²	1413 (65.6)	5453 (58.9)	6860 (60.1)	13726 (60.1)	248 (69.1)	2186 (64.4)	2416 (64.1)	4850 (64.5)
>=30 kg/m ²	731 (33.9)	3753 (40.5)	4496 (39.4)	8980 (39.3)	111 (30.9)	1182 (34.8)	1324 (35.1)	2617 (34.8)
Missing	11 (0.5)	50 (0.5)	59 (0.5)	120 (0.5)	0	24 (0.7)	29 (0.8)	53 (0.7)

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Table 14.1.3.2.2.2
Baseline Demographics and Characteristics by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
Occupational Risk, n (%) [2]	2021 (93.8)	8140 (87.9)	10123 (88.7)	20284 (88.9)	289 (80.5)	2097 (61.8)	2377 (63.1)	4763 (63.3)
Healthcare Workers	1220 (56.6)	2117 (22.9)	3341 (29.3)	6678 (29.3)	165 (46.0)	338 (10.0)	468 (12.4)	971 (12.9)
Emergency Response	76 (3.5)	201 (2.2)	281 (2.5)	558 (2.4)	4 (1.1)	15 (0.4)	21 (0.6)	40 (0.5)
Retail or Restaurant Operations	113 (5.2)	768 (8.3)	858 (7.5)	1739 (7.6)	5 (1.4)	94 (2.8)	100 (2.7)	199 (2.6)
Manufacturing and Production Operations	55 (2.6)	336 (3.6)	391 (3.4)	782 (3.4)	3 (0.8)	27 (0.8)	35 (0.9)	65 (0.9)
Warehouse Shipping and Fulfillment Centers	24 (1.1)	139 (1.5)	181 (1.6)	344 (1.5)	0 (0.4)	12 (0.4)	9 (0.2)	21 (0.3)
Transportation and Delivery Services	66 (3.1)	353 (3.8)	434 (3.8)	853 (3.7)	2 (0.6)	59 (1.7)	50 (1.3)	111 (1.5)
Border Protection and Military Personnel	15 (0.7)	48 (0.5)	65 (0.6)	128 (0.6)	1 (0.3)	5 (0.1)	3 (<0.1)	9 (0.1)
Personal Care and In-Home Services	75 (3.5)	332 (3.6)	405 (3.5)	812 (3.6)	7 (1.9)	54 (1.6)	67 (1.8)	128 (1.7)
Hospitality and Tourism Workers	13 (0.6)	171 (1.8)	201 (1.8)	385 (1.7)	3 (0.8)	40 (1.2)	37 (1.0)	80 (1.1)
Pastoral, Social or Public Health Workers	38 (1.8)	326 (3.5)	386 (3.4)	750 (3.3)	4 (1.1)	136 (4.0)	149 (4.0)	289 (3.8)
Educators and Students	147 (6.8)	1240 (13.4)	1365 (12.0)	2752 (12.1)	11 (3.1)	159 (4.7)	186 (4.9)	356 (4.7)
Other	391 (18.1)	3007 (32.5)	3415 (29.9)	6813 (29.8)	100 (27.9)	1332 (39.3)	1435 (38.1)	2867 (38.1)

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Table 14.1.3.2.2.2
Baseline Demographics and Characteristics by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
Location and Living	1783	7795	9601	19179	291	2816	3135	6242
Circumstances Risk, n (%) [2]	(82.7)	(84.2)	(84.1)	(84.0)	(81.1)	(83.0)	(83.2)	(83.0)
Resides in Nursing Home or	1	8	24	33	2	18	11	31
Assisted Living Facility	(<0.1)	(<0.1)	(0.2)	(0.1)	(0.6)	(0.5)	(0.3)	(0.4)
Resides in Multi-Family	58	290	397	745	7	58	66	131
Dwelling	(2.7)	(3.1)	(3.5)	(3.3)	(1.9)	(1.7)	(1.8)	(1.7)
Resides in High Density	195	878	1038	2111	23	217	253	493
Housing	(9.0)	(9.5)	(9.1)	(9.2)	(6.4)	(6.4)	(6.7)	(6.6)
Resides in Low Density,	200	1036	1248	2484	19	237	244	500
Multi-Family Setting	(9.3)	(11.2)	(10.9)	(10.9)	(5.3)	(7.0)	(6.5)	(6.6)
Resides in a Single Family	1220	4926	6117	12263	226	2034	2285	4545
Home	(56.6)	(53.2)	(53.6)	(53.7)	(63.0)	(60.0)	(60.6)	(60.4)
Other	265	1382	1649	3296	30	498	549	1077
	(12.3)	(14.9)	(14.4)	(14.4)	(8.4)	(14.7)	(14.6)	(14.3)

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Table 14.1.3.2.2.2
Baseline Demographics and Characteristics by Age Group in Open-Label Phase
Safety Set

Baseline refers to the baseline in blinded phase.

Percentages are based on the number of safety subjects.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
- [4] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [5] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [6] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Table 14.2.2.1.3.8.1
Summary of COVID-19* Based on Adjudication Committee Assessments in Open-Label Phase
Per-Protocol Set

	Placebo (N=2104)	Placebo-mRNA-1273 (N=12060)	mRNA-1273 (N=14287)
Number of Subjects at Risk [1]	1175	11234	13704
Number of Subjects with COVID-19*, n (%) [2]	3 (0.3)	56 (0.5)	19 (0.1)
Before First Injection of mRNA-1273 in Open-Label Phase		17 (0.2)	
From First Injection up to Second Injection of mRNA-1273 in Open-Label Phase		37 (0.3)	
From Second Injection up to 14 Days After Second Injection of mRNA-1273 in Open-Label Phase		1 (<0.1)	
>=14 Days After Second Injection of mRNA-1273 in Open-Label Phase		1 (<0.1)	
Number of Subjects Censored, n (%) [2]	1172 (99.7)	11178 (99.5)	13685 (99.9)
Person-Years [3]	38.8		2386.6
Incidence Rate per 1,000 Person-Years (95% CI) [4]	77.378 (15.957, 226.131)		7.961 (4.793, 12.432)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at scheduled visits without eligible symptoms within 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Subjects at risk are defined as subjects who started the open-label phase before or on efficacy data cutoff date, had no prior SARS-CoV-2 infection (defined by positive post-baseline RT-PCR or Elecsys results) and were not a COVID-19 case up to participant decision visit (PDV) or unblinding date, whichever is earlier.

[2] Percentages are based on number of subjects at risk.

[3] Person-years is defined as the total years from PDV/unblinding date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[4] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

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Table 14.2.2.1.3.8.2
Summary of COVID-19* Based on Adjudication Committee Assessments in Open-Label Phase
mITT Set

	Placebo (N=2416)	Placebo-mRNA-1273 (N=12329)	mRNA-1273 (N=14746)
Number of Subjects at Risk [1]	1233	11449	13939
Number of Subjects with COVID-19*, n (%) [2]	3 (0.2)	58 (0.5)	19 (0.1)
Before First Injection of mRNA-1273 in Open-Label Phase		18 (0.2)	
From First Injection up to Second Injection of mRNA-1273 in Open-Label Phase		38 (0.3)	
From Second Injection up to 14 Days After Second Injection of mRNA-1273 in Open-Label Phase		1 (<0.1)	
>=14 Days After Second Injection of mRNA-1273 in Open-Label Phase		1 (<0.1)	
Number of Subjects Censored, n (%) [2]	1230 (99.8)	11391 (99.5)	13920 (99.9)
Person-Years [3]	42.7		2426.2
Incidence Rate per 1,000 Person-Years (95% CI) [4]	70.191 (14.475, 205.128)		7.831 (4.715, 12.229)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at scheduled visits without eligible symptoms within 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Subjects at risk are defined as subjects who started the open-label phase before or on efficacy data cutoff date, had no prior SARS-CoV-2 infection (defined by positive post-baseline RT-PCR or Elecsys results) and were not a COVID-19 case up to participant decision visit (PDV) or unblinding date, whichever is earlier.

[2] Percentages are based on number of subjects at risk.

[3] Person-years is defined as the total years from PDV/unblinding date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[4] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

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Table 14.2.2.1.4.8.1
Summary of COVID-19* in Open-Label Phase
Per-Protocol Set

	Placebo (N=2104)	Placebo-mRNA-1273 (N=12060)	mRNA-1273 (N=14287)
Number of Subjects at Risk [1]	1175	11234	13704
Number of Subjects with COVID-19*, n (%) [2]	3 (0.3)	78 (0.7)	28 (0.2)
Before First Injection of mRNA-1273 in Open-Label Phase		19 (0.2)	
From First Injection up to Second Injection of mRNA-1273 in Open-Label Phase		57 (0.5)	
From Second Injection up to 14 Days After Second Injection of mRNA-1273 in Open-Label Phase		1 (<0.1)	
>=14 Days After Second Injection of mRNA-1273 in Open-Label Phase		1 (<0.1)	
Number of Subjects Censored, n (%) [2]	1172 (99.7)	11156 (99.3)	13676 (99.8)
Person-Years [3]	38.8		2385.5
Incidence Rate per 1,000 Person-Years (95% CI) [4]	77.378 (15.957, 226.131)		11.738 (7.800, 16.964)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at scheduled visits without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Subjects at risk are defined as subjects who started the open-label phase before or on efficacy data cutoff date, had no prior SARS-CoV-2 infection (defined by positive post-baseline RT-PCR or Elecsys results) and were not a COVID-19 case up to participant decision visit (PDV) or unblinding date, whichever is earlier.

[2] Percentages are based on number of subjects at risk.

[3] Person-years is defined as the total years from PDV/unblinding date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[4] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

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Table 14.2.2.1.4.8.2
Summary of COVID-19* in Open-Label Phase
mITT Set

	Placebo (N=2416)	Placebo-mRNA-1273 (N=12329)	mRNA-1273 (N=14746)
Number of Subjects at Risk [1]	1233	11449	13939
Number of Subjects with COVID-19*, n (%) [2]	3 (0.2)	81 (0.7)	28 (0.2)
Before First Injection of mRNA-1273 in Open-Label Phase		20 (0.2)	
From First Injection up to Second Injection of mRNA-1273 in Open-Label Phase		59 (0.5)	
From Second Injection up to 14 Days After Second Injection of mRNA-1273 in Open-Label Phase		1 (<0.1)	
>=14 Days After Second Injection of mRNA-1273 in Open-Label Phase		1 (<0.1)	
Number of Subjects Censored, n (%) [2]	1230 (99.8)	11368 (99.3)	13911 (99.8)
Person-Years [3]	42.7		2425.2
Incidence Rate per 1,000 Person-Years (95% CI) [4]	70.191 (14.475, 205.128)		11.546 (7.672, 16.687)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at scheduled visits without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Subjects at risk are defined as subjects who started the open-label phase before or on efficacy data cutoff date, had no prior SARS-CoV-2 infection (defined by positive post-baseline RT-PCR or Elecsys results) and were not a COVID-19 case up to participant decision visit (PDV) or unblinding date, whichever is earlier.

[2] Percentages are based on number of subjects at risk.

[3] Person-years is defined as the total years from PDV/unblinding date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[4] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

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Table 14.2.2.2.3.8.1
Summary of Severe COVID-19* Based on Adjudication Committee Assessments in Open-Label Phase
Per-Protocol Set

	Placebo (N=2104)	Placebo-mRNA-1273 (N=12060)	mRNA-1273 (N=14287)
Number of Subjects at Risk [1]	1175	11234	13704
Number of Subjects with Severe COVID-19*, n (%) [2]	1 (<0.1)	8 (<0.1)	1 (<0.1)
Before First Injection of mRNA-1273 in Open-Label Phase		4 (<0.1)	
From First Injection up to Second Injection of mRNA-1273 in Open-Label Phase		4 (<0.1)	
From Second Injection up to 14 Days After Second Injection of mRNA-1273 in Open-Label Phase		0	
>=14 Days After Second Injection of mRNA-1273 in Open-Label Phase		0	
Number of Subjects Censored, n (%) [2]	1174 (>99.9)	11226 (>99.9)	13703 (>99.9)
Person-Years [3]	39.1		2388.3
Incidence Rate per 1,000 Person-Years (95% CI) [4]	25.546 (0.647, 142.331)		0.419 (0.011, 2.333)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at scheduled visits without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Subjects at risk are defined as subjects who started the open-label phase before or on efficacy data cutoff date, had no prior SARS-CoV-2 infection (defined by positive post-baseline RT-PCR or Elecsys results) and were not a COVID-19 case up to participant decision visit (PDV) or unblinding date, whichever is earlier.

[2] Percentages are based on number of subjects at risk.

[3] Person-years is defined as the total years from PDV/unblinding date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[4] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

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Table 14.2.2.2.3.8.2
Summary of Severe COVID-19* Based on Adjudication Committee Assessments in Open-Label Phase
mITT Set

	Placebo (N=2416)	Placebo-mRNA-1273 (N=12329)	mRNA-1273 (N=14746)
Number of Subjects at Risk [1]	1233	11449	13939
Number of Subjects with Severe COVID-19*, n (%) [2]	1 (<0.1)	8 (<0.1)	1 (<0.1)
Before First Injection of mRNA-1273 in Open-Label Phase		4 (<0.1)	
From First Injection up to Second Injection of mRNA-1273 in Open-Label Phase		4 (<0.1)	
From Second Injection up to 14 Days After Second Injection of mRNA-1273 in Open-Label Phase		0	
>=14 Days After Second Injection of mRNA-1273 in Open-Label Phase		0	
Number of Subjects Censored, n (%) [2]	1232 (>99.9)	11441 (>99.9)	13938 (>99.9)
Person-Years [3]	43.1		2428.0
Incidence Rate per 1,000 Person-Years (95% CI) [4]	23.193 (0.587, 129.225)		0.412 (0.010, 2.295)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at scheduled visits without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Subjects at risk are defined as subjects who started the open-label phase before or on efficacy data cutoff date, had no prior SARS-CoV-2 infection (defined by positive post-baseline RT-PCR or Elecsys results) and were not a COVID-19 case up to participant decision visit (PDV) or unblinding date, whichever is earlier.

[2] Percentages are based on number of subjects at risk.

[3] Person-years is defined as the total years from PDV/unblinding date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[4] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

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Table 14.2.2.2.4.8.1
Summary of Severe COVID-19* in Open-Label Phase
Per-Protocol Set

	Placebo (N=2104)	Placebo-mRNA-1273 (N=12060)	mRNA-1273 (N=14287)
Number of Subjects at Risk [1]	1175	11234	13704
Number of Subjects with Severe COVID-19*, n (%) [2]	1 (<0.1)	13 (0.1)	1 (<0.1)
Before First Injection of mRNA-1273 in Open-Label Phase		5 (<0.1)	
From First Injection up to Second Injection of mRNA-1273 in Open-Label Phase		8 (<0.1)	
From Second Injection up to 14 Days After Second Injection of mRNA-1273 in Open-Label Phase		0	
>=14 Days After Second Injection of mRNA-1273 in Open-Label Phase		0	
Number of Subjects Censored, n (%) [2]	1174 (>99.9)	11221 (99.9)	13703 (>99.9)
Person-Years [3]	39.1		2388.3
Incidence Rate per 1,000 Person-Years (95% CI) [4]	25.546 (0.647, 142.331)		0.419 (0.011, 2.333)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at scheduled visits without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Subjects at risk are defined as subjects who started the open-label phase before or on efficacy data cutoff date, had no prior SARS-CoV-2 infection (defined by positive post-baseline RT-PCR or Elecsys results) and were not a COVID-19 case up to participant decision visit (PDV) or unblinding date, whichever is earlier.

[2] Percentages are based on number of subjects at risk.

[3] Person-years is defined as the total years from PDV/unblinding date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[4] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

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Table 14.2.2.2.4.8.2
Summary of Severe COVID-19* in Open-Label Phase
mITT Set

	Placebo (N=2416)	Placebo-mRNA-1273 (N=12329)	mRNA-1273 (N=14746)
Number of Subjects at Risk [1]	1233	11449	13939
Number of Subjects with Severe COVID-19*, n (%) [2]	1 (<0.1)	13 (0.1)	1 (<0.1)
Before First Injection of mRNA-1273 in Open-Label Phase		5 (<0.1)	
From First Injection up to Second Injection of mRNA-1273 in Open-Label Phase		8 (<0.1)	
From Second Injection up to 14 Days After Second Injection of mRNA-1273 in Open-Label Phase		0	
>=14 Days After Second Injection of mRNA-1273 in Open-Label Phase		0	
Number of Subjects Censored, n (%) [2]	1232 (>99.9)	11436 (99.9)	13938 (>99.9)
Person-Years [3]	43.1		2428.0
Incidence Rate per 1,000 Person-Years (95% CI) [4]	23.193 (0.587, 129.225)		0.412 (0.010, 2.295)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at scheduled visits without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Subjects at risk are defined as subjects who started the open-label phase before or on efficacy data cutoff date, had no prior SARS-CoV-2 infection (defined by positive post-baseline RT-PCR or Elecsys results) and were not a COVID-19 case up to participant decision visit (PDV) or unblinding date, whichever is earlier.

[2] Percentages are based on number of subjects at risk.

[3] Person-years is defined as the total years from PDV/unblinding date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[4] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

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Table 14.2.2.4.2.7.1
Summary of Secondary Definition of COVID-19* in Open-Label Phase
Per-Protocol Set

	Placebo (N=2104)	Placebo-mRNA-1273 (N=12060)	mRNA-1273 (N=14287)
Number of Subjects at Risk [1]	1175	11234	13704
Number of Subjects with Secondary Definition of COVID-19*, n (%) [2]	4 (0.3)	89 (0.8)	39 (0.3)
Before First Injection of mRNA-1273 in Open-Label Phase		20 (0.2)	
From First Injection up to Second Injection of mRNA-1273 in Open-Label Phase		65 (0.6)	
From Second Injection up to 14 Days After Second Injection of mRNA-1273 in Open-Label Phase		3 (<0.1)	
>=14 Days After Second Injection of mRNA-1273 in Open-Label Phase		1 (<0.1)	
Number of Subjects Censored, n (%) [2]	1171 (99.7)	11145 (99.2)	13665 (99.7)
Person-Years [3]	38.6		2384.4
Incidence Rate per 1,000 Person-Years (95% CI) [4]	103.713 (28.258, 265.546)		16.357 (11.631, 22.360)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at scheduled visits without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Subjects at risk are defined as subjects who started the open-label phase before or on efficacy data cutoff date, had no prior SARS-CoV-2 infection (defined by positive post-baseline RT-PCR or Elecsys results) and were not a COVID-19 case up to participant decision visit (PDV) or unblinding date, whichever is earlier.

[2] Percentages are based on number of subjects at risk.

[3] Person-years is defined as the total years from PDV/unblinding date to the date of secondary definition of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[4] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

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Table 14.2.2.4.2.7.2
Summary of Secondary Definition of COVID-19* in Open-Label Phase
mITT Set

	Placebo (N=2416)	Placebo-mRNA-1273 (N=12329)	mRNA-1273 (N=14746)
Number of Subjects at Risk [1]	1233	11449	13939
Number of Subjects with Secondary Definition of COVID-19*, n (%) [2]	4 (0.3)	93 (0.8)	39 (0.3)
Before First Injection of mRNA-1273 in Open-Label Phase		22 (0.2)	
From First Injection up to Second Injection of mRNA-1273 in Open-Label Phase		67 (0.6)	
From Second Injection up to 14 Days After Second Injection of mRNA-1273 in Open-Label Phase		3 (<0.1)	
>=14 Days After Second Injection of mRNA-1273 in Open-Label Phase		1 (<0.1)	
Number of Subjects Censored, n (%) [2]	1229 (99.7)	11356 (99.2)	13900 (99.7)
Person-Years [3]	42.5		2424.0
Incidence Rate per 1,000 Person-Years (95% CI) [4]	94.034 (25.621, 240.763)		16.089 (11.441, 21.994)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at scheduled visits without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Subjects at risk are defined as subjects who started the open-label phase before or on efficacy data cutoff date, had no prior SARS-CoV-2 infection (defined by positive post-baseline RT-PCR or Elecsys results) and were not a COVID-19 case up to participant decision visit (PDV) or unblinding date, whichever is earlier.

[2] Percentages are based on number of subjects at risk.

[3] Person-years is defined as the total years from PDV/unblinding date to the date of secondary definition of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[4] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

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Table 14.3.1.30.1.1
Summary of Unsolicited TEAE in Open-Label Phase
Safety Set

	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination				
All	41 (1.6)	2446 (19.3)	1729 (11.4)	4216 (13.9)
Serious	7 (0.3)	148 (1.2)	141 (0.9)	296 (1.0)
Fatal	1 (<0.1)	3 (<0.1)	7 (<0.1)	11 (<0.1)
Medically-Attended	37 (1.5)	1509 (11.9)	1457 (9.6)	3003 (9.9)
Leading to Discontinuation from Study Vaccine	0	12 (<0.1)	2 (<0.1)	14 (<0.1)
Leading to Discontinuation from Participation in the Study	1 (<0.1)	4 (<0.1)	7 (<0.1)	12 (<0.1)
Severe	4 (0.2)	179 (1.4)	147 (1.0)	330 (1.1)
Unsolicited TEAEs Related to Study Vaccination				
All	0	758 (6.0)	22 (0.1)	780 (2.6)
Serious	0	4 (<0.1)	0	4 (<0.1)
Fatal	0	0	0	0
Medically-Attended	0	74 (0.6)	9 (<0.1)	83 (0.3)
Leading to Discontinuation from Study Vaccine	0	4 (<0.1)	0	4 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0	0
Severe	0	24 (0.2)	1 (<0.1)	25 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.30.1.2
Summary of Unsolicited TEAE by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo	Placebo-	mRNA-1273	Total	Placebo	Placebo-	mRNA-1273	Total
	(N=2155)	(N=9256)	(N=11415)	(N=22826)	(N=359)	(N=3392)	(N=3769)	(N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination								
All	34 (1.6)	1692 (18.3)	1193 (10.5)	2919 (12.8)	7 (1.9)	754 (22.2)	536 (14.2)	1297 (17.2)
Serious	5 (0.2)	83 (0.9)	81 (0.7)	169 (0.7)	2 (0.6)	65 (1.9)	60 (1.6)	127 (1.7)
Fatal	0	2 (<0.1)	4 (<0.1)	6 (<0.1)	1 (0.3)	1 (<0.1)	3 (<0.1)	5 (<0.1)
Medically-Attended	30 (1.4)	998 (10.8)	986 (8.6)	2014 (8.8)	7 (1.9)	511 (15.1)	471 (12.5)	989 (13.2)
Leading to Discontinuation from Study Vaccine	0	11 (0.1)	2 (<0.1)	13 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Leading to Discontinuation from Participation in the Study	0	2 (<0.1)	4 (<0.1)	6 (<0.1)	1 (0.3)	2 (<0.1)	3 (<0.1)	6 (<0.1)
Severe	3 (0.1)	104 (1.1)	87 (0.8)	194 (0.8)	1 (0.3)	75 (2.2)	60 (1.6)	136 (1.8)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.30.1.2
Summary of Unsolicited TEAE by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo	Placebo-	mRNA-1273	Total	Placebo	Placebo-	mRNA-1273	Total
	(N=2155)	mRNA-1273	(N=9256)	(N=22826)	(N=359)	mRNA-1273	(N=3392)	(N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Unsolicited TEAEs Related to								
Study Vaccination								
All	0	564	16	580	0	194	6	200
		(6.1)	(0.1)	(2.5)		(5.7)	(0.2)	(2.7)
Serious	0	3	0	3	0	1	0	1
		(<0.1)		(<0.1)		(<0.1)		(<0.1)
Fatal	0	0	0	0	0	0	0	0
Medically-Attended	0	60	4	64	0	14	5	19
		(0.6)	(<0.1)	(0.3)		(0.4)	(0.1)	(0.3)
Leading to Discontinuation	0	4	0	4	0	0	0	0
from Study Vaccine		(<0.1)		(<0.1)				
Leading to Discontinuation	0	0	0	0	0	0	0	0
from Participation in								
the Study								
Severe	0	14	1	15	0	10	0	10
		(0.2)	(<0.1)	(<0.1)		(0.3)		(0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	41 (1.6)	2446 (19.3)	1729 (11.4)	4216 (13.9)
Number of Unsolicited Adverse Events	66	4814	2557	7437
Infections and infestations	11 (0.4)	546 (4.3)	552 (3.6)	1109 (3.7)
Urinary tract infection	0	63 (0.5)	67 (0.4)	130 (0.4)
COVID-19	4 (0.2)	60 (0.5)	41 (0.3)	105 (0.3)
Upper respiratory tract infection	2 (<0.1)	51 (0.4)	54 (0.4)	107 (0.4)
Sinusitis	0	38 (0.3)	32 (0.2)	70 (0.2)
Rhinovirus infection	1 (<0.1)	25 (0.2)	20 (0.1)	46 (0.2)
Viral infection	0	21 (0.2)	37 (0.2)	58 (0.2)
Tooth infection	0	17 (0.1)	15 (<0.1)	32 (0.1)
Suspected COVID-19	0	16 (0.1)	37 (0.2)	53 (0.2)
Pharyngitis streptococcal	0	15 (0.1)	4 (<0.1)	19 (<0.1)
Diverticulitis	0	13 (0.1)	6 (<0.1)	19 (<0.1)
Gastroenteritis	0	12 (<0.1)	12 (<0.1)	24 (<0.1)
Herpes zoster	0	12 (<0.1)	14 (<0.1)	26 (<0.1)
Asymptomatic COVID-19	0	11 (<0.1)	14 (<0.1)	25 (<0.1)
Tooth abscess	1 (<0.1)	11 (<0.1)	15 (<0.1)	27 (<0.1)
Otitis media	0	10 (<0.1)	3 (<0.1)	13 (<0.1)
Pneumonia	0	10 (<0.1)	6 (<0.1)	16 (<0.1)
Cellulitis	0	9 (<0.1)	13 (<0.1)	22 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Acute sinusitis	0	7 (<0.1)	8 (<0.1)	15 (<0.1)
Onychomycosis	0	7 (<0.1)	0	7 (<0.1)
Pharyngitis	0	7 (<0.1)	6 (<0.1)	13 (<0.1)
Appendicitis	0	6 (<0.1)	5 (<0.1)	11 (<0.1)
Bronchitis	0	6 (<0.1)	11 (<0.1)	17 (<0.1)
Conjunctivitis	0	6 (<0.1)	6 (<0.1)	12 (<0.1)
Ear infection	0	6 (<0.1)	6 (<0.1)	12 (<0.1)
Cystitis	0	5 (<0.1)	4 (<0.1)	9 (<0.1)
Folliculitis	0	5 (<0.1)	1 (<0.1)	6 (<0.1)
Hordeolum	0	5 (<0.1)	6 (<0.1)	11 (<0.1)
Localised infection	0	5 (<0.1)	3 (<0.1)	8 (<0.1)
Oral herpes	0	5 (<0.1)	7 (<0.1)	12 (<0.1)
Sepsis	0	5 (<0.1)	4 (<0.1)	9 (<0.1)
Bacterial vaginosis	1 (<0.1)	4 (<0.1)	4 (<0.1)	9 (<0.1)
Coronavirus infection	0	4 (<0.1)	3 (<0.1)	7 (<0.1)
Staphylococcal infection	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Viral upper respiratory tract infection	0	4 (<0.1)	10 (<0.1)	14 (<0.1)
Vulvovaginal mycotic infection	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Fungal skin infection	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Gastroenteritis viral	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Gingivitis	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Helicobacter infection	1 (<0.1)	3 (<0.1)	2 (<0.1)	6 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Herpes simplex	0	3 (<0.1)	0	3 (<0.1)
Infected bite	0	3 (<0.1)	0	3 (<0.1)
Kidney infection	0	3 (<0.1)	0	3 (<0.1)
Respiratory tract infection	0	3 (<0.1)	4 (<0.1)	7 (<0.1)
Abscess limb	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Appendicitis perforated	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Arthritis bacterial	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Candida infection	0	2 (<0.1)	0	2 (<0.1)
Eye infection	0	2 (<0.1)	6 (<0.1)	8 (<0.1)
Fungal infection	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Gastroenteritis bacterial	0	2 (<0.1)	0	2 (<0.1)
Infected dermal cyst	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Osteomyelitis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Otitis externa	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Parotitis	0	2 (<0.1)	0	2 (<0.1)
Rhinitis	0	2 (<0.1)	0	2 (<0.1)
Tinea pedis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Vulvovaginal candidiasis	0	2 (<0.1)	5 (<0.1)	7 (<0.1)
Wound infection	0	2 (<0.1)	0	2 (<0.1)
Appendiceal abscess	0	1 (<0.1)	0	1 (<0.1)
Arthritis infective	0	1 (<0.1)	0	1 (<0.1)
Breast cellulitis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301310101.sas 21JUN2021 03:13

Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
COVID-19 pneumonia	0	1 (<0.1)	0	1 (<0.1)
Chlamydial infection	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chronic sinusitis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Conjunctivitis viral	0	1 (<0.1)	0	1 (<0.1)
Endophthalmitis	0	1 (<0.1)	0	1 (<0.1)
Escherichia infection	0	1 (<0.1)	0	1 (<0.1)
Eyelid infection	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Furuncle	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastrointestinal bacterial overgrowth	0	1 (<0.1)	0	1 (<0.1)
Genital herpes	0	1 (<0.1)	0	1 (<0.1)
Genital herpes simplex	0	1 (<0.1)	0	1 (<0.1)
Genital infection fungal	0	1 (<0.1)	0	1 (<0.1)
Groin abscess	0	1 (<0.1)	0	1 (<0.1)
Helicobacter gastritis	0	1 (<0.1)	0	1 (<0.1)
Hepatic infection	0	1 (<0.1)	0	1 (<0.1)
Impetigo	0	1 (<0.1)	0	1 (<0.1)
Infected cyst	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Infectious mononucleosis	0	1 (<0.1)	0	1 (<0.1)
Influenza	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Labyrinthitis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lower respiratory tract infection	0	1 (<0.1)	0	1 (<0.1)
Medical device site joint infection	0	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301310101.sas 21JUN2021 03:13

Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Meningitis	0	1 (<0.1)	0	1 (<0.1)
Nasal vestibulitis	0	1 (<0.1)	0	1 (<0.1)
Nasopharyngitis	1 (<0.1)	1 (<0.1)	3 (<0.1)	5 (<0.1)
Nipple infection	0	1 (<0.1)	0	1 (<0.1)
Oesophageal candidiasis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ophthalmic herpes simplex	0	1 (<0.1)	0	1 (<0.1)
Oral candidiasis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Osteomyelitis bacterial	0	1 (<0.1)	0	1 (<0.1)
Papilloma viral infection	0	1 (<0.1)	4 (<0.1)	5 (<0.1)
Paronychia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Periorbital cellulitis	0	1 (<0.1)	0	1 (<0.1)
Pertussis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pilonidal cyst	0	1 (<0.1)	0	1 (<0.1)
Post procedural infection	0	1 (<0.1)	0	1 (<0.1)
Postoperative abscess	0	1 (<0.1)	0	1 (<0.1)
Postoperative wound infection	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Pseudomonas infection	0	1 (<0.1)	0	1 (<0.1)
Pulpitis dental	0	1 (<0.1)	0	1 (<0.1)
Pyelonephritis	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Root canal infection	0	1 (<0.1)	0	1 (<0.1)
Staphylococcal sepsis	0	1 (<0.1)	0	1 (<0.1)
Syphilis	0	1 (<0.1)	0	1 (<0.1)

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MedDRA version 23.0.

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Tinea manuum	0	1 (<0.1)	0	1 (<0.1)
Tonsillitis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Trichomoniasis	0	1 (<0.1)	0	1 (<0.1)
Urethritis chlamydial	0	1 (<0.1)	0	1 (<0.1)
Uterine infection	0	1 (<0.1)	0	1 (<0.1)
Vaginal infection	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Viral sinusitis	0	1 (<0.1)	0	1 (<0.1)
Abscess	0	0	1 (<0.1)	1 (<0.1)
Abscess neck	0	0	1 (<0.1)	1 (<0.1)
Abscess oral	0	0	2 (<0.1)	2 (<0.1)
American trypanosomiasis	0	0	1 (<0.1)	1 (<0.1)
Bacterial diarrhoea	0	0	1 (<0.1)	1 (<0.1)
Body tinea	0	0	1 (<0.1)	1 (<0.1)
Bronchitis bacterial	0	0	1 (<0.1)	1 (<0.1)
Cervicitis	0	0	1 (<0.1)	1 (<0.1)
Clostridium difficile infection	0	0	1 (<0.1)	1 (<0.1)
Diarrhoea infectious	0	0	1 (<0.1)	1 (<0.1)
Enterovirus infection	0	0	1 (<0.1)	1 (<0.1)
Epididymitis	0	0	2 (<0.1)	2 (<0.1)
Escherichia urinary tract infection	0	0	1 (<0.1)	1 (<0.1)
Gonorrhoea	0	0	1 (<0.1)	1 (<0.1)
Laryngitis viral	0	0	1 (<0.1)	1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Lice infestation	1 (<0.1)	0	0	1 (<0.1)
Lip infection	0	0	1 (<0.1)	1 (<0.1)
Necrotising fasciitis	0	0	1 (<0.1)	1 (<0.1)
Ophthalmic herpes zoster	0	0	1 (<0.1)	1 (<0.1)
Orchitis	0	0	1 (<0.1)	1 (<0.1)
Oropharyngeal candidiasis	0	0	1 (<0.1)	1 (<0.1)
Otitis media acute	0	0	2 (<0.1)	2 (<0.1)
Pericarditis infective	1 (<0.1)	0	0	1 (<0.1)
Perirectal abscess	0	0	1 (<0.1)	1 (<0.1)
Pharyngeal abscess	0	0	1 (<0.1)	1 (<0.1)
Pneumonia bacterial	0	0	1 (<0.1)	1 (<0.1)
Proctitis chlamydial	0	0	2 (<0.1)	2 (<0.1)
Respiratory syncytial virus infection	0	0	1 (<0.1)	1 (<0.1)
Sialoadenitis	0	0	1 (<0.1)	1 (<0.1)
Sinusitis bacterial	0	0	2 (<0.1)	2 (<0.1)
Skin infection	0	0	3 (<0.1)	3 (<0.1)
Staphylococcal bacteraemia	0	0	1 (<0.1)	1 (<0.1)
Streptococcal infection	0	0	1 (<0.1)	1 (<0.1)
Tinea versicolour	0	0	2 (<0.1)	2 (<0.1)
Urethritis	0	0	1 (<0.1)	1 (<0.1)
Vestibular neuronitis	0	0	1 (<0.1)	1 (<0.1)
Vestibulitis	0	0	1 (<0.1)	1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.1)	42 (0.3)	63 (0.4)	108 (0.4)
Basal cell carcinoma	0	14 (0.1)	6 (<0.1)	20 (<0.1)
Lipoma	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Squamous cell carcinoma of skin	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Melanocytic naevus	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Benign neoplasm of skin	0	1 (<0.1)	0	1 (<0.1)
Bladder neoplasm	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blepharal papilloma	0	1 (<0.1)	0	1 (<0.1)
Breast cancer	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Castleman's disease	0	1 (<0.1)	0	1 (<0.1)
Colon adenoma	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ear neoplasm malignant	0	1 (<0.1)	0	1 (<0.1)
Fibroadenoma of breast	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fibrous histiocyoma	0	1 (<0.1)	0	1 (<0.1)
Intraductal proliferative breast lesion	0	1 (<0.1)	0	1 (<0.1)
Malignant melanoma	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Metastases to lung	0	1 (<0.1)	0	1 (<0.1)
Myelodysplastic syndrome	0	1 (<0.1)	0	1 (<0.1)
Oesophageal adenocarcinoma	0	1 (<0.1)	0	1 (<0.1)
Pancreatic carcinoma	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pancreatic carcinoma metastatic	0	1 (<0.1)	0	1 (<0.1)
Pancreatic carcinoma stage IV	0	1 (<0.1)	0	1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Prostate cancer	0	1 (<0.1)	7 (<0.1)	8 (<0.1)
Prostate cancer stage I	0	1 (<0.1)	0	1 (<0.1)
Renal cancer	0	1 (<0.1)	0	1 (<0.1)
Uterine leiomyoma	1 (<0.1)	1 (<0.1)	5 (<0.1)	7 (<0.1)
Acrochordon	0	0	1 (<0.1)	1 (<0.1)
B-cell lymphoma	0	0	1 (<0.1)	1 (<0.1)
Borderline mucinous tumour of ovary	0	0	1 (<0.1)	1 (<0.1)
Chronic lymphocytic leukaemia	0	0	1 (<0.1)	1 (<0.1)
Colorectal cancer metastatic	1 (<0.1)	0	0	1 (<0.1)
Cutaneous T-cell lymphoma	0	0	1 (<0.1)	1 (<0.1)
Endometrial cancer	0	0	1 (<0.1)	1 (<0.1)
Eye naevus	0	0	1 (<0.1)	1 (<0.1)
High-grade B-cell lymphoma	0	0	1 (<0.1)	1 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	0	1 (<0.1)	2 (<0.1)
Lung adenocarcinoma	0	0	1 (<0.1)	1 (<0.1)
Lung neoplasm malignant	0	0	1 (<0.1)	1 (<0.1)
Lymphoma	0	0	1 (<0.1)	1 (<0.1)
Neoplasm skin	0	0	1 (<0.1)	1 (<0.1)
Oesophageal carcinoma	0	0	1 (<0.1)	1 (<0.1)
Oral fibroma	0	0	1 (<0.1)	1 (<0.1)
Papillary thyroid cancer	0	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Pheochromocytoma	0	0	1 (<0.1)	1 (<0.1)
Salivary gland cancer stage IV	0	0	1 (<0.1)	1 (<0.1)
Skin cancer	0	0	2 (<0.1)	2 (<0.1)
Skin papilloma	0	0	1 (<0.1)	1 (<0.1)
Squamous cell carcinoma	0	0	3 (<0.1)	3 (<0.1)
Throat cancer	0	0	2 (<0.1)	2 (<0.1)
Thyroid cancer	0	0	1 (<0.1)	1 (<0.1)
Uterine cancer	0	0	1 (<0.1)	1 (<0.1)
Vocal cord neoplasm	0	0	1 (<0.1)	1 (<0.1)
Blood and lymphatic system disorders	0	57 (0.5)	24 (0.2)	81 (0.3)
Lymphadenopathy	0	41 (0.3)	11 (<0.1)	52 (0.2)
Anaemia	0	6 (<0.1)	3 (<0.1)	9 (<0.1)
Iron deficiency anaemia	0	2 (<0.1)	5 (<0.1)	7 (<0.1)
Hyperchromic anaemia	0	1 (<0.1)	0	1 (<0.1)
Immune thrombocytopenia	0	1 (<0.1)	0	1 (<0.1)
Increased tendency to bruise	0	1 (<0.1)	0	1 (<0.1)
Leukocytosis	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Lymph node calcification	0	1 (<0.1)	0	1 (<0.1)
Lymph node pain	0	1 (<0.1)	0	1 (<0.1)
Lymphadenitis	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Blood and lymphatic system disorders (Cont.)				
Thrombocytopenia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Haemoconcentration	0	0	1 (<0.1)	1 (<0.1)
Splenomegaly	0	0	1 (<0.1)	1 (<0.1)
Immune system disorders	0	24 (0.2)	29 (0.2)	53 (0.2)
Seasonal allergy	0	17 (0.1)	19 (0.1)	36 (0.1)
Anaphylactic reaction	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Food allergy	0	2 (<0.1)	0	2 (<0.1)
Drug hypersensitivity	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Hypersensitivity	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Sarcoidosis	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Allergy to arthropod sting	0	0	1 (<0.1)	1 (<0.1)
Endocrine disorders	0	14 (0.1)	25 (0.2)	39 (0.1)
Hypothyroidism	0	9 (<0.1)	15 (<0.1)	24 (<0.1)
Autoimmune thyroiditis	0	2 (<0.1)	0	2 (<0.1)
Basedow's disease	0	2 (<0.1)	0	2 (<0.1)
Thyroid mass	0	2 (<0.1)	4 (<0.1)	6 (<0.1)
Adrenal mass	0	0	1 (<0.1)	1 (<0.1)
Goitre	0	0	2 (<0.1)	2 (<0.1)
Hyperandrogenism	0	0	1 (<0.1)	1 (<0.1)
Hyperprolactinaemia	0	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

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Endocrine disorders (Cont.)				
Hyperthyroidism	0	0	1 (<0.1)	1 (<0.1)
Hypogonadism	0	0	1 (<0.1)	1 (<0.1)
Metabolism and nutrition disorders	0	109 (0.9)	97 (0.6)	206 (0.7)
Hypercholesterolaemia	0	18 (0.1)	14 (<0.1)	32 (0.1)
Type 2 diabetes mellitus	0	17 (0.1)	20 (0.1)	37 (0.1)
Vitamin D deficiency	0	16 (0.1)	14 (<0.1)	30 (<0.1)
Hyperlipidaemia	0	15 (0.1)	17 (0.1)	32 (0.1)
Gout	0	7 (<0.1)	4 (<0.1)	11 (<0.1)
Decreased appetite	0	6 (<0.1)	1 (<0.1)	7 (<0.1)
Diabetes mellitus	0	6 (<0.1)	4 (<0.1)	10 (<0.1)
Iron deficiency	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Dehydration	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Diabetes mellitus inadequate control	0	3 (<0.1)	0	3 (<0.1)
Glucose tolerance impaired	0	3 (<0.1)	8 (<0.1)	11 (<0.1)
Hyperglycaemia	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Hypokalaemia	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Obesity	0	3 (<0.1)	0	3 (<0.1)
Vitamin B12 deficiency	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Abnormal weight gain	0	1 (<0.1)	0	1 (<0.1)
Electrolyte imbalance	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fluid overload	0	1 (<0.1)	0	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)				
Hyperkalaemia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypertriglyceridaemia	0	1 (<0.1)	0	1 (<0.1)
Hypoglycaemia	0	1 (<0.1)	0	1 (<0.1)
Hyponatraemia	0	1 (<0.1)	0	1 (<0.1)
Lactic acidosis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Magnesium deficiency	0	1 (<0.1)	0	1 (<0.1)
Postprandial hypoglycaemia	0	1 (<0.1)	0	1 (<0.1)
Type 1 diabetes mellitus	0	1 (<0.1)	0	1 (<0.1)
Diabetic ketoacidosis	0	0	1 (<0.1)	1 (<0.1)
Dyslipidaemia	0	0	1 (<0.1)	1 (<0.1)
Haemochromatosis	0	0	1 (<0.1)	1 (<0.1)
Hypercalcaemia	0	0	2 (<0.1)	2 (<0.1)
Insulin resistance	0	0	1 (<0.1)	1 (<0.1)
Metabolic acidosis	0	0	1 (<0.1)	1 (<0.1)
Vitamin C deficiency	0	0	1 (<0.1)	1 (<0.1)
Psychiatric disorders	3 (0.1)	89 (0.7)	83 (0.5)	175 (0.6)
Anxiety	1 (<0.1)	34 (0.3)	23 (0.2)	58 (0.2)
Depression	0	32 (0.3)	27 (0.2)	59 (0.2)
Insomnia	0	13 (0.1)	13 (<0.1)	26 (<0.1)
Attention deficit hyperactivity disorder	0	9 (<0.1)	11 (<0.1)	20 (<0.1)
Suicidal ideation	0	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Adjustment disorder	0	1 (<0.1)	0	1 (<0.1)
Affective disorder	0	1 (<0.1)	0	1 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)	0	1 (<0.1)
Bipolar disorder	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Confusional state	0	1 (<0.1)	0	1 (<0.1)
Hallucination	0	1 (<0.1)	0	1 (<0.1)
Nightmare	0	1 (<0.1)	0	1 (<0.1)
Panic attack	0	1 (<0.1)	0	1 (<0.1)
Paranoia	0	1 (<0.1)	0	1 (<0.1)
Post-traumatic stress disorder	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Schizophrenia	0	1 (<0.1)	0	1 (<0.1)
Substance abuse	0	1 (<0.1)	0	1 (<0.1)
Adjustment disorder with depressed mood	0	0	1 (<0.1)	1 (<0.1)
Agitation	1 (<0.1)	0	0	1 (<0.1)
Autism spectrum disorder	0	0	1 (<0.1)	1 (<0.1)
Binge eating	0	0	1 (<0.1)	1 (<0.1)
Bipolar I disorder	0	0	1 (<0.1)	1 (<0.1)
Delirium	1 (<0.1)	0	0	1 (<0.1)
Dissociative identity disorder	0	0	1 (<0.1)	1 (<0.1)
Drug dependence	1 (<0.1)	0	0	1 (<0.1)
Dysphemia	0	0	1 (<0.1)	1 (<0.1)
Initial insomnia	0	0	1 (<0.1)	1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Intentional self-injury	0	0	1 (<0.1)	1 (<0.1)
Libido decreased	0	0	1 (<0.1)	1 (<0.1)
Major depression	0	0	1 (<0.1)	1 (<0.1)
Mental status changes	0	0	1 (<0.1)	1 (<0.1)
Mood swings	0	0	1 (<0.1)	1 (<0.1)
Stress	0	0	1 (<0.1)	1 (<0.1)
Substance use disorder	0	0	1 (<0.1)	1 (<0.1)
Suicide attempt	0	0	2 (<0.1)	2 (<0.1)
Thinking abnormal	1 (<0.1)	0	0	1 (<0.1)
Nervous system disorders	2 (<0.1)	338 (2.7)	127 (0.8)	467 (1.5)
Headache	1 (<0.1)	233 (1.8)	46 (0.3)	280 (0.9)
Dizziness	1 (<0.1)	27 (0.2)	11 (<0.1)	39 (0.1)
Ageusia	0	11 (<0.1)	3 (<0.1)	14 (<0.1)
Paraesthesia	0	11 (<0.1)	5 (<0.1)	16 (<0.1)
Hypoaesthesia	0	7 (<0.1)	4 (<0.1)	11 (<0.1)
Migraine	0	7 (<0.1)	7 (<0.1)	14 (<0.1)
Sciatica	0	7 (<0.1)	7 (<0.1)	14 (<0.1)
Syncope	0	6 (<0.1)	2 (<0.1)	8 (<0.1)
Anosmia	0	5 (<0.1)	3 (<0.1)	8 (<0.1)
Carpal tunnel syndrome	0	4 (<0.1)	4 (<0.1)	8 (<0.1)
Cerebrovascular accident	0	4 (<0.1)	5 (<0.1)	9 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Restless legs syndrome	0	4 (<0.1)	2 (<0.1)	6 (<0.1)
Tension headache	0	4 (<0.1)	0	4 (<0.1)
Neuropathy peripheral	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Presyncope	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Trigeminal neuralgia	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Cervical radiculopathy	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Dysgeusia	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Nerve compression	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Amyotrophic lateral sclerosis	0	1 (<0.1)	0	1 (<0.1)
Aphasia	0	1 (<0.1)	0	1 (<0.1)
Balance disorder	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Brain stem infarction	0	1 (<0.1)	0	1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cerebellar ataxia	0	1 (<0.1)	0	1 (<0.1)
Cerebral artery stenosis	0	1 (<0.1)	0	1 (<0.1)
Disturbance in attention	0	1 (<0.1)	0	1 (<0.1)
Haemorrhage intracranial	0	1 (<0.1)	0	1 (<0.1)
Hypogeusia	0	1 (<0.1)	0	1 (<0.1)
Ischaemic cerebral infarction	0	1 (<0.1)	0	1 (<0.1)
Lacunar infarction	0	1 (<0.1)	0	1 (<0.1)
Loss of consciousness	0	1 (<0.1)	0	1 (<0.1)
Lumbar radiculopathy	0	1 (<0.1)	0	1 (<0.1)

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MedDRA version 23.0.

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Lumbosacral radiculopathy	0	1 (<0.1)	0	1 (<0.1)
Memory impairment	0	1 (<0.1)	0	1 (<0.1)
Migraine with aura	0	1 (<0.1)	0	1 (<0.1)
Narcolepsy	0	1 (<0.1)	0	1 (<0.1)
Neuralgia	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Piriformis syndrome	0	1 (<0.1)	0	1 (<0.1)
Radiculopathy	0	1 (<0.1)	0	1 (<0.1)
Seizure	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sinus headache	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Taste disorder	0	1 (<0.1)	0	1 (<0.1)
Transient ischaemic attack	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tremor	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Amnesia	0	0	1 (<0.1)	1 (<0.1)
Aura	0	0	1 (<0.1)	1 (<0.1)
Burning sensation	0	0	1 (<0.1)	1 (<0.1)
Carotid arteriosclerosis	0	0	1 (<0.1)	1 (<0.1)
Carotid artery aneurysm	0	0	1 (<0.1)	1 (<0.1)
Cerebral ischaemia	0	0	1 (<0.1)	1 (<0.1)
Cluster headache	0	0	2 (<0.1)	2 (<0.1)
Exertional headache	0	0	1 (<0.1)	1 (<0.1)
Hemiparesis	0	0	1 (<0.1)	1 (<0.1)
Migraine without aura	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.1
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Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Nystagmus	0	0	2 (<0.1)	2 (<0.1)
Peripheral sensory neuropathy	0	0	1 (<0.1)	1 (<0.1)
Post herpetic neuralgia	0	0	2 (<0.1)	2 (<0.1)
Shift work disorder	0	0	1 (<0.1)	1 (<0.1)
Somnolence	0	0	1 (<0.1)	1 (<0.1)
Spinal cord compression	0	0	1 (<0.1)	1 (<0.1)
Transient global amnesia	0	0	1 (<0.1)	1 (<0.1)
Eye disorders	0	42 (0.3)	30 (0.2)	72 (0.2)
Cataract	0	9 (<0.1)	9 (<0.1)	18 (<0.1)
Glaucoma	0	4 (<0.1)	0	4 (<0.1)
Blepharitis	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Conjunctival haemorrhage	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dacryostenosis acquired	0	2 (<0.1)	0	2 (<0.1)
Diplopia	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Eye irritation	0	2 (<0.1)	0	2 (<0.1)
Eye pain	0	2 (<0.1)	0	2 (<0.1)
Visual impairment	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Chalazion	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Conjunctivitis allergic	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Diabetic retinopathy	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dry eye	0	1 (<0.1)	3 (<0.1)	4 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)				
Eyelid rash	0	1 (<0.1)	0	1 (<0.1)
Macular degeneration	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Macular fibrosis	0	1 (<0.1)	0	1 (<0.1)
Normal tension glaucoma	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Periorbital oedema	0	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Retinal artery occlusion	0	1 (<0.1)	0	1 (<0.1)
Retinal detachment	0	1 (<0.1)	0	1 (<0.1)
Retinal tear	0	1 (<0.1)	0	1 (<0.1)
Swelling of eyelid	0	1 (<0.1)	0	1 (<0.1)
Uveitis	0	1 (<0.1)	0	1 (<0.1)
Vision blurred	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vitreous floaters	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vitreous haemorrhage	0	1 (<0.1)	0	1 (<0.1)
Dermatochalasis	0	0	1 (<0.1)	1 (<0.1)
Episcleritis	0	0	1 (<0.1)	1 (<0.1)
Lacrimation increased	0	0	1 (<0.1)	1 (<0.1)
Neovascular age-related macular degeneration	0	0	1 (<0.1)	1 (<0.1)
Ocular hyperaemia	0	0	1 (<0.1)	1 (<0.1)
Ocular rosacea	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Ear and labyrinth disorders	1 (<0.1)	36 (0.3)	32 (0.2)	69 (0.2)
Vertigo	1 (<0.1)	13 (0.1)	14 (<0.1)	28 (<0.1)
Tinnitus	0	6 (<0.1)	4 (<0.1)	10 (<0.1)
Ear discomfort	0	3 (<0.1)	0	3 (<0.1)
Ear pain	0	3 (<0.1)	4 (<0.1)	7 (<0.1)
Deafness unilateral	0	2 (<0.1)	0	2 (<0.1)
Ear canal erythema	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Cerumen impaction	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Deafness neurosensory	0	1 (<0.1)	0	1 (<0.1)
Ear congestion	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ear pruritus	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Excessive cerumen production	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
External ear inflammation	0	1 (<0.1)	0	1 (<0.1)
Meniere's disease	0	1 (<0.1)	0	1 (<0.1)
Tympanic membrane disorder	0	1 (<0.1)	0	1 (<0.1)
Tympanic membrane hyperaemia	0	1 (<0.1)	0	1 (<0.1)
Vertigo positional	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Middle ear effusion	0	0	1 (<0.1)	1 (<0.1)
Cardiac disorders	1 (<0.1)	67 (0.5)	55 (0.4)	123 (0.4)
Palpitations	0	8 (<0.1)	5 (<0.1)	13 (<0.1)
Tachycardia	0	8 (<0.1)	6 (<0.1)	14 (<0.1)
Atrial fibrillation	0	7 (<0.1)	7 (<0.1)	14 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Coronary artery disease	0	6 (<0.1)	8 (<0.1)	14 (<0.1)
Bradycardia	0	4 (<0.1)	2 (<0.1)	6 (<0.1)
Cardiac failure	0	4 (<0.1)	0	4 (<0.1)
Myocardial infarction	0	4 (<0.1)	2 (<0.1)	6 (<0.1)
Sinus tachycardia	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Acute myocardial infarction	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Cardiac failure congestive	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Angina pectoris	0	2 (<0.1)	5 (<0.1)	7 (<0.1)
Angina unstable	0	2 (<0.1)	0	2 (<0.1)
Arrhythmia	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Bundle branch block left	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Supraventricular tachycardia	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Ventricular extrasystoles	0	2 (<0.1)	0	2 (<0.1)
Ventricular tachycardia	0	2 (<0.1)	0	2 (<0.1)
Acute coronary syndrome	0	1 (<0.1)	0	1 (<0.1)
Aortic valve incompetence	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Atrial flutter	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Atrioventricular block complete	0	1 (<0.1)	0	1 (<0.1)
Bifascicular block	0	1 (<0.1)	0	1 (<0.1)
Cardiac failure acute	0	1 (<0.1)	0	1 (<0.1)
Cardiac flutter	0	1 (<0.1)	0	1 (<0.1)

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Safety Set

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Cardiac disorders (Cont.)				
Cardiovascular disorder	0	1 (<0.1)	0	1 (<0.1)
Coronary artery occlusion	0	1 (<0.1)	0	1 (<0.1)
Left ventricular hypertrophy	0	1 (<0.1)	0	1 (<0.1)
Sinus node dysfunction	0	1 (<0.1)	0	1 (<0.1)
Acute left ventricular failure	0	0	2 (<0.1)	2 (<0.1)
Bundle branch block right	0	0	1 (<0.1)	1 (<0.1)
Cardiac arrest	0	0	1 (<0.1)	1 (<0.1)
Cardiac disorder	0	0	1 (<0.1)	1 (<0.1)
Cardiomyopathy	0	0	1 (<0.1)	1 (<0.1)
Coronary artery insufficiency	0	0	1 (<0.1)	1 (<0.1)
Extrasystoles	0	0	1 (<0.1)	1 (<0.1)
Ischaemic cardiomyopathy	0	0	1 (<0.1)	1 (<0.1)
Left atrial enlargement	0	0	1 (<0.1)	1 (<0.1)
Mitral valve incompetence	0	0	3 (<0.1)	3 (<0.1)
Postural orthostatic tachycardia syndrome	0	0	1 (<0.1)	1 (<0.1)
Pulseless electrical activity	0	0	1 (<0.1)	1 (<0.1)
Supraventricular extrasystoles	0	0	1 (<0.1)	1 (<0.1)
Ventricular arrhythmia	1 (<0.1)	0	0	1 (<0.1)
Vascular disorders	2 (<0.1)	155 (1.2)	104 (0.7)	261 (0.9)
Hypertension	2 (<0.1)	129 (1.0)	82 (0.5)	213 (0.7)
Deep vein thrombosis	0	4 (<0.1)	3 (<0.1)	7 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)				
Hot flush	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Hypotension	0	3 (<0.1)	4 (<0.1)	7 (<0.1)
Lymphoedema	0	3 (<0.1)	0	3 (<0.1)
Aortic stenosis	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Diastolic hypertension	0	1 (<0.1)	0	1 (<0.1)
Essential hypertension	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Flushing	0	1 (<0.1)	0	1 (<0.1)
Hypertensive crisis	0	1 (<0.1)	0	1 (<0.1)
Hypertensive urgency	0	1 (<0.1)	0	1 (<0.1)
Labile blood pressure	0	1 (<0.1)	0	1 (<0.1)
Orthostatic hypotension	0	1 (<0.1)	0	1 (<0.1)
Peripheral arterial occlusive disease	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Peripheral vascular disorder	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Peripheral venous disease	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Prehypertension	0	1 (<0.1)	0	1 (<0.1)
Raynaud's phenomenon	0	1 (<0.1)	0	1 (<0.1)
Systolic hypertension	0	1 (<0.1)	0	1 (<0.1)
Aortic aneurysm	0	0	1 (<0.1)	1 (<0.1)
Aortic arteriosclerosis	0	0	1 (<0.1)	1 (<0.1)
Aortic dissection	0	0	1 (<0.1)	1 (<0.1)
Haematoma	0	0	3 (<0.1)	3 (<0.1)
Intermittent claudication	0	0	1 (<0.1)	1 (<0.1)

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Safety Set

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Vascular disorders (Cont.)				
Jugular vein thrombosis	0	0	1 (<0.1)	1 (<0.1)
Phlebitis	0	0	1 (<0.1)	1 (<0.1)
Subclavian vein thrombosis	0	0	1 (<0.1)	1 (<0.1)
Vascular insufficiency	0	0	1 (<0.1)	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	3 (0.1)	194 (1.5)	152 (1.0)	349 (1.2)
Cough	1 (<0.1)	45 (0.4)	33 (0.2)	79 (0.3)
Rhinorrhoea	1 (<0.1)	44 (0.3)	25 (0.2)	70 (0.2)
Nasal congestion	1 (<0.1)	42 (0.3)	34 (0.2)	77 (0.3)
Oropharyngeal pain	1 (<0.1)	37 (0.3)	37 (0.2)	75 (0.2)
Dyspnoea	0	15 (0.1)	16 (0.1)	31 (0.1)
Asthma	0	12 (<0.1)	12 (<0.1)	24 (<0.1)
Epistaxis	0	9 (<0.1)	4 (<0.1)	13 (<0.1)
Sinus congestion	0	8 (<0.1)	8 (<0.1)	16 (<0.1)
Tachypnoea	0	7 (<0.1)	2 (<0.1)	9 (<0.1)
Sneezing	0	6 (<0.1)	3 (<0.1)	9 (<0.1)
Sleep apnoea syndrome	0	5 (<0.1)	6 (<0.1)	11 (<0.1)
Wheezing	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Acute respiratory failure	0	3 (<0.1)	0	3 (<0.1)
Chronic obstructive pulmonary disease	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Pleural effusion	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Productive cough	0	3 (<0.1)	1 (<0.1)	4 (<0.1)

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Respiratory, thoracic and mediastinal disorders (Cont.)				
Rhinitis allergic	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Atelectasis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dyspnoea exertional	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Pulmonary embolism	0	2 (<0.1)	5 (<0.1)	7 (<0.1)
Pulmonary mass	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Sinus pain	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Allergic cough	0	1 (<0.1)	0	1 (<0.1)
Asthma exercise induced	0	1 (<0.1)	0	1 (<0.1)
Bronchitis chronic	0	1 (<0.1)	0	1 (<0.1)
Dry throat	0	1 (<0.1)	0	1 (<0.1)
Emphysema	0	1 (<0.1)	0	1 (<0.1)
Hypoxia	0	1 (<0.1)	0	1 (<0.1)
Interstitial lung disease	0	1 (<0.1)	0	1 (<0.1)
Lower respiratory tract congestion	0	1 (<0.1)	0	1 (<0.1)
Nasal inflammation	0	1 (<0.1)	0	1 (<0.1)
Nasal polyps	0	1 (<0.1)	0	1 (<0.1)
Nasal septum deviation	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Paranasal sinus discomfort	0	1 (<0.1)	0	1 (<0.1)
Paranasal sinus hypersecretion	0	1 (<0.1)	0	1 (<0.1)
Pharyngeal erythema	0	1 (<0.1)	0	1 (<0.1)
Pneumothorax	0	1 (<0.1)	0	1 (<0.1)

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Safety Set

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Respiratory, thoracic and mediastinal disorders (Cont.)				
Reflux laryngitis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory disorder	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Respiratory failure	0	1 (<0.1)	0	1 (<0.1)
Rhonchi	0	1 (<0.1)	0	1 (<0.1)
Throat irritation	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	1 (<0.1)	1 (<0.1)	3 (<0.1)
Upper-airway cough syndrome	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Allergic sinusitis	0	0	1 (<0.1)	1 (<0.1)
Dysphonia	0	0	1 (<0.1)	1 (<0.1)
Laryngeal polyp	0	0	1 (<0.1)	1 (<0.1)
Lung disorder	0	0	1 (<0.1)	1 (<0.1)
Mediastinal cyst	0	0	1 (<0.1)	1 (<0.1)
Mediastinal mass	0	0	1 (<0.1)	1 (<0.1)
Nasal dryness	0	0	1 (<0.1)	1 (<0.1)
Pharyngeal ulceration	0	0	1 (<0.1)	1 (<0.1)
Pulmonary fibrosis	0	0	1 (<0.1)	1 (<0.1)
Pulmonary hypertension	0	0	1 (<0.1)	1 (<0.1)
Pulmonary oedema	0	0	1 (<0.1)	1 (<0.1)
Respiratory tract congestion	0	0	4 (<0.1)	4 (<0.1)
Rhinalgia	0	0	1 (<0.1)	1 (<0.1)
Sinus disorder	0	0	1 (<0.1)	1 (<0.1)

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MedDRA version 23.0.

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Vocal cord polyp	0	0	1 (<0.1)	1 (<0.1)
Gastrointestinal disorders	5 (0.2)	253 (2.0)	150 (1.0)	408 (1.3)
Nausea	1 (<0.1)	76 (0.6)	20 (0.1)	97 (0.3)
Diarrhoea	1 (<0.1)	43 (0.3)	27 (0.2)	71 (0.2)
Vomiting	0	26 (0.2)	7 (<0.1)	33 (0.1)
Gastrooesophageal reflux disease	2 (<0.1)	24 (0.2)	23 (0.2)	49 (0.2)
Abdominal pain	0	17 (0.1)	5 (<0.1)	22 (<0.1)
Dental caries	0	15 (0.1)	5 (<0.1)	20 (<0.1)
Toothache	1 (<0.1)	11 (<0.1)	3 (<0.1)	15 (<0.1)
Abdominal pain upper	0	9 (<0.1)	5 (<0.1)	14 (<0.1)
Constipation	0	9 (<0.1)	8 (<0.1)	17 (<0.1)
Abdominal discomfort	0	6 (<0.1)	1 (<0.1)	7 (<0.1)
Haemorrhoids	0	6 (<0.1)	3 (<0.1)	9 (<0.1)
Abdominal pain lower	0	3 (<0.1)	4 (<0.1)	7 (<0.1)
Dyspepsia	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Hiatus hernia	0	3 (<0.1)	4 (<0.1)	7 (<0.1)
Inguinal hernia	0	3 (<0.1)	0	3 (<0.1)
Colitis	0	2 (<0.1)	0	2 (<0.1)
Gastritis	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Gastrointestinal haemorrhage	0	2 (<0.1)	2 (<0.1)	4 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Large intestine polyp	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Tooth impacted	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Umbilical hernia	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Abdominal hernia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Abdominal tenderness	0	1 (<0.1)	0	1 (<0.1)
Anal fissure	0	1 (<0.1)	0	1 (<0.1)
Aphthous ulcer	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Colitis microscopic	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Duodenal ulcer perforation	0	1 (<0.1)	0	1 (<0.1)
Enlarged uvula	0	1 (<0.1)	0	1 (<0.1)
Enteritis	0	1 (<0.1)	0	1 (<0.1)
Flatulence	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Food poisoning	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Gastric ulcer	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastritis erosive	0	1 (<0.1)	0	1 (<0.1)
Gastrointestinal inflammation	0	1 (<0.1)	0	1 (<0.1)
Gastrointestinal pain	0	1 (<0.1)	0	1 (<0.1)
Haematochezia	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Haemorrhoidal haemorrhage	0	1 (<0.1)	0	1 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)	0	1 (<0.1)
Ileus paralytic	0	1 (<0.1)	0	1 (<0.1)
Impaired gastric emptying	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Internal hernia	0	1 (<0.1)	0	1 (<0.1)
Intestinal obstruction	0	1 (<0.1)	0	1 (<0.1)
Lip blister	0	1 (<0.1)	0	1 (<0.1)
Lip oedema	0	1 (<0.1)	0	1 (<0.1)
Lip swelling	0	1 (<0.1)	0	1 (<0.1)
Mouth ulceration	0	1 (<0.1)	0	1 (<0.1)
Oesophageal rupture	0	1 (<0.1)	0	1 (<0.1)
Oral disorder	0	1 (<0.1)	0	1 (<0.1)
Pancreatitis	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Pancreatitis acute	0	1 (<0.1)	0	1 (<0.1)
Parotid gland enlargement	0	1 (<0.1)	0	1 (<0.1)
Peptic ulcer	0	1 (<0.1)	0	1 (<0.1)
Periodontal disease	0	1 (<0.1)	0	1 (<0.1)
Proctalgia	0	1 (<0.1)	0	1 (<0.1)
Pulpless tooth	0	1 (<0.1)	0	1 (<0.1)
Salivary gland calculus	0	1 (<0.1)	0	1 (<0.1)
Small intestinal obstruction	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Stomatitis	0	1 (<0.1)	0	1 (<0.1)
Tooth disorder	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Transient lingual papillitis	0	1 (<0.1)	0	1 (<0.1)
Abdominal distension	0	0	2 (<0.1)	2 (<0.1)
Anal fistula	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Barrett's oesophagus	0	0	1 (<0.1)	1 (<0.1)
Crohn's disease	0	0	2 (<0.1)	2 (<0.1)
Diverticulum	1 (<0.1)	0	1 (<0.1)	2 (<0.1)
Duodenal ulcer	0	0	1 (<0.1)	1 (<0.1)
Enterovesical fistula	0	0	1 (<0.1)	1 (<0.1)
Erosive oesophagitis	0	0	1 (<0.1)	1 (<0.1)
Faeces soft	0	0	1 (<0.1)	1 (<0.1)
Gastric polyps	0	0	1 (<0.1)	1 (<0.1)
Gastrointestinal disorder	0	0	1 (<0.1)	1 (<0.1)
Glossitis	0	0	1 (<0.1)	1 (<0.1)
Glossodynia	0	0	1 (<0.1)	1 (<0.1)
Ileus	0	0	2 (<0.1)	2 (<0.1)
Irritable bowel syndrome	0	0	2 (<0.1)	2 (<0.1)
Oral pain	0	0	1 (<0.1)	1 (<0.1)
Pancreatic failure	0	0	1 (<0.1)	1 (<0.1)
Portal hypertensive gastropathy	0	0	1 (<0.1)	1 (<0.1)
Proctitis	0	0	1 (<0.1)	1 (<0.1)
Rectal polyp	0	0	1 (<0.1)	1 (<0.1)
Rectal prolapse	0	0	1 (<0.1)	1 (<0.1)
Submaxillary gland enlargement	0	0	1 (<0.1)	1 (<0.1)
Varices oesophageal	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Hepatobiliary disorders	1 (<0.1)	9 (<0.1)	16 (0.1)	26 (<0.1)
Cholecystitis	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Cholelithiasis	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hepatic steatosis	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Bile duct obstruction	0	1 (<0.1)	0	1 (<0.1)
Cholangitis	0	1 (<0.1)	0	1 (<0.1)
Hepatomegaly	0	1 (<0.1)	0	1 (<0.1)
Biliary colic	0	0	1 (<0.1)	1 (<0.1)
Cholecystitis acute	0	0	2 (<0.1)	2 (<0.1)
Cholelithiasis obstructive	0	0	1 (<0.1)	1 (<0.1)
Hepatic cirrhosis	0	0	1 (<0.1)	1 (<0.1)
Hepatic lesion	0	0	2 (<0.1)	2 (<0.1)
Hyperbilirubinaemia	1 (<0.1)	0	1 (<0.1)	2 (<0.1)
Skin and subcutaneous tissue disorders	5 (0.2)	124 (1.0)	63 (0.4)	192 (0.6)
Rash	1 (<0.1)	20 (0.2)	6 (<0.1)	27 (<0.1)
Urticaria	0	17 (0.1)	5 (<0.1)	22 (<0.1)
Pruritus	0	13 (0.1)	1 (<0.1)	14 (<0.1)
Dermatitis contact	0	7 (<0.1)	5 (<0.1)	12 (<0.1)
Skin lesion	0	6 (<0.1)	2 (<0.1)	8 (<0.1)
Actinic keratosis	0	5 (<0.1)	4 (<0.1)	9 (<0.1)
Dermal cyst	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Dermatitis allergic	0	4 (<0.1)	1 (<0.1)	5 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Rosacea	0	4 (<0.1)	3 (<0.1)	7 (<0.1)
Acne	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Dermatitis	0	3 (<0.1)	4 (<0.1)	7 (<0.1)
Drug eruption	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Night sweats	0	3 (<0.1)	0	3 (<0.1)
Rash maculo-papular	0	3 (<0.1)	0	3 (<0.1)
Rash pruritic	0	3 (<0.1)	0	3 (<0.1)
Alopecia	0	2 (<0.1)	0	2 (<0.1)
Decubitus ulcer	0	2 (<0.1)	0	2 (<0.1)
Eczema	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Erythema	0	2 (<0.1)	4 (<0.1)	6 (<0.1)
Pain of skin	0	2 (<0.1)	0	2 (<0.1)
Seborrhoeic dermatitis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Skin ulcer	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Acne cystic	0	1 (<0.1)	0	1 (<0.1)
Angioedema	0	1 (<0.1)	0	1 (<0.1)
Asteatosis	0	1 (<0.1)	0	1 (<0.1)
Dermatitis atopic	0	1 (<0.1)	0	1 (<0.1)
Dry skin	0	1 (<0.1)	0	1 (<0.1)
Ecchymosis	0	1 (<0.1)	0	1 (<0.1)
Erythema nodosum	0	1 (<0.1)	0	1 (<0.1)
Hyperhidrosis	0	1 (<0.1)	0	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Ingrowing nail	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Lichen planus	0	1 (<0.1)	0	1 (<0.1)
Lichen sclerosus	0	1 (<0.1)	0	1 (<0.1)
Nail discolouration	0	1 (<0.1)	0	1 (<0.1)
Pityriasis	0	1 (<0.1)	0	1 (<0.1)
Pruritus allergic	0	1 (<0.1)	0	1 (<0.1)
Rash erythematous	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Skin mass	0	1 (<0.1)	0	1 (<0.1)
Skin necrosis	0	1 (<0.1)	0	1 (<0.1)
Subcutaneous emphysema	0	1 (<0.1)	0	1 (<0.1)
Urticaria papular	0	1 (<0.1)	0	1 (<0.1)
Vitiligo	0	1 (<0.1)	0	1 (<0.1)
Fixed eruption	0	0	1 (<0.1)	1 (<0.1)
Hidradenitis	0	0	1 (<0.1)	1 (<0.1)
Ingrown hair	0	0	1 (<0.1)	1 (<0.1)
Perioral dermatitis	1 (<0.1)	0	3 (<0.1)	4 (<0.1)
Precancerous skin lesion	1 (<0.1)	0	0	1 (<0.1)
Psoriasis	1 (<0.1)	0	3 (<0.1)	4 (<0.1)
Rash vesicular	0	0	1 (<0.1)	1 (<0.1)
Sensitive skin	1 (<0.1)	0	0	1 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders	4 (0.2)	331 (2.6)	217 (1.4)	552 (1.8)
Myalgia	1 (<0.1)	79 (0.6)	20 (0.1)	100 (0.3)
Arthralgia	1 (<0.1)	57 (0.5)	28 (0.2)	86 (0.3)
Pain in extremity	0	55 (0.4)	18 (0.1)	73 (0.2)
Back pain	1 (<0.1)	28 (0.2)	35 (0.2)	64 (0.2)
Osteoarthritis	0	21 (0.2)	17 (0.1)	38 (0.1)
Musculoskeletal pain	0	18 (0.1)	8 (<0.1)	26 (<0.1)
Neck pain	0	11 (<0.1)	3 (<0.1)	14 (<0.1)
Muscle spasms	0	10 (<0.1)	6 (<0.1)	16 (<0.1)
Tendonitis	0	9 (<0.1)	8 (<0.1)	17 (<0.1)
Bursitis	0	8 (<0.1)	8 (<0.1)	16 (<0.1)
Arthritis	0	6 (<0.1)	5 (<0.1)	11 (<0.1)
Osteoporosis	0	6 (<0.1)	8 (<0.1)	14 (<0.1)
Musculoskeletal chest pain	0	5 (<0.1)	5 (<0.1)	10 (<0.1)
Intervertebral disc degeneration	0	4 (<0.1)	0	4 (<0.1)
Trigger finger	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Joint swelling	0	3 (<0.1)	0	3 (<0.1)
Limb discomfort	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Muscular weakness	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Rheumatoid arthritis	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Rotator cuff syndrome	0	3 (<0.1)	7 (<0.1)	10 (<0.1)
Costochondritis	0	2 (<0.1)	0	2 (<0.1)
Flank pain	0	2 (<0.1)	5 (<0.1)	7 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Groin pain	0	2 (<0.1)	0	2 (<0.1)
Intervertebral disc protrusion	0	2 (<0.1)	6 (<0.1)	8 (<0.1)
Joint range of motion decreased	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Lumbar spinal stenosis	0	2 (<0.1)	0	2 (<0.1)
Muscle twitching	0	2 (<0.1)	0	2 (<0.1)
Musculoskeletal stiffness	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Neck mass	0	2 (<0.1)	0	2 (<0.1)
Pain in jaw	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Plantar fasciitis	0	2 (<0.1)	4 (<0.1)	6 (<0.1)
Ankle impingement	0	1 (<0.1)	0	1 (<0.1)
Ankylosing spondylitis	0	1 (<0.1)	0	1 (<0.1)
Arthritis reactive	0	1 (<0.1)	0	1 (<0.1)
Axillary mass	0	1 (<0.1)	0	1 (<0.1)
Bone disorder	0	1 (<0.1)	0	1 (<0.1)
Bone swelling	0	1 (<0.1)	0	1 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)	0	1 (<0.1)
Dupuytren's contracture	0	1 (<0.1)	0	1 (<0.1)
Exostosis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Intervertebral disc displacement	0	1 (<0.1)	0	1 (<0.1)
Joint hyperextension	0	1 (<0.1)	0	1 (<0.1)
Joint noise	0	1 (<0.1)	0	1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Joint stiffness	0	1 (<0.1)	0	1 (<0.1)
Muscle swelling	0	1 (<0.1)	0	1 (<0.1)
Musculoskeletal discomfort	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Myositis	0	1 (<0.1)	0	1 (<0.1)
Patellofemoral pain syndrome	0	1 (<0.1)	0	1 (<0.1)
Polyarthrititis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Psoriatic arthropathy	0	1 (<0.1)	0	1 (<0.1)
Pubic pain	0	1 (<0.1)	0	1 (<0.1)
Scleroderma	0	1 (<0.1)	0	1 (<0.1)
Synovial cyst	0	1 (<0.1)	0	1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vertebral lateral recess stenosis	0	1 (<0.1)	0	1 (<0.1)
Cervical spinal stenosis	0	0	1 (<0.1)	1 (<0.1)
Chondrocalcinosis	0	0	1 (<0.1)	1 (<0.1)
Haemarthrosis	0	0	1 (<0.1)	1 (<0.1)
Intervertebral disc disorder	0	0	1 (<0.1)	1 (<0.1)
Metatarsalgia	0	0	1 (<0.1)	1 (<0.1)
Myofascial pain syndrome	0	0	1 (<0.1)	1 (<0.1)
Osteopenia	0	0	3 (<0.1)	3 (<0.1)
Periarthritis	0	0	1 (<0.1)	1 (<0.1)
Sacroiliitis	0	0	1 (<0.1)	1 (<0.1)

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MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301310101.sas 21JUN2021 03:13

Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Scoliosis	0	0	1 (<0.1)	1 (<0.1)
Spinal osteoarthritis	0	0	4 (<0.1)	4 (<0.1)
Spinal pain	1 (<0.1)	0	0	1 (<0.1)
Spondylitis	0	0	3 (<0.1)	3 (<0.1)
Spondylolisthesis	0	0	1 (<0.1)	1 (<0.1)
Tenosynovitis stenans	0	0	1 (<0.1)	1 (<0.1)
Torticollis	0	0	1 (<0.1)	1 (<0.1)
Renal and urinary disorders	1 (<0.1)	36 (0.3)	35 (0.2)	72 (0.2)
Nephrolithiasis	0	18 (0.1)	9 (<0.1)	27 (<0.1)
Dysuria	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Haematuria	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Acute kidney injury	0	2 (<0.1)	4 (<0.1)	6 (<0.1)
Hypertonic bladder	1 (<0.1)	2 (<0.1)	3 (<0.1)	6 (<0.1)
Ureterolithiasis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Urinary retention	0	2 (<0.1)	0	2 (<0.1)
Chronic kidney disease	0	1 (<0.1)	0	1 (<0.1)
Micturition urgency	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pollakiuria	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Renal colic	0	1 (<0.1)	0	1 (<0.1)
Renal failure	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)				
Renal injury	0	1 (<0.1)	0	1 (<0.1)
Stress urinary incontinence	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bladder prolapse	0	0	1 (<0.1)	1 (<0.1)
Bladder spasm	0	0	1 (<0.1)	1 (<0.1)
Incontinence	0	0	1 (<0.1)	1 (<0.1)
Ketonuria	0	0	1 (<0.1)	1 (<0.1)
Nephritis	0	0	1 (<0.1)	1 (<0.1)
Proteinuria	0	0	1 (<0.1)	1 (<0.1)
Renal cyst	0	0	2 (<0.1)	2 (<0.1)
Renal pain	0	0	1 (<0.1)	1 (<0.1)
Urinary incontinence	0	0	2 (<0.1)	2 (<0.1)
Urine abnormality	0	0	1 (<0.1)	1 (<0.1)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	6 (<0.1)	3 (<0.1)	10 (<0.1)
Pregnancy	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Abortion spontaneous	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Gestational diabetes	1 (<0.1)	0	1 (<0.1)	2 (<0.1)
Reproductive system and breast disorders	0	35 (0.3)	41 (0.3)	76 (0.3)
Ovarian cyst	0	4 (<0.1)	3 (<0.1)	7 (<0.1)
Prostatomegaly	0	4 (<0.1)	0	4 (<0.1)
Breast mass	0	3 (<0.1)	6 (<0.1)	9 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Breast pain	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Cervical dysplasia	0	3 (<0.1)	0	3 (<0.1)
Benign prostatic hyperplasia	0	2 (<0.1)	6 (<0.1)	8 (<0.1)
Endometriosis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Erectile dysfunction	0	2 (<0.1)	0	2 (<0.1)
Menstruation irregular	0	2 (<0.1)	0	2 (<0.1)
Prostatitis	0	2 (<0.1)	5 (<0.1)	7 (<0.1)
Uterine polyp	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Haemospermia	0	1 (<0.1)	0	1 (<0.1)
Pelvic pain	0	1 (<0.1)	0	1 (<0.1)
Perineal disorder	0	1 (<0.1)	0	1 (<0.1)
Postmenopausal haemorrhage	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Scrotal disorder	0	1 (<0.1)	0	1 (<0.1)
Uterine cyst	0	1 (<0.1)	0	1 (<0.1)
Vaginal discharge	0	1 (<0.1)	0	1 (<0.1)
Vaginal haemorrhage	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Adnexa uteri pain	0	0	1 (<0.1)	1 (<0.1)
Breast discharge	0	0	1 (<0.1)	1 (<0.1)
Dysmenorrhoea	0	0	1 (<0.1)	1 (<0.1)
Endometrial hyperplasia	0	0	1 (<0.1)	1 (<0.1)
Endometrial thickening	0	0	1 (<0.1)	1 (<0.1)
Gynaecomastia	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Menometrorrhagia	0	0	1 (<0.1)	1 (<0.1)
Pelvic cyst	0	0	1 (<0.1)	1 (<0.1)
Pelvic prolapse	0	0	1 (<0.1)	1 (<0.1)
Polycystic ovaries	0	0	1 (<0.1)	1 (<0.1)
Sexual dysfunction	0	0	1 (<0.1)	1 (<0.1)
Uterine haemorrhage	0	0	1 (<0.1)	1 (<0.1)
Uterine prolapse	0	0	3 (<0.1)	3 (<0.1)
Uterine spasm	0	0	1 (<0.1)	1 (<0.1)
Congenital, familial and genetic disorders	0	5 (<0.1)	5 (<0.1)	10 (<0.1)
Arnold-Chiari malformation	0	1 (<0.1)	0	1 (<0.1)
Congenital knee deformity	0	1 (<0.1)	0	1 (<0.1)
Methylenetetrahydrofolate reductase deficiency	0	1 (<0.1)	0	1 (<0.1)
Thalassaemia beta	0	1 (<0.1)	0	1 (<0.1)
Type IIa hyperlipidaemia	0	1 (<0.1)	0	1 (<0.1)
Corneal dystrophy	0	0	1 (<0.1)	1 (<0.1)
Enteric duplication	0	0	1 (<0.1)	1 (<0.1)
Hydrocele	0	0	1 (<0.1)	1 (<0.1)
Type V hyperlipidaemia	0	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions	4 (0.2)	714 (5.6)	97 (0.6)	815 (2.7)
Injection site pain	0	451 (3.6)	8 (<0.1)	459 (1.5)
Fatigue	2 (<0.1)	211 (1.7)	38 (0.3)	251 (0.8)
Pain	2 (<0.1)	175 (1.4)	19 (0.1)	196 (0.6)
Pyrexia	1 (<0.1)	167 (1.3)	15 (<0.1)	183 (0.6)
Chills	1 (<0.1)	136 (1.1)	16 (0.1)	153 (0.5)
Injection site erythema	0	39 (0.3)	0	39 (0.1)
Injection site swelling	0	25 (0.2)	1 (<0.1)	26 (<0.1)
Injection site pruritus	0	19 (0.2)	0	19 (<0.1)
Injection site rash	0	17 (0.1)	0	17 (<0.1)
Chest pain	1 (<0.1)	14 (0.1)	7 (<0.1)	22 (<0.1)
Injection site bruising	0	9 (<0.1)	0	9 (<0.1)
Injection site urticaria	0	8 (<0.1)	0	8 (<0.1)
Malaise	0	7 (<0.1)	0	7 (<0.1)
Peripheral swelling	1 (<0.1)	7 (<0.1)	3 (<0.1)	11 (<0.1)
Oedema peripheral	0	6 (<0.1)	6 (<0.1)	12 (<0.1)
Influenza like illness	0	5 (<0.1)	1 (<0.1)	6 (<0.1)
Injection site lymphadenopathy	0	5 (<0.1)	0	5 (<0.1)
Non-cardiac chest pain	0	5 (<0.1)	3 (<0.1)	8 (<0.1)
Axillary pain	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Chest discomfort	0	4 (<0.1)	3 (<0.1)	7 (<0.1)
Injection site induration	0	3 (<0.1)	0	3 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Asthenia	0	2 (<0.1)	0	2 (<0.1)
Cyst	0	2 (<0.1)	0	2 (<0.1)
Feeling hot	0	2 (<0.1)	0	2 (<0.1)
Injection site inflammation	0	2 (<0.1)	0	2 (<0.1)
Injection site joint pain	0	2 (<0.1)	0	2 (<0.1)
Injection site mass	0	2 (<0.1)	0	2 (<0.1)
Injection site nodule	0	2 (<0.1)	0	2 (<0.1)
Injection site warmth	0	2 (<0.1)	0	2 (<0.1)
Swelling face	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Vaccination site pain	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Discomfort	0	1 (<0.1)	0	1 (<0.1)
Drug intolerance	0	1 (<0.1)	0	1 (<0.1)
Early satiety	0	1 (<0.1)	0	1 (<0.1)
Exercise tolerance decreased	0	1 (<0.1)	0	1 (<0.1)
Facial pain	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gait disturbance	0	1 (<0.1)	0	1 (<0.1)
Generalised oedema	0	1 (<0.1)	0	1 (<0.1)
Inflammation	0	1 (<0.1)	0	1 (<0.1)
Injection site discolouration	0	1 (<0.1)	0	1 (<0.1)
Injection site discomfort	0	1 (<0.1)	0	1 (<0.1)
Injection site erosion	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Injection site irritation	0	1 (<0.1)	0	1 (<0.1)
Injection site papule	0	1 (<0.1)	0	1 (<0.1)
Injection site reaction	0	1 (<0.1)	0	1 (<0.1)
Nodule	0	1 (<0.1)	0	1 (<0.1)
Precancerous condition	0	1 (<0.1)	0	1 (<0.1)
Swelling	0	1 (<0.1)	0	1 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	1 (<0.1)	1 (<0.1)	3 (<0.1)
Vaccination site erythema	0	1 (<0.1)	0	1 (<0.1)
Vaccination site lymphadenopathy	0	1 (<0.1)	0	1 (<0.1)
Vaccination site urticaria	0	1 (<0.1)	0	1 (<0.1)
Vaccination site warmth	0	1 (<0.1)	0	1 (<0.1)
Xerosis	0	1 (<0.1)	0	1 (<0.1)
Complication associated with device	0	0	1 (<0.1)	1 (<0.1)
Incarcerated hernia	0	0	1 (<0.1)	1 (<0.1)
Medical device site haemorrhage	0	0	1 (<0.1)	1 (<0.1)
Medical device site pain	0	0	1 (<0.1)	1 (<0.1)
Papillitis	0	0	1 (<0.1)	1 (<0.1)
Pelvic mass	0	0	1 (<0.1)	1 (<0.1)
Sudden death	0	0	1 (<0.1)	1 (<0.1)
Vessel puncture site pain	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations	3 (0.1)	64 (0.5)	52 (0.3)	119 (0.4)
Blood pressure increased	2 (<0.1)	15 (0.1)	7 (<0.1)	24 (<0.1)
Blood cholesterol increased	0	5 (<0.1)	7 (<0.1)	12 (<0.1)
Blood testosterone decreased	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Cardiac murmur	0	3 (<0.1)	0	3 (<0.1)
Hepatic enzyme increased	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Blood glucose increased	0	2 (<0.1)	0	2 (<0.1)
Blood pressure diastolic increased	0	2 (<0.1)	0	2 (<0.1)
Blood triglycerides increased	0	2 (<0.1)	0	2 (<0.1)
Glycosylated haemoglobin increased	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Heart rate irregular	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Liver function test increased	0	2 (<0.1)	0	2 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)	4 (<0.1)	6 (<0.1)
Anticoagulation drug level above therapeutic	0	1 (<0.1)	0	1 (<0.1)
Blood bilirubin increased	0	1 (<0.1)	0	1 (<0.1)
Blood potassium decreased	0	1 (<0.1)	0	1 (<0.1)
Blood pressure systolic increased	0	1 (<0.1)	0	1 (<0.1)
Blood uric acid increased	0	1 (<0.1)	0	1 (<0.1)
Blood urine present	0	1 (<0.1)	0	1 (<0.1)
Body temperature increased	0	1 (<0.1)	0	1 (<0.1)
Cells in urine	0	1 (<0.1)	0	1 (<0.1)
Culture urine positive	0	1 (<0.1)	0	1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)				
Full blood count abnormal	0	1 (<0.1)	0	1 (<0.1)
Haemoglobin decreased	1 (<0.1)	1 (<0.1)	1 (<0.1)	3 (<0.1)
Heart rate increased	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Intraocular pressure increased	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Metabolic function test abnormal	0	1 (<0.1)	0	1 (<0.1)
Oxygen saturation decreased	0	1 (<0.1)	0	1 (<0.1)
Platelet count decreased	0	1 (<0.1)	0	1 (<0.1)
Progesterone decreased	0	1 (<0.1)	0	1 (<0.1)
Transaminases increased	0	1 (<0.1)	0	1 (<0.1)
Vitamin D decreased	0	1 (<0.1)	4 (<0.1)	5 (<0.1)
White blood cell count decreased	0	1 (<0.1)	0	1 (<0.1)
Alanine aminotransferase increased	0	0	2 (<0.1)	2 (<0.1)
Angiotensin converting enzyme increased	0	0	1 (<0.1)	1 (<0.1)
Antinuclear antibody increased	0	0	1 (<0.1)	1 (<0.1)
Antipsychotic drug level increased	0	0	1 (<0.1)	1 (<0.1)
Aspartate aminotransferase increased	0	0	2 (<0.1)	2 (<0.1)
Blood alkaline phosphatase increased	0	0	1 (<0.1)	1 (<0.1)
Blood calcium increased	0	0	1 (<0.1)	1 (<0.1)
Blood creatinine decreased	0	0	1 (<0.1)	1 (<0.1)
Blood lactic acid increased	0	0	1 (<0.1)	1 (<0.1)
Brain scan abnormal	0	0	1 (<0.1)	1 (<0.1)
Cardiac stress test abnormal	0	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)				
Cortisol decreased	0	0	1 (<0.1)	1 (<0.1)
Electrocardiogram QT prolonged	0	0	1 (<0.1)	1 (<0.1)
Liver function test abnormal	0	0	1 (<0.1)	1 (<0.1)
Mammogram abnormal	0	0	1 (<0.1)	1 (<0.1)
Nitrite urine present	0	0	1 (<0.1)	1 (<0.1)
Red blood cell count decreased	0	0	1 (<0.1)	1 (<0.1)
Serum ferritin decreased	0	0	1 (<0.1)	1 (<0.1)
Smear cervix abnormal	0	0	1 (<0.1)	1 (<0.1)
Smooth muscle antibody positive	0	0	1 (<0.1)	1 (<0.1)
Urine calcium increased	0	0	1 (<0.1)	1 (<0.1)
Weight increased	0	0	3 (<0.1)	3 (<0.1)
White blood cell count increased	0	0	1 (<0.1)	1 (<0.1)
White blood cells urine positive	0	0	1 (<0.1)	1 (<0.1)
Injury, poisoning and procedural complications	3 (0.1)	222 (1.8)	181 (1.2)	406 (1.3)
Procedural pain	0	26 (0.2)	21 (0.1)	47 (0.2)
Muscle strain	0	21 (0.2)	15 (<0.1)	36 (0.1)
Fall	0	15 (0.1)	11 (<0.1)	26 (<0.1)
Ligament sprain	0	14 (0.1)	10 (<0.1)	24 (<0.1)
Tooth fracture	0	14 (0.1)	7 (<0.1)	21 (<0.1)
Skin laceration	0	13 (0.1)	15 (<0.1)	28 (<0.1)
Limb injury	0	12 (<0.1)	3 (<0.1)	15 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Animal bite	0	10 (<0.1)	0	10 (<0.1)
Contusion	0	8 (<0.1)	5 (<0.1)	13 (<0.1)
Meniscus injury	0	8 (<0.1)	7 (<0.1)	15 (<0.1)
Foot fracture	0	6 (<0.1)	6 (<0.1)	12 (<0.1)
Road traffic accident	0	6 (<0.1)	4 (<0.1)	10 (<0.1)
Stress fracture	0	6 (<0.1)	3 (<0.1)	9 (<0.1)
Hand fracture	0	5 (<0.1)	2 (<0.1)	7 (<0.1)
Fibula fracture	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Joint injury	0	4 (<0.1)	2 (<0.1)	6 (<0.1)
Radius fracture	0	4 (<0.1)	0	4 (<0.1)
Tendon rupture	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Ankle fracture	1 (<0.1)	3 (<0.1)	2 (<0.1)	6 (<0.1)
Arthropod bite	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Concussion	0	3 (<0.1)	6 (<0.1)	9 (<0.1)
Dental restoration failure	0	3 (<0.1)	0	3 (<0.1)
Epicondylitis	0	3 (<0.1)	4 (<0.1)	7 (<0.1)
Lip injury	0	3 (<0.1)	0	3 (<0.1)
Upper limb fracture	0	3 (<0.1)	4 (<0.1)	7 (<0.1)
Anaemia postoperative	0	2 (<0.1)	0	2 (<0.1)
Cartilage injury	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Corneal abrasion	0	2 (<0.1)	1 (<0.1)	3 (<0.1)

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MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301310101.sas 21JUN2021 03:13

Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Eye injury	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Femur fracture	0	2 (<0.1)	0	2 (<0.1)
Ligament rupture	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Post-traumatic pain	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Rib fracture	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Wrist fracture	0	2 (<0.1)	4 (<0.1)	6 (<0.1)
Accidental overdose	0	1 (<0.1)	0	1 (<0.1)
Avulsion fracture	0	1 (<0.1)	0	1 (<0.1)
Back injury	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Bite	0	1 (<0.1)	0	1 (<0.1)
Bone contusion	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Brain contusion	0	1 (<0.1)	0	1 (<0.1)
Burn oral cavity	0	1 (<0.1)	0	1 (<0.1)
Burns first degree	0	1 (<0.1)	0	1 (<0.1)
Clavicle fracture	1 (<0.1)	1 (<0.1)	0	2 (<0.1)
Eyelid injury	0	1 (<0.1)	0	1 (<0.1)
Gun shot wound	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Head injury	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Iliotibial band syndrome	0	1 (<0.1)	0	1 (<0.1)
Incision site discharge	0	1 (<0.1)	0	1 (<0.1)
Incisional hernia	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Joint dislocation	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Lisfranc fracture	0	1 (<0.1)	0	1 (<0.1)
Lumbar vertebral fracture	0	1 (<0.1)	0	1 (<0.1)
Mouth injury	0	1 (<0.1)	0	1 (<0.1)
Muscle injury	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Neck injury	0	1 (<0.1)	0	1 (<0.1)
Pneumothorax traumatic	0	1 (<0.1)	0	1 (<0.1)
Post procedural constipation	0	1 (<0.1)	0	1 (<0.1)
Post procedural fever	0	1 (<0.1)	0	1 (<0.1)
Post procedural hypotension	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Post procedural pruritus	0	1 (<0.1)	0	1 (<0.1)
Post procedural swelling	0	1 (<0.1)	0	1 (<0.1)
Procedural complication	0	1 (<0.1)	0	1 (<0.1)
Procedural nausea	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Radiation associated pain	0	1 (<0.1)	0	1 (<0.1)
Radiation skin injury	0	1 (<0.1)	0	1 (<0.1)
Skin abrasion	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin injury	0	1 (<0.1)	0	1 (<0.1)
Spinal compression fracture	0	1 (<0.1)	0	1 (<0.1)
Subcutaneous haematoma	0	1 (<0.1)	0	1 (<0.1)
Tibia fracture	0	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Ulna fracture	0	1 (<0.1)	0	1 (<0.1)
Venomous sting	0	1 (<0.1)	0	1 (<0.1)
Wound	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Acetabulum fracture	0	0	1 (<0.1)	1 (<0.1)
Animal scratch	0	0	2 (<0.1)	2 (<0.1)
Cervical vertebral fracture	0	0	1 (<0.1)	1 (<0.1)
Chemical burn	0	0	1 (<0.1)	1 (<0.1)
Chillblains	0	0	1 (<0.1)	1 (<0.1)
Exposure during pregnancy	0	0	1 (<0.1)	1 (<0.1)
Exposure to toxic agent	0	0	2 (<0.1)	2 (<0.1)
Eye contusion	0	0	1 (<0.1)	1 (<0.1)
Facial bones fracture	0	0	2 (<0.1)	2 (<0.1)
Foreign body in eye	0	0	1 (<0.1)	1 (<0.1)
Foreign body ingestion	0	0	1 (<0.1)	1 (<0.1)
Fracture displacement	0	0	1 (<0.1)	1 (<0.1)
Fractured sacrum	0	0	1 (<0.1)	1 (<0.1)
Hip fracture	0	0	2 (<0.1)	2 (<0.1)
Humerus fracture	0	0	1 (<0.1)	1 (<0.1)
Injury	0	0	1 (<0.1)	1 (<0.1)
Limb crushing injury	0	0	1 (<0.1)	1 (<0.1)
Lower limb fracture	0	0	3 (<0.1)	3 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Muscle rupture	0	0	1 (<0.1)	1 (<0.1)
Patella fracture	0	0	1 (<0.1)	1 (<0.1)
Pelvic fracture	0	0	1 (<0.1)	1 (<0.1)
Poisoning	0	0	1 (<0.1)	1 (<0.1)
Post procedural haematoma	0	0	1 (<0.1)	1 (<0.1)
Post procedural haemorrhage	0	0	1 (<0.1)	1 (<0.1)
Seroma	0	0	1 (<0.1)	1 (<0.1)
Soft tissue injury	0	0	1 (<0.1)	1 (<0.1)
Spinal cord injury	0	0	1 (<0.1)	1 (<0.1)
Splinter	0	0	1 (<0.1)	1 (<0.1)
Stab wound	1 (<0.1)	0	0	1 (<0.1)
Sunburn	0	0	1 (<0.1)	1 (<0.1)
Suture related complication	0	0	1 (<0.1)	1 (<0.1)
Tendon injury	0	0	1 (<0.1)	1 (<0.1)
Thermal burn	0	0	1 (<0.1)	1 (<0.1)
Thoracic vertebral fracture	0	0	1 (<0.1)	1 (<0.1)
Ulnar nerve injury	0	0	1 (<0.1)	1 (<0.1)
Vaccination complication	0	0	1 (<0.1)	1 (<0.1)
Wound dehiscence	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures	0	5 (<0.1)	1 (<0.1)	6 (<0.1)
Colostomy	0	1 (<0.1)	0	1 (<0.1)
Elbow operation	0	1 (<0.1)	0	1 (<0.1)
Hip arthroplasty	0	1 (<0.1)	0	1 (<0.1)
Micrographic skin surgery	0	1 (<0.1)	0	1 (<0.1)
Shoulder arthroplasty	0	1 (<0.1)	0	1 (<0.1)
Gastric bypass	0	0	1 (<0.1)	1 (<0.1)
Social circumstances	0	0	1 (<0.1)	1 (<0.1)
Physical assault	0	0	1 (<0.1)	1 (<0.1)
Product issues	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Device failure	0	1 (<0.1)	0	1 (<0.1)
Device physical property issue	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Device breakage	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	34 (1.6)	1692 (18.3)	1193 (10.5)	2919 (12.8)	7 (1.9)	754 (22.2)	536 (14.2)	1297 (17.2)
Number of Unsolicited Adverse Events	55	3402	1733	5190	11	1412	824	2247
Infections and infestations	10 (0.5)	395 (4.3)	420 (3.7)	825 (3.6)	1 (0.3)	151 (4.5)	132 (3.5)	284 (3.8)
Urinary tract infection	0	41 (0.4)	47 (0.4)	88 (0.4)	0	22 (0.6)	20 (0.5)	42 (0.6)
COVID-19	4 (0.2)	45 (0.5)	33 (0.3)	82 (0.4)	0	15 (0.4)	8 (0.2)	23 (0.3)
Upper respiratory tract infection	2 (<0.1)	40 (0.4)	48 (0.4)	90 (0.4)	0	11 (0.3)	6 (0.2)	17 (0.2)
Sinusitis	0	24 (0.3)	22 (0.2)	46 (0.2)	0	14 (0.4)	10 (0.3)	24 (0.3)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Rhinovirus infection	1 (<0.1)	21 (0.2)	17 (0.1)	39 (0.2)	0	4 (0.1)	3 (<0.1)	7 (<0.1)
Viral infection	0	17 (0.2)	30 (0.3)	47 (0.2)	0	4 (0.1)	7 (0.2)	11 (0.1)
Tooth infection	0	9 (<0.1)	10 (<0.1)	19 (<0.1)	0	8 (0.2)	5 (0.1)	13 (0.2)
Suspected COVID-19	0	14 (0.2)	31 (0.3)	45 (0.2)	0	2 (<0.1)	6 (0.2)	8 (0.1)
Pharyngitis streptococcal	0	13 (0.1)	2 (<0.1)	15 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Diverticulitis	0	7 (<0.1)	2 (<0.1)	9 (<0.1)	0	6 (0.2)	4 (0.1)	10 (0.1)
Gastroenteritis	0	8 (<0.1)	11 (<0.1)	19 (<0.1)	0	4 (0.1)	1 (<0.1)	5 (<0.1)
Herpes zoster	0	9 (<0.1)	10 (<0.1)	19 (<0.1)	0	3 (<0.1)	4 (0.1)	7 (<0.1)
Asymptomatic COVID-19	0	10 (0.1)	11 (<0.1)	21 (<0.1)	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Tooth abscess	1 (<0.1)	8 (<0.1)	10 (<0.1)	19 (<0.1)	0	3 (<0.1)	5 (0.1)	8 (0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Otitis media	0	9 (<0.1)	3 (<0.1)	12 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Pneumonia	0	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	6 (0.2)	3 (<0.1)	9 (0.1)
Cellulitis	0	6 (<0.1)	10 (<0.1)	16 (<0.1)	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Acute sinusitis	0	7 (<0.1)	6 (<0.1)	13 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Onychomycosis	0	6 (<0.1)	0	6 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Pharyngitis	0	7 (<0.1)	6 (<0.1)	13 (<0.1)	0	0	0	0
Appendicitis	0	5 (<0.1)	4 (<0.1)	9 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bronchitis	0	4 (<0.1)	10 (<0.1)	14 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Conjunctivitis	0	4 (<0.1)	5 (<0.1)	9 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Ear infection	0	4 (<0.1)	6 (<0.1)	10 (<0.1)	0	2 (<0.1)	0	2 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Cystitis	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Folliculitis	0	4 (<0.1)	1 (<0.1)	5 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Hordeolum	0	2 (<0.1)	4 (<0.1)	6 (<0.1)	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Localised infection	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Oral herpes	0	3 (<0.1)	4 (<0.1)	7 (<0.1)	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Sepsis	0	3 (<0.1)	3 (<0.1)	6 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bacterial vaginosis	1 (<0.1)	4 (<0.1)	4 (<0.1)	9 (<0.1)	0	0	0	0
Coronavirus infection	0	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	0	0	0
Staphylococcal infection	0	3 (<0.1)	0	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Viral upper respiratory tract infection	0	3 (<0.1)	9 (<0.1)	12 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vulvovaginal mycotic infection	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Fungal skin infection	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastroenteritis viral	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gingivitis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Helicobacter infection	1 (<0.1)	3 (<0.1)	2 (<0.1)	6 (<0.1)	0	0	0	0
Herpes simplex	0	3 (<0.1)	0	3 (<0.1)	0	0	0	0
Infected bite	0	3 (<0.1)	0	3 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Kidney infection	0	3 (<0.1)	0	3 (<0.1)	0	0	0	0
Respiratory tract infection	0	3 (<0.1)	4 (<0.1)	7 (<0.1)	0	0	0	0
Abscess limb	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	0	0	0
Appendicitis perforated	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	0	0	0
Arthritis bacterial	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Candida infection	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Eye infection	0	1 (<0.1)	4 (<0.1)	5 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Fungal infection	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Gastroenteritis bacterial	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Infected dermal cyst	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Osteomyelitis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Otitis externa	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Parotitis	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Rhinitis	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Tinea pedis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Vulvovaginal candidiasis	0	1 (<0.1)	4 (<0.1)	5 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Wound infection	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Appendiceal abscess	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Arthritis infective	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Breast cellulitis	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
COVID-19 pneumonia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Chlamydial infection	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Chronic sinusitis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Conjunctivitis viral	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Endophthalmitis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Escherichia infection	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Eyelid infection	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Furuncle	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Gastrointestinal bacterial overgrowth	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Genital herpes	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Genital herpes simplex	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Genital infection fungal	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Groin abscess	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Helicobacter gastritis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Hepatic infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Impetigo	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Infected cyst	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Infectious mononucleosis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Influenza	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Labyrinthitis	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Lower respiratory tract infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Medical device site joint infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Meningitis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Nasal vestibulitis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Nasopharyngitis	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Nipple infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Oesophageal candidiasis	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Ophthalmic herpes simplex	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Oral candidiasis	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Osteomyelitis bacterial	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Papilloma viral infection	0	1 (<0.1)	4 (<0.1)	5 (<0.1)	0	0	0	0
Paronychia	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Periorbital cellulitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pertussis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Pilonidal cyst	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Post procedural infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Postoperative abscess	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Postoperative wound infection	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Pseudomonas infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pulpitis dental	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pyelonephritis	0	0	3 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Root canal infection	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Staphylococcal sepsis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Syphilis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Tinea manuum	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Tonsillitis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Trichomoniasis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Urethritis chlamydial	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Uterine infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Vaginal infection	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Viral sinusitis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Abscess	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Abscess neck	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Abscess oral	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
American trypanosomiasis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Bacterial diarrhoea	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Body tinea	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Bronchitis bacterial	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Cervicitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Clostridium difficile infection	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Diarrhoea infectious	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Enterovirus infection	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Epididymitis	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Safety Set

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Infections and infestations (Cont.)								
Gonorrhoea	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Laryngitis viral	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Lice infestation	0	0	0	0	1 (0.3)	0	0	1 (<0.1)
Lip infection	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Necrotising fasciitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Ophthalmic herpes zoster	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Orchitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Oropharyngeal candidiasis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Otitis media acute	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Pericarditis infective	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0

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Infections and infestations (Cont.)								
Perirectal abscess	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pharyngeal abscess	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pneumonia bacterial	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Proctitis chlamydial	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Sialoadenitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Sinusitis bacterial	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Skin infection	0	0	2 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Staphylococcal bacteraemia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Infections and infestations (Cont.)								
Streptococcal infection	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Tinea versicolour	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Urethritis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Vestibular neuronitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Vestibulitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.1)	21 (0.2)	31 (0.3)	55 (0.2)	0	21 (0.6)	32 (0.8)	53 (0.7)
Basal cell carcinoma	0	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	10 (0.3)	3 (<0.1)	13 (0.2)

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Lipoma	0	3 (<0.1)	2 (<0.1)	5 (<0.1)	0	0	0	0
Squamous cell carcinoma of skin	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Melanocytic naevus	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Benign neoplasm of skin	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Bladder neoplasm	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Blepharal papilloma	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Breast cancer	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Castleman's disease	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Colon adenoma	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Ear neoplasm malignant	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Fibroadenoma of breast	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Fibrous histiocyoma	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Intraductal proliferative breast lesion	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Malignant melanoma	0	0	0	0	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Metastases to lung	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Myelodysplastic syndrome	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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MedDRA version 23.0.

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Oesophageal adenocarcinoma	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pancreatic carcinoma	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Pancreatic carcinoma metastatic	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pancreatic carcinoma stage IV	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Prostate cancer	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	5 (0.1)	5 (<0.1)
Prostate cancer stage I	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Renal cancer	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Uterine leiomyoma	1 (<0.1)	1 (<0.1)	5 (<0.1)	7 (<0.1)	0	0	0	0
Acrochordon	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
B-cell lymphoma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Borderline mucinous tumour of ovary	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Chronic lymphocytic leukaemia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Colorectal cancer metastatic	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0

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Safety Set

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	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Cutaneous T-cell lymphoma	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Endometrial cancer	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Eye naevus	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
High-grade B-cell lymphoma	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	0	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Lung adenocarcinoma	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Lung neoplasm malignant	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Lymphoma	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Neoplasm skin	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Oesophageal carcinoma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Oral fibroma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Papillary thyroid cancer	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Phaeochromocytoma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Salivary gland cancer stage IV	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Skin cancer	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Skin papilloma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Squamous cell carcinoma	0	0	1 (<0.1)	1 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Throat cancer	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Thyroid cancer	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Uterine cancer	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Vocal cord neoplasm	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Blood and lymphatic system disorders	0	44 (0.5)	21 (0.2)	65 (0.3)	0	13 (0.4)	3 (<0.1)	16 (0.2)
Lymphadenopathy	0	35 (0.4)	11 (<0.1)	46 (0.2)	0	6 (0.2)	0	6 (<0.1)

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	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Blood and lymphatic system disorders (Cont.)								
Anaemia	0	4 (<0.1)	1 (<0.1)	5 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Iron deficiency anaemia	0	1 (<0.1)	5 (<0.1)	6 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Hyperchromic anaemia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Immune thrombocytopenia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Increased tendency to bruise	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Leukocytosis	0	0	2 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Lymph node calcification	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Lymph node pain	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Lymphadenitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

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	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Blood and lymphatic system disorders (Cont.)								
Thrombocytopenia	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Haemoconcentration	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Splenomegaly	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Immune system disorders	0	16 (0.2)	22 (0.2)	38 (0.2)	0	8 (0.2)	7 (0.2)	15 (0.2)
Seasonal allergy	0	10 (0.1)	14 (0.1)	24 (0.1)	0	7 (0.2)	5 (0.1)	12 (0.2)
Anaphylactic reaction	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Food allergy	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Drug hypersensitivity	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Hypersensitivity	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Immune system disorders (Cont.)								
Sarcoidosis	0	0	2 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Allergy to arthropod sting	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Endocrine disorders	0	10 (0.1)	13 (0.1)	23 (0.1)	0	4 (0.1)	12 (0.3)	16 (0.2)
Hypothyroidism	0	5 (<0.1)	9 (<0.1)	14 (<0.1)	0	4 (0.1)	6 (0.2)	10 (0.1)
Autoimmune thyroiditis	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Basedow's disease	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Thyroid mass	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	3 (<0.1)	3 (<0.1)
Adrenal mass	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Goitre	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Endocrine disorders (Cont.)								
Hyperandrogenism	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Hyperprolactinaemia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Hyperthyroidism	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Hypogonadism	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Metabolism and nutrition disorders	0	65 (0.7)	60 (0.5)	125 (0.5)	0	44 (1.3)	37 (1.0)	81 (1.1)
Hypercholesterolaemia	0	9 (<0.1)	7 (<0.1)	16 (<0.1)	0	9 (0.3)	7 (0.2)	16 (0.2)
Type 2 diabetes mellitus	0	12 (0.1)	13 (0.1)	25 (0.1)	0	5 (0.1)	7 (0.2)	12 (0.2)
Vitamin D deficiency	0	13 (0.1)	11 (<0.1)	24 (0.1)	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Hyperlipidaemia	0	7 (<0.1)	9 (<0.1)	16 (<0.1)	0	8 (0.2)	8 (0.2)	16 (0.2)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Metabolism and nutrition disorders (Cont.)								
Gout	0	4 (<0.1)	1 (<0.1)	5 (<0.1)	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Decreased appetite	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	3 (<0.1)	0	3 (<0.1)
Diabetes mellitus	0	5 (<0.1)	2 (<0.1)	7 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Iron deficiency	0	0	1 (<0.1)	1 (<0.1)	0	4 (0.1)	0	4 (<0.1)
Dehydration	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Diabetes mellitus inadequate control	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Glucose tolerance impaired	0	3 (<0.1)	6 (<0.1)	9 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Hyperglycaemia	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypokalaemia	0	0	4 (<0.1)	4 (<0.1)	0	3 (<0.1)	1 (<0.1)	4 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Metabolism and nutrition disorders (Cont.)								
Obesity	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Vitamin B12 deficiency	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Abnormal weight gain	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Electrolyte imbalance	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fluid overload	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Hyperkalaemia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Hypertriglyceridaemia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Hypoglycaemia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Hyponatraemia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Lactic acidosis	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Metabolism and nutrition disorders (Cont.)								
Magnesium deficiency	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Postprandial hypoglycaemia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Type 1 diabetes mellitus	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Diabetic ketoacidosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Dyslipidaemia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Haemochromatosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Hypercalcaemia	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Insulin resistance	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Metabolic acidosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Vitamin C deficiency	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Psychiatric disorders	2 (<0.1)	77 (0.8)	71 (0.6)	150 (0.7)	1 (0.3)	12 (0.4)	12 (0.3)	25 (0.3)
Anxiety	1 (<0.1)	31 (0.3)	22 (0.2)	54 (0.2)	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Depression	0	26 (0.3)	22 (0.2)	48 (0.2)	0	6 (0.2)	5 (0.1)	11 (0.1)
Insomnia	0	11 (0.1)	7 (<0.1)	18 (<0.1)	0	2 (<0.1)	6 (0.2)	8 (0.1)
Attention deficit hyperactivity disorder	0	9 (<0.1)	11 (<0.1)	20 (<0.1)	0	0	0	0
Suicidal ideation	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Adjustment disorder	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Affective disorder	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Alcohol withdrawal syndrome	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Bipolar disorder	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Confusional state	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Psychiatric disorders (Cont.)								
Hallucination	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Nightmare	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Panic attack	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Paranoia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Post-traumatic stress disorder	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Schizophrenia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Substance abuse	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Adjustment disorder with depressed mood	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Psychiatric disorders (Cont.)								
Agitation	0	0	0	0	1 (0.3)	0	0	1 (<0.1)
Autism spectrum disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Binge eating	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Bipolar I disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Delirium	0	0	0	0	1 (0.3)	0	0	1 (<0.1)
Dissociative identity disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Drug dependence	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0
Dysphemia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Initial insomnia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Psychiatric disorders (Cont.)								
Intentional self-injury	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Libido decreased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Major depression	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Mental status changes	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Mood swings	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Stress	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Substance use disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Suicide attempt	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Thinking abnormal	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Nervous system disorders	2 (<0.1)	259 (2.8)	85 (0.7)	346 (1.5)	0	79 (2.3)	42 (1.1)	121 (1.6)
Headache	1 (<0.1)	188 (2.0)	34 (0.3)	223 (1.0)	0	45 (1.3)	12 (0.3)	57 (0.8)
Dizziness	1 (<0.1)	17 (0.2)	6 (<0.1)	24 (0.1)	0	10 (0.3)	5 (0.1)	15 (0.2)
Ageusia	0	8 (<0.1)	3 (<0.1)	11 (<0.1)	0	3 (<0.1)	0	3 (<0.1)
Paraesthesia	0	10 (0.1)	2 (<0.1)	12 (<0.1)	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Hypoaesthesia	0	5 (<0.1)	2 (<0.1)	7 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Migraine	0	6 (<0.1)	6 (<0.1)	12 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sciatica	0	6 (<0.1)	6 (<0.1)	12 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Syncope	0	4 (<0.1)	1 (<0.1)	5 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Anosmia	0	3 (<0.1)	2 (<0.1)	5 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Carpal tunnel syndrome	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cerebrovascular accident	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Nervous system disorders (Cont.)								
Restless legs syndrome	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	3 (<0.1)	0	3 (<0.1)
Tension headache	0	4 (<0.1)	0	4 (<0.1)	0	0	0	0
Neuropathy peripheral	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Presyncope	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Trigeminal neuralgia	0	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cervical radiculopathy	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Dysgeusia	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Nerve compression	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Amyotrophic lateral sclerosis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Nervous system disorders (Cont.)								
Aphasia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Balance disorder	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Brain stem infarction	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Carotid artery stenosis	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Cerebellar ataxia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Cerebral artery stenosis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Disturbance in attention	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Haemorrhage intracranial	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Hypogeusia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Nervous system disorders (Cont.)								
Ischaemic cerebral infarction	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Lacunar infarction	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Loss of consciousness	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Lumbar radiculopathy	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Lumbosacral radiculopathy	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Memory impairment	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Migraine with aura	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Narcolepsy	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Neuralgia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

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	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Nervous system disorders (Cont.)								
Piriformis syndrome	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Radiculopathy	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Seizure	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Sinus headache	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Taste disorder	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Transient ischaemic attack	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tremor	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Amnesia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Aura	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Burning sensation	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

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Nervous system disorders (Cont.)								
Carotid arteriosclerosis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Carotid artery aneurysm	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Cerebral ischaemia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Cluster headache	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Exertional headache	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Hemiparesis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Migraine without aura	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Nystagmus	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Peripheral sensory neuropathy	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Safety Set

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Nervous system disorders (Cont.)								
Post herpetic neuralgia	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Shift work disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Somnolence	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Spinal cord compression	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Transient global amnesia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Eye disorders	0	24 (0.3)	15 (0.1)	39 (0.2)	0	18 (0.5)	15 (0.4)	33 (0.4)
Cataract	0	4 (<0.1)	5 (<0.1)	9 (<0.1)	0	5 (0.1)	4 (0.1)	9 (0.1)
Glaucoma	0	3 (<0.1)	0	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Blepharitis	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Safety Set

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	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Eye disorders (Cont.)								
Conjunctival haemorrhage	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dacryostenosis acquired	0	0	0	0	0	2 (<0.1)	0	2 (<0.1)
Diplopia	0	0	0	0	0	2 (<0.1)	1	3 (<0.1)
Eye irritation	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Eye pain	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Visual impairment	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Chalazion	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Conjunctivitis allergic	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Diabetic retinopathy	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dry eye	0	0	2 (<0.1)	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eyelid rash	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Eye disorders (Cont.)								
Macular degeneration	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Macular fibrosis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Normal tension glaucoma	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Periorbital oedema	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Periorbital swelling	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Retinal artery occlusion	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Retinal detachment	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Retinal tear	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Swelling of eyelid	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Uveitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Vision blurred	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Eye disorders (Cont.)								
Vitreous floaters	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Vitreous haemorrhage	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Dermatochalasis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Episcleritis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Lacrimation increased	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Neovascular age-related macular degeneration	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Ocular hyperaemia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Ocular rosacea	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Ear and labyrinth disorders	1 (<0.1)	28 (0.3)	25 (0.2)	54 (0.2)	0	8 (0.2)	7 (0.2)	15 (0.2)
Vertigo	1 (<0.1)	8 (<0.1)	10 (<0.1)	19 (<0.1)	0	5 (0.1)	4 (0.1)	9 (0.1)
Tinnitus	0	5 (<0.1)	4 (<0.1)	9 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Ear discomfort	0	3 (<0.1)	0	3 (<0.1)	0	0	0	0
Ear pain	0	3 (<0.1)	2 (<0.1)	5 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Deafness unilateral	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Ear canal erythema	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	0	0	0
Cerumen impaction	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Deafness neurosensory	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Ear congestion	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Ear pruritus	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Ear and labyrinth disorders (Cont.)								
Excessive cerumen production	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
External ear inflammation	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Meniere's disease	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Tympanic membrane disorder	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Tympanic membrane hyperaemia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Vertigo positional	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	0	0
Middle ear effusion	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Cardiac disorders	0	31 (0.3)	24 (0.2)	55 (0.2)	1 (0.3)	36 (1.1)	31 (0.8)	68 (0.9)
Palpitations	0	6 (<0.1)	5 (<0.1)	11 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Tachycardia	0	5 (<0.1)	6 (<0.1)	11 (<0.1)	0	3 (<0.1)	0	3 (<0.1)
Atrial fibrillation	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	6 (0.2)	6 (0.2)	12 (0.2)
Coronary artery disease	0	0	2 (<0.1)	2 (<0.1)	0	6 (0.2)	6 (0.2)	12 (0.2)
Bradycardia	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Cardiac failure	0	1 (<0.1)	0	1 (<0.1)	0	3 (<0.1)	0	3 (<0.1)
Myocardial infarction	0	1 (<0.1)	0	1 (<0.1)	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Sinus tachycardia	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Acute myocardial infarction	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Cardiac failure congestive	0	0	1 (<0.1)	1 (<0.1)	0	3 (<0.1)	4 (0.1)	7 (<0.1)
Angina pectoris	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Cardiac disorders (Cont.)								
Angina unstable	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Arrhythmia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Bundle branch block left	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Supraventricular tachycardia	0	2 (<0.1)	0	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Ventricular extrasystoles	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Ventricular tachycardia	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Acute coronary syndrome	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Aortic valve incompetence	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Cardiac disorders (Cont.)								
Atrial flutter	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Atrioventricular block complete	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Bifascicular block	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Cardiac failure acute	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Cardiac flutter	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Cardiovascular disorder	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Coronary artery occlusion	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Left ventricular hypertrophy	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Sinus node dysfunction	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Cardiac disorders (Cont.)								
Acute left ventricular failure	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Bundle branch block right	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Cardiac arrest	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Cardiac disorder	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Cardiomyopathy	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Coronary artery insufficiency	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Extrasystoles	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Ischaemic cardiomyopathy	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Left atrial enlargement	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Cardiac disorders (Cont.)								
Mitral valve incompetence	0	0	0	0	0	0	3 (<0.1)	3 (<0.1)
Postural orthostatic tachycardia syndrome	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pulseless electrical activity	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Supraventricular extrasystoles	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Ventricular arrhythmia	0	0	0	0	1 (0.3)	0	0	1 (<0.1)
Vascular disorders	2 (<0.1)	101 (1.1)	55 (0.5)	158 (0.7)	0	54 (1.6)	49 (1.3)	103 (1.4)
Hypertension	2 (<0.1)	88 (1.0)	46 (0.4)	136 (0.6)	0	41 (1.2)	36 (1.0)	77 (1.0)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Vascular disorders (Cont.)								
Deep vein thrombosis	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Hot flush	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	0	0	0
Hypotension	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Lymphoedema	0	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Aortic stenosis	0	0	0	0	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Diastolic hypertension	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Essential hypertension	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Flushing	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Hypertensive crisis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Hypertensive urgency	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Labile blood pressure	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Vascular disorders (Cont.)								
Orthostatic hypotension	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Peripheral arterial occlusive disease	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Peripheral vascular disorder	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Peripheral venous disease	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Prehypertension	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Raynaud's phenomenon	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Systolic hypertension	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Aortic aneurysm	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Aortic arteriosclerosis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Vascular disorders (Cont.)								
Aortic dissection	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Haematoma	0	0	1 (<0.1)	1 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Intermittent claudication	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Jugular vein thrombosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Phlebitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Subclavian vein thrombosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Vascular insufficiency	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	3 (0.1)	143 (1.5)	114 (1.0)	260 (1.1)	0	51 (1.5)	38 (1.0)	89 (1.2)
Cough	1 (<0.1)	41 (0.4)	25 (0.2)	67 (0.3)	0	4 (0.1)	8 (0.2)	12 (0.2)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)								
Rhinorrhoea	1 (<0.1)	39 (0.4)	19 (0.2)	59 (0.3)	0	5 (0.1)	6 (0.2)	11 (0.1)
Nasal congestion	1 (<0.1)	36 (0.4)	28 (0.2)	65 (0.3)	0	6 (0.2)	6 (0.2)	12 (0.2)
Oropharyngeal pain	1 (<0.1)	34 (0.4)	29 (0.3)	64 (0.3)	0	3 (<0.1)	8 (0.2)	11 (0.1)
Dyspnoea	0	6 (<0.1)	11 (<0.1)	17 (<0.1)	0	9 (0.3)	5 (0.1)	14 (0.2)
Asthma	0	11 (0.1)	10 (<0.1)	21 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Epistaxis	0	5 (<0.1)	1 (<0.1)	6 (<0.1)	0	4 (0.1)	3 (<0.1)	7 (<0.1)
Sinus congestion	0	8 (<0.1)	7 (<0.1)	15 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Tachypnoea	0	6 (<0.1)	2 (<0.1)	8 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Sneezing	0	5 (<0.1)	3 (<0.1)	8 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)								
Sleep apnoea syndrome	0	3 (<0.1)	6 (<0.1)	9 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Wheezing	0	1 (<0.1)	0	1 (<0.1)	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Acute respiratory failure	0	0	0	0	0	3 (<0.1)	0	3 (<0.1)
Chronic obstructive pulmonary disease	0	0	3 (<0.1)	3 (<0.1)	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Pleural effusion	0	0	0	0	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Productive cough	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rhinitis allergic	0	1 (<0.1)	5 (<0.1)	6 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Atelectasis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)								
Dyspnoea exertional	0	0	0	0	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Pulmonary embolism	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Pulmonary mass	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Sinus pain	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Allergic cough	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Asthma exercise induced	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Bronchitis chronic	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Dry throat	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Emphysema	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Safety Set

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	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)								
Hypoxia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Interstitial lung disease	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Lower respiratory tract congestion	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Nasal inflammation	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Nasal polyps	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Nasal septum deviation	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Paranasal sinus discomfort	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Safety Set

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Respiratory, thoracic and mediastinal disorders (Cont.)								
Paranasal sinus hypersecretion	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pharyngeal erythema	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pneumothorax	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Reflux laryngitis	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Respiratory disorder	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	0	0
Respiratory failure	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Rhonchi	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Throat irritation	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0

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Safety Set

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	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)								
Tonsillar hypertrophy	1 (<0.1)	1 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Upper-airway cough syndrome	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Allergic sinusitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Dysphonia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Laryngeal polyp	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Lung disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Mediastinal cyst	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Mediastinal mass	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Nasal dryness	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Safety Set

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Respiratory, thoracic and mediastinal disorders (Cont.)								
Pharyngeal ulceration	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pulmonary fibrosis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Pulmonary hypertension	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Pulmonary oedema	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Respiratory tract congestion	0	0	4 (<0.1)	4 (<0.1)	0	0	0	0
Rhinalgia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Sinus disorder	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Vocal cord polyp	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Gastrointestinal disorders	3 (0.1)	189 (2.0)	99 (0.9)	291 (1.3)	2 (0.6)	64 (1.9)	51 (1.4)	117 (1.6)
Nausea	1 (<0.1)	63 (0.7)	13 (0.1)	77 (0.3)	0	13 (0.4)	7 (0.2)	20 (0.3)
Diarrhoea	1 (<0.1)	34 (0.4)	17 (0.1)	52 (0.2)	0	9 (0.3)	10 (0.3)	19 (0.3)
Vomiting	0	21 (0.2)	4 (<0.1)	25 (0.1)	0	5 (0.1)	3 (<0.1)	8 (0.1)
Gastrooesophageal reflux disease	1 (<0.1)	15 (0.2)	15 (0.1)	31 (0.1)	1 (0.3)	9 (0.3)	8 (0.2)	18 (0.2)
Abdominal pain	0	16 (0.2)	4 (<0.1)	20 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dental caries	0	12 (0.1)	5 (<0.1)	17 (<0.1)	0	3 (<0.1)	0	3 (<0.1)
Toothache	1 (<0.1)	8 (<0.1)	1 (<0.1)	10 (<0.1)	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Abdominal pain upper	0	6 (<0.1)	3 (<0.1)	9 (<0.1)	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Constipation	0	8 (<0.1)	4 (<0.1)	12 (<0.1)	0	1 (<0.1)	4 (0.1)	5 (<0.1)
Abdominal discomfort	0	4 (<0.1)	1 (<0.1)	5 (<0.1)	0	2 (<0.1)	0	2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)								
Haemorrhoids	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	5 (0.1)	0	5 (<0.1)
Abdominal pain lower	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dyspepsia	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hiatus hernia	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Inguinal hernia	0	0	0	0	0	3 (<0.1)	0	3 (<0.1)
Colitis	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Gastritis	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Gastrointestinal haemorrhage	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Large intestine polyp	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)								
Tooth impacted	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Umbilical hernia	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Abdominal hernia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Abdominal tenderness	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Anal fissure	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Aphthous ulcer	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Colitis microscopic	0	0	2 (<0.1)	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Duodenal ulcer perforation	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Enlarged uvula	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Enteritis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)								
Flatulence	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Food poisoning	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	0	0	0
Gastric ulcer	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Gastritis erosive	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Gastrointestinal inflammation	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Gastrointestinal pain	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Haematochezia	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Haemorrhoidal haemorrhage	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Safety Set

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Gastrointestinal disorders (Cont.)								
Ileus paralytic	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Impaired gastric emptying	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Internal hernia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Intestinal obstruction	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Lip blister	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Lip oedema	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Lip swelling	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Mouth ulceration	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Oesophageal rupture	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Oral disorder	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Safety Set

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Gastrointestinal disorders (Cont.)								
Pancreatitis	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	0	0	0
Pancreatitis acute	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Parotid gland enlargement	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Peptic ulcer	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Periodontal disease	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Proctalgia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Pulpless tooth	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Salivary gland calculus	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Small intestinal obstruction	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)								
Stomatitis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Tooth disorder	0	1 (<0.1)	0	1 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Transient lingual papillitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Abdominal distension	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Anal fistula	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Barrett's oesophagus	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Crohn's disease	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Diverticulum	0	0	0	0	1 (0.3)	0	1 (<0.1)	2 (<0.1)
Duodenal ulcer	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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MedDRA version 23.0.

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)								
Enterovesical fistula	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Erosive oesophagitis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Faeces soft	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Gastric polyps	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Gastrointestinal disorder	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Glossitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Glossodynia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Ileus	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Irritable bowel syndrome	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Oral pain	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)								
Pancreatic failure	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Portal hypertensive gastropathy	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Proctitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Rectal polyp	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Rectal prolapse	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Submaxillary gland enlargement	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Varices oesophageal	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Hepatobiliary disorders	0	7 (<0.1)	9 (<0.1)	16 (<0.1)	1 (0.3)	2 (<0.1)	7 (0.2)	10 (0.1)
Cholecystitis	0	3 (<0.1)	4 (<0.1)	7 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Cholelithiasis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hepatic steatosis	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Bile duct obstruction	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Cholangitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Hepatomegaly	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Biliary colic	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Cholecystitis acute	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Cholelithiasis obstructive	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Hepatic cirrhosis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Hepatic lesion	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Hepatobiliary disorders (Cont.)								
Hyperbilirubinaemia	0	0	0	0	1 (0.3)	0	1 (<0.1)	2 (<0.1)
Skin and subcutaneous tissue disorders	3 (0.1)	74 (0.8)	39 (0.3)	116 (0.5)	2 (0.6)	50 (1.5)	24 (0.6)	76 (1.0)
Rash	1 (<0.1)	11 (0.1)	5 (<0.1)	17 (<0.1)	0	9 (0.3)	1 (<0.1)	10 (0.1)
Urticaria	0	12 (0.1)	2 (<0.1)	14 (<0.1)	0	5 (0.1)	3 (<0.1)	8 (0.1)
Pruritus	0	10 (0.1)	0	10 (<0.1)	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Dermatitis contact	0	5 (<0.1)	5 (<0.1)	10 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Skin lesion	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	4 (0.1)	1 (<0.1)	5 (<0.1)
Actinic keratosis	0	0	1 (<0.1)	1 (<0.1)	0	5 (0.1)	3 (<0.1)	8 (0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Skin and subcutaneous tissue disorders (Cont.)								
Dermal cyst	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Dermatitis allergic	0	3 (<0.1)	0	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rosacea	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Acne	0	3 (<0.1)	4 (<0.1)	7 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Dermatitis	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Drug eruption	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Night sweats	0	3 (<0.1)	0	3 (<0.1)	0	0	0	0
Rash maculo-papular	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Rash pruritic	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Alopecia	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Skin and subcutaneous tissue disorders (Cont.)								
Decubitus ulcer	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Eczema	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Erythema	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Pain of skin	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Seborrheic dermatitis	0	0	0	0	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Skin ulcer	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Acne cystic	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Angioedema	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Asteatosis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Dermatitis atopic	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Skin and subcutaneous tissue disorders (Cont.)								
Dry skin	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Ecchymosis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Erythema nodosum	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Hyperhidrosis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Ingrowing nail	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Lichen planus	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Lichen sclerosus	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Nail discolouration	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Pityriasis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Pruritus allergic	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

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Skin and subcutaneous tissue disorders (Cont.)								
Rash erythematous	0	1 (<0.1)	0	1 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Skin mass	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Skin necrosis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Subcutaneous emphysema	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Urticaria papular	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Vitiligo	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Fixed eruption	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Hidradenitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Ingrown hair	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Perioral dermatitis	1 (<0.1)	0	3 (<0.1)	4 (<0.1)	0	0	0	0

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Safety Set

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Skin and subcutaneous tissue disorders (Cont.)								
Precancerous skin lesion	0	0	0	0	1 (0.3)	0	0	1 (<0.1)
Psoriasis	1 (<0.1)	0	2 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Rash vesicular	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Sensitive skin	0	0	0	0	1 (0.3)	0	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	4 (0.2)	217 (2.3)	126 (1.1)	347 (1.5)	0	114 (3.4)	91 (2.4)	205 (2.7)
Myalgia	1 (<0.1)	53 (0.6)	12 (0.1)	66 (0.3)	0	26 (0.8)	8 (0.2)	34 (0.5)
Arthralgia	1 (<0.1)	36 (0.4)	18 (0.2)	55 (0.2)	0	21 (0.6)	10 (0.3)	31 (0.4)
Pain in extremity	0	43 (0.5)	15 (0.1)	58 (0.3)	0	12 (0.4)	3 (<0.1)	15 (0.2)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

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	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)								
Back pain	1 (<0.1)	21 (0.2)	20 (0.2)	42 (0.2)	0	7 (0.2)	15 (0.4)	22 (0.3)
Osteoarthritis	0	8 (<0.1)	4 (<0.1)	12 (<0.1)	0	13 (0.4)	13 (0.3)	26 (0.3)
Musculoskeletal pain	0	12 (0.1)	5 (<0.1)	17 (<0.1)	0	6 (0.2)	3 (<0.1)	9 (0.1)
Neck pain	0	8 (<0.1)	1 (<0.1)	9 (<0.1)	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Muscle spasms	0	8 (<0.1)	5 (<0.1)	13 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Tendonitis	0	7 (<0.1)	7 (<0.1)	14 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bursitis	0	5 (<0.1)	2 (<0.1)	7 (<0.1)	0	3 (<0.1)	6 (0.2)	9 (0.1)
Arthritis	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	4 (0.1)	3 (<0.1)	7 (<0.1)
Osteoporosis	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	4 (0.1)	5 (0.1)	9 (0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)								
Musculoskeletal chest pain	0	3 (<0.1)	3 (<0.1)	6 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Intervertebral disc degeneration	0	2 (<0.1)	0	2 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Trigger finger	0	1 (<0.1)	0	1 (<0.1)	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Joint swelling	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Limb discomfort	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Muscular weakness	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Rotator cuff syndrome	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	2 (<0.1)	4 (0.1)	6 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)								
Costochondritis	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Flank pain	0	1 (<0.1)	4 (<0.1)	5 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Groin pain	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Intervertebral disc protrusion	0	2 (<0.1)	5 (<0.1)	7 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Joint range of motion decreased	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Lumbar spinal stenosis	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Muscle twitching	0	0	0	0	0	2 (<0.1)	0	2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)								
Musculoskeletal stiffness	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Neck mass	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Pain in jaw	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Plantar fasciitis	0	2 (<0.1)	4 (<0.1)	6 (<0.1)	0	0	0	0
Ankle impingement	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Ankylosing spondylitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Arthritis reactive	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Axillary mass	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Bone disorder	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)								
Bone swelling	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Chondrocalcinosis pyrophosphate	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Dupuytren's contracture	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Exostosis	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Intervertebral disc displacement	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Joint hyperextension	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Joint noise	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)								
Joint stiffness	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Muscle swelling	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Musculoskeletal discomfort	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Myositis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Patellofemoral pain syndrome	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Polyarthrititis	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Psoriatic arthropathy	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pubic pain	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)								
Scleroderma	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Synovial cyst	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Temporomandibular joint syndrome	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	0	0
Vertebral lateral recess stenosis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Cervical spinal stenosis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Chondrocalcinosis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Haemarthrosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)								
Intervertebral disc disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Metatarsalgia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Myofascial pain syndrome	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Osteopenia	0	0	0	0	0	0	3 (<0.1)	3 (<0.1)
Periarthritis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Sacroiliitis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Scoliosis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Spinal osteoarthritis	0	0	2 (<0.1)	2 (<0.1)	0	0	2 (<0.1)	2 (<0.1)

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Percentages are based on the number of safety subjects.

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)								
Spinal pain	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0
Spondylitis	0	0	0	0	0	0	3 (<0.1)	3 (<0.1)
Spondylolisthesis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Tenosynovitis stenans	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Torticollis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Renal and urinary disorders	0	14 (0.2)	18 (0.2)	32 (0.1)	1 (0.3)	22 (0.6)	17 (0.5)	40 (0.5)
Nephrolithiasis	0	8 (<0.1)	5 (<0.1)	13 (<0.1)	0	10 (0.3)	4 (0.1)	14 (0.2)
Dysuria	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Renal and urinary disorders (Cont.)								
Haematuria	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Acute kidney injury	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hypertonic bladder	0	0	2 (<0.1)	2 (<0.1)	1 (0.3)	2 (<0.1)	1 (<0.1)	4 (<0.1)
Ureterolithiasis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Urinary retention	0	0	0	0	0	2 (<0.1)	0	2 (<0.1)
Chronic kidney disease	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Micturition urgency	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Pollakiuria	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Renal colic	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Renal failure	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Renal and urinary disorders (Cont.)								
Renal injury	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Stress urinary incontinence	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Bladder prolapse	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Bladder spasm	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Incontinence	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Ketonuria	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Nephritis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Proteinuria	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Renal cyst	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Renal pain	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Renal and urinary disorders (Cont.)								
Urinary incontinence	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Urine abnormality	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	6 (<0.1)	3 (<0.1)	10 (<0.1)	0	0	0	0
Pregnancy	0	4 (<0.1)	1 (<0.1)	5 (<0.1)	0	0	0	0
Abortion spontaneous	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	0	0	0
Gestational diabetes	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Reproductive system and breast disorders	0	22 (0.2)	26 (0.2)	48 (0.2)	0	13 (0.4)	15 (0.4)	28 (0.4)
Ovarian cyst	0	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	0	0	0
Prostatomegaly	0	2 (<0.1)	0	2 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Breast mass	0	1 (<0.1)	5 (<0.1)	6 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Breast pain	0	3 (<0.1)	0	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Cervical dysplasia	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Benign prostatic hyperplasia	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	1 (<0.1)	4 (0.1)	5 (<0.1)
Endometriosis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Erectile dysfunction	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Menstruation irregular	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Reproductive system and breast disorders (Cont.)								
Prostatitis	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Uterine polyp	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Haematospermia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Pelvic pain	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Perineal disorder	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Postmenopausal haemorrhage	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Scrotal disorder	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Uterine cyst	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Vaginal discharge	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Vaginal haemorrhage	0	0	3 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Reproductive system and breast disorders (Cont.)								
Adnexa uteri pain	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Breast discharge	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Dysmenorrhoea	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Endometrial hyperplasia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Endometrial thickening	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Gynaecomastia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Menometrorrhagia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pelvic cyst	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Pelvic prolapse	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Polycystic ovaries	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Reproductive system and breast disorders (Cont.)								
Sexual dysfunction	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Uterine haemorrhage	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Uterine prolapse	0	0	1 (<0.1)	1 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Uterine spasm	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Congenital, familial and genetic disorders	0	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Arnold-Chiari malformation	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Congenital knee deformity	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Congenital, familial and genetic disorders (Cont.)								
Methylenetetrahydrofolate reductase deficiency	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Thalassaemia beta	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Type IIa hyperlipidaemia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Corneal dystrophy	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Enteric duplication	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Hydrocele	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Type V hyperlipidaemia	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
General disorders and administration site conditions	3 (0.1)	505 (5.5)	71 (0.6)	579 (2.5)	1 (0.3)	209 (6.2)	26 (0.7)	236 (3.1)
Injection site pain	0	324 (3.5)	8 (<0.1)	332 (1.5)	0	127 (3.7)	0	127 (1.7)
Fatigue	2 (<0.1)	148 (1.6)	27 (0.2)	177 (0.8)	0	63 (1.9)	11 (0.3)	74 (1.0)
Pain	2 (<0.1)	132 (1.4)	13 (0.1)	147 (0.6)	0	43 (1.3)	6 (0.2)	49 (0.7)
Pyrexia	1 (<0.1)	132 (1.4)	10 (<0.1)	143 (0.6)	0	35 (1.0)	5 (0.1)	40 (0.5)
Chills	1 (<0.1)	106 (1.1)	12 (0.1)	119 (0.5)	0	30 (0.9)	4 (0.1)	34 (0.5)
Injection site erythema	0	31 (0.3)	0	31 (0.1)	0	8 (0.2)	0	8 (0.1)
Injection site swelling	0	22 (0.2)	1 (<0.1)	23 (0.1)	0	3 (<0.1)	0	3 (<0.1)
Injection site pruritus	0	14 (0.2)	0	14 (<0.1)	0	5 (0.1)	0	5 (<0.1)
Injection site rash	0	12 (0.1)	0	12 (<0.1)	0	5 (0.1)	0	5 (<0.1)

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Safety Set

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	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)								
Chest pain	1 (<0.1)	3 (<0.1)	5 (<0.1)	9 (<0.1)	0	11 (0.3)	2 (<0.1)	13 (0.2)
Injection site bruising	0	7 (<0.1)	0	7 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Injection site urticaria	0	7 (<0.1)	0	7 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Malaise	0	5 (<0.1)	0	5 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Peripheral swelling	0	4 (<0.1)	3 (<0.1)	7 (<0.1)	1 (0.3)	3 (<0.1)	0	4 (<0.1)
Oedema peripheral	0	2 (<0.1)	4 (<0.1)	6 (<0.1)	0	4 (0.1)	2 (<0.1)	6 (<0.1)
Influenza like illness	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Injection site lymphadenopathy	0	4 (<0.1)	0	4 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)								
Non-cardiac chest pain	0	4 (<0.1)	2 (<0.1)	6 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Axillary pain	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Chest discomfort	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Injection site induration	0	3 (<0.1)	0	3 (<0.1)	0	0	0	0
Asthenia	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Cyst	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Feeling hot	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Injection site inflammation	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Injection site joint pain	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

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General disorders and administration site conditions (Cont.)								
Injection site mass	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Injection site nodule	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Injection site warmth	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Swelling face	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Vaccination site pain	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Discomfort	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Drug intolerance	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Early satiety	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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General disorders and administration site conditions (Cont.)								
Exercise tolerance decreased	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Facial pain	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Gait disturbance	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Generalised oedema	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Inflammation	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Injection site discolouration	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Injection site discomfort	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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General disorders and administration site conditions (Cont.)								
Injection site erosion	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Injection site irritation	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Injection site papule	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Injection site reaction	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Nodule	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Precancerous condition	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Swelling	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Systemic inflammatory response syndrome	1 (<0.1)	1 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0

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General disorders and administration site conditions (Cont.)								
Vaccination site erythema	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Vaccination site lymphadenopathy	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Vaccination site urticaria	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Vaccination site warmth	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Xerosis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Complication associated with device	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Incarcerated hernia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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General disorders and administration site conditions (Cont.)								
Medical device site haemorrhage	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Medical device site pain	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Papillitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pelvic mass	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Sudden death	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Vessel puncture site pain	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Investigations	3 (0.1)	37 (0.4)	37 (0.3)	77 (0.3)	0	27 (0.8)	15 (0.4)	42 (0.6)
Blood pressure increased	2 (<0.1)	11 (0.1)	4 (<0.1)	17 (<0.1)	0	4 (0.1)	3 (<0.1)	7 (<0.1)
Blood cholesterol increased	0	4 (<0.1)	6 (<0.1)	10 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood testosterone decreased	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	0	0	0
Cardiac murmur	0	0	0	0	0	3 (<0.1)	0	3 (<0.1)
Hepatic enzyme increased	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood glucose increased	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Blood pressure diastolic increased	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Blood triglycerides increased	0	0	0	0	0	2 (<0.1)	0	2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

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Investigations (Cont.)								
Glycosylated haemoglobin increased	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Heart rate irregular	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Liver function test increased	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Prostatic specific antigen increased	0	0	3 (<0.1)	3 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Anticoagulation drug level above therapeutic	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Blood bilirubin increased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Blood potassium decreased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Investigations (Cont.)								
Blood pressure systolic increased	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Blood uric acid increased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Blood urine present	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Body temperature increased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Cells in urine	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Culture urine positive	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Fibrin D dimer increased	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Full blood count abnormal	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Haemoglobin decreased	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Heart rate increased	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0

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Investigations (Cont.)								
Intraocular pressure increased	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Metabolic function test abnormal	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Oxygen saturation decreased	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Platelet count decreased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Progesterone decreased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Transaminases increased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Vitamin D decreased	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
White blood cell count decreased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Investigations (Cont.)								
Alanine aminotransferase increased	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Angiotensin converting enzyme increased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Antinuclear antibody increased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Antipsychotic drug level increased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Aspartate aminotransferase increased	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)

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System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Investigations (Cont.)								
Blood alkaline phosphatase increased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Blood calcium increased	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Blood creatinine decreased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Blood lactic acid increased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Brain scan abnormal	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Cardiac stress test abnormal	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Cortisol decreased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Electrocardiogram QT prolonged	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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MedDRA version 23.0.

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Investigations (Cont.)								
Liver function test abnormal	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Mammogram abnormal	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Nitrite urine present	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Red blood cell count decreased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Serum ferritin decreased	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Smear cervix abnormal	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Smooth muscle antibody positive	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Urine calcium increased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301310102.sas 21JUN2021 03:13

Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Investigations (Cont.)								
Weight increased	0	0	3 (<0.1)	3 (<0.1)	0	0	0	0
White blood cell count increased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
White blood cells urine positive	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Injury, poisoning and procedural complications	3 (0.1)	147 (1.6)	134 (1.2)	284 (1.2)	0	75 (2.2)	47 (1.2)	122 (1.6)
Procedural pain	0	18 (0.2)	17 (0.1)	35 (0.2)	0	8 (0.2)	4 (0.1)	12 (0.2)
Muscle strain	0	15 (0.2)	12 (0.1)	27 (0.1)	0	6 (0.2)	3 (<0.1)	9 (0.1)
Fall	0	8 (<0.1)	4 (<0.1)	12 (<0.1)	0	7 (0.2)	7 (0.2)	14 (0.2)

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301310102.sas 21JUN2021 03:13

Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Ligament sprain	0	9 (<0.1)	7 (<0.1)	16 (<0.1)	0	5 (0.1)	3 (<0.1)	8 (0.1)
Tooth fracture	0	6 (<0.1)	6 (<0.1)	12 (<0.1)	0	8 (0.2)	1 (<0.1)	9 (0.1)
Skin laceration	0	7 (<0.1)	8 (<0.1)	15 (<0.1)	0	6 (0.2)	7 (0.2)	13 (0.2)
Limb injury	0	8 (<0.1)	3 (<0.1)	11 (<0.1)	0	4 (0.1)	0	4 (<0.1)
Animal bite	0	7 (<0.1)	0	7 (<0.1)	0	3 (<0.1)	0	3 (<0.1)
Contusion	0	5 (<0.1)	3 (<0.1)	8 (<0.1)	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Meniscus injury	0	7 (<0.1)	6 (<0.1)	13 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Foot fracture	0	4 (<0.1)	5 (<0.1)	9 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Road traffic accident	0	5 (<0.1)	4 (<0.1)	9 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Stress fracture	0	6 (<0.1)	3 (<0.1)	9 (<0.1)	0	0	0	0
Hand fracture	0	4 (<0.1)	1 (<0.1)	5 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fibula fracture	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Joint injury	0	3 (<0.1)	2 (<0.1)	5 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Radius fracture	0	3 (<0.1)	0	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Tendon rupture	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Ankle fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)	4 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Arthropod bite	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	0	0	0
Concussion	0	2 (<0.1)	6 (<0.1)	8 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Dental restoration failure	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Epicondylitis	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lip injury	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Upper limb fracture	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Anaemia postoperative	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Cartilage injury	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Corneal abrasion	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Eye injury	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Femur fracture	0	0	0	0	0	2 (<0.1)	0	2 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Ligament rupture	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Post-traumatic pain	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Rib fracture	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Wrist fracture	0	1 (<0.1)	4 (<0.1)	5 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Accidental overdose	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Avulsion fracture	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Back injury	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bite	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Bone contusion	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Brain contusion	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Burn oral cavity	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Burns first degree	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Clavicle fracture	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	0	0	0	0
Eyelid injury	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Gun shot wound	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Head injury	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Iliotibial band syndrome	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Incision site discharge	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Incisional hernia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Joint dislocation	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lisfranc fracture	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Lumbar vertebral fracture	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Mouth injury	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Muscle injury	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Neck injury	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Pneumothorax traumatic	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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MedDRA version 23.0.

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Post procedural constipation	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Post procedural fever	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Post procedural hypotension	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Post procedural pruritus	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Post procedural swelling	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Procedural complication	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Procedural nausea	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Radiation associated pain	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301310102.sas 21JUN2021 03:13

Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Radiation skin injury	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Skin abrasion	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Skin injury	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Spinal compression fracture	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Subcutaneous haematoma	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Tibia fracture	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	0	0
Ulna fracture	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Venomous sting	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Wound	0	0	2 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

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	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Acetabulum fracture	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Animal scratch	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Cervical vertebral fracture	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Chemical burn	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Chillblains	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Exposure during pregnancy	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Exposure to toxic agent	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Eye contusion	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Facial bones fracture	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Foreign body in eye	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Foreign body ingestion	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Fracture displacement	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Fractured sacrum	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Hip fracture	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Humerus fracture	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Injury	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Limb crushing injury	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Lower limb fracture	0	0	3 (<0.1)	3 (<0.1)	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Muscle rupture	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Patella fracture	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pelvic fracture	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Poisoning	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Post procedural haematoma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Post procedural haemorrhage	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Seroma	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Soft tissue injury	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Spinal cord injury	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301310102.sas 21JUN2021 03:13

Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Splinter	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Stab wound	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0
Sunburn	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Suture related complication	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Tendon injury	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Thermal burn	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Thoracic vertebral fracture	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Ulnar nerve injury	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Vaccination complication	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301310102.sas 21JUN2021 03:13

Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Wound dehiscence	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Surgical and medical procedures	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	3 (<0.1)	0	3 (<0.1)
Colostomy	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Elbow operation	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Hip arthroplasty	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Micrographic skin surgery	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Shoulder arthroplasty	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.31.1.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Surgical and medical procedures (Cont.)								
Gastric bypass	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Social circumstances	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Physical assault	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Product issues	0	0	2 (<0.1)	2 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Device failure	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Device physical property issue	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Device breakage	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.32.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	7 (0.3)	148 (1.2)	141 (0.9)	296 (1.0)
Number of Unsolicited Adverse Events	8	190	181	379
Infections and infestations	1 (<0.1)	31 (0.2)	23 (0.2)	55 (0.2)
Pneumonia	0	5 (<0.1)	2 (<0.1)	7 (<0.1)
Appendicitis	0	4 (<0.1)	3 (<0.1)	7 (<0.1)
Sepsis	0	4 (<0.1)	3 (<0.1)	7 (<0.1)
COVID-19	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Appendicitis perforated	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Arthritis bacterial	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Diverticulitis	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Osteomyelitis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Appendiceal abscess	0	1 (<0.1)	0	1 (<0.1)
Breast cellulitis	0	1 (<0.1)	0	1 (<0.1)
COVID-19 pneumonia	0	1 (<0.1)	0	1 (<0.1)
Cystitis	0	1 (<0.1)	0	1 (<0.1)
Hepatic infection	0	1 (<0.1)	0	1 (<0.1)
Medical device site joint infection	0	1 (<0.1)	0	1 (<0.1)
Meningitis	0	1 (<0.1)	0	1 (<0.1)
Oesophageal candidiasis	0	1 (<0.1)	0	1 (<0.1)
Osteomyelitis bacterial	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.32.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Post procedural infection	0	1 (<0.1)	0	1 (<0.1)
Staphylococcal sepsis	0	1 (<0.1)	0	1 (<0.1)
Wound infection	0	1 (<0.1)	0	1 (<0.1)
Cellulitis	0	0	2 (<0.1)	2 (<0.1)
Epididymitis	0	0	1 (<0.1)	1 (<0.1)
Escherichia urinary tract infection	0	0	1 (<0.1)	1 (<0.1)
Orchitis	0	0	1 (<0.1)	1 (<0.1)
Pericarditis infective	1 (<0.1)	0	0	1 (<0.1)
Perirectal abscess	0	0	1 (<0.1)	1 (<0.1)
Pneumonia bacterial	0	0	1 (<0.1)	1 (<0.1)
Respiratory syncytial virus infection	0	0	1 (<0.1)	1 (<0.1)
Staphylococcal bacteraemia	0	0	1 (<0.1)	1 (<0.1)
Streptococcal infection	0	0	1 (<0.1)	1 (<0.1)
Urinary tract infection	0	0	3 (<0.1)	3 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (<0.1)	8 (<0.1)	12 (<0.1)	22 (<0.1)
Castleman's disease	0	1 (<0.1)	0	1 (<0.1)
Metastases to lung	0	1 (<0.1)	0	1 (<0.1)
Myelodysplastic syndrome	0	1 (<0.1)	0	1 (<0.1)
Oesophageal adenocarcinoma	0	1 (<0.1)	0	1 (<0.1)
Pancreatic carcinoma metastatic	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.32.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Pancreatic carcinoma stage IV	0	1 (<0.1)	0	1 (<0.1)
Prostate cancer	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Renal cancer	0	1 (<0.1)	0	1 (<0.1)
Borderline mucinous tumour of ovary	0	0	1 (<0.1)	1 (<0.1)
Breast cancer	0	0	1 (<0.1)	1 (<0.1)
Colorectal cancer metastatic	1 (<0.1)	0	0	1 (<0.1)
High-grade B-cell lymphoma	0	0	1 (<0.1)	1 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	0	0	1 (<0.1)
Oesophageal carcinoma	0	0	1 (<0.1)	1 (<0.1)
Phaeochromocytoma	0	0	1 (<0.1)	1 (<0.1)
Salivary gland cancer stage IV	0	0	1 (<0.1)	1 (<0.1)
Thyroid cancer	0	0	1 (<0.1)	1 (<0.1)
Uterine cancer	0	0	1 (<0.1)	1 (<0.1)
Uterine leiomyoma	0	0	1 (<0.1)	1 (<0.1)
Blood and lymphatic system disorders	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Anaemia	0	2 (<0.1)	0	2 (<0.1)
Immune thrombocytopenia	0	1 (<0.1)	0	1 (<0.1)
Leukocytosis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.32.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Immune system disorders	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Anaphylactic reaction	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Endocrine disorders	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Autoimmune thyroiditis	0	1 (<0.1)	0	1 (<0.1)
Adrenal mass	0	0	1 (<0.1)	1 (<0.1)
Goitre	0	0	1 (<0.1)	1 (<0.1)
Metabolism and nutrition disorders	0	1 (<0.1)	6 (<0.1)	7 (<0.1)
Obesity	0	1 (<0.1)	0	1 (<0.1)
Dehydration	0	0	1 (<0.1)	1 (<0.1)
Diabetic ketoacidosis	0	0	1 (<0.1)	1 (<0.1)
Gout	0	0	1 (<0.1)	1 (<0.1)
Hyperglycaemia	0	0	1 (<0.1)	1 (<0.1)
Hyperkalaemia	0	0	1 (<0.1)	1 (<0.1)
Lactic acidosis	0	0	1 (<0.1)	1 (<0.1)
Psychiatric disorders	2 (<0.1)	3 (<0.1)	9 (<0.1)	14 (<0.1)
Suicidal ideation	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Depression	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Agitation	1 (<0.1)	0	0	1 (<0.1)
Bipolar I disorder	0	0	1 (<0.1)	1 (<0.1)
Delirium	1 (<0.1)	0	0	1 (<0.1)

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Table 14.3.1.32.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Drug dependence	1 (<0.1)	0	0	1 (<0.1)
Intentional self-injury	0	0	1 (<0.1)	1 (<0.1)
Major depression	0	0	1 (<0.1)	1 (<0.1)
Post-traumatic stress disorder	0	0	1 (<0.1)	1 (<0.1)
Substance use disorder	0	0	1 (<0.1)	1 (<0.1)
Suicide attempt	0	0	2 (<0.1)	2 (<0.1)
Nervous system disorders	0	11 (<0.1)	11 (<0.1)	22 (<0.1)
Cerebrovascular accident	0	4 (<0.1)	3 (<0.1)	7 (<0.1)
Paraesthesia	0	2 (<0.1)	0	2 (<0.1)
Amyotrophic lateral sclerosis	0	1 (<0.1)	0	1 (<0.1)
Brain stem infarction	0	1 (<0.1)	0	1 (<0.1)
Haemorrhage intracranial	0	1 (<0.1)	0	1 (<0.1)
Ischaemic cerebral infarction	0	1 (<0.1)	0	1 (<0.1)
Sciatica	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Balance disorder	0	0	1 (<0.1)	1 (<0.1)
Carotid artery stenosis	0	0	1 (<0.1)	1 (<0.1)
Presyncope	0	0	1 (<0.1)	1 (<0.1)
Seizure	0	0	1 (<0.1)	1 (<0.1)
Syncope	0	0	1 (<0.1)	1 (<0.1)
Transient global amnesia	0	0	1 (<0.1)	1 (<0.1)
Transient ischaemic attack	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.32.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders	0	3 (<0.1)	0	3 (<0.1)
Diplopia	0	1 (<0.1)	0	1 (<0.1)
Retinal artery occlusion	0	1 (<0.1)	0	1 (<0.1)
Retinal tear	0	1 (<0.1)	0	1 (<0.1)
Ear and labyrinth disorders	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vertigo	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardiac disorders	1 (<0.1)	22 (0.2)	20 (0.1)	43 (0.1)
Coronary artery disease	0	4 (<0.1)	4 (<0.1)	8 (<0.1)
Myocardial infarction	0	4 (<0.1)	2 (<0.1)	6 (<0.1)
Acute myocardial infarction	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Angina unstable	0	2 (<0.1)	0	2 (<0.1)
Cardiac failure	0	2 (<0.1)	0	2 (<0.1)
Cardiac failure congestive	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Acute coronary syndrome	0	1 (<0.1)	0	1 (<0.1)
Aortic valve incompetence	0	1 (<0.1)	0	1 (<0.1)
Arrhythmia	0	1 (<0.1)	0	1 (<0.1)
Atrial fibrillation	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Atrial flutter	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Atrioventricular block complete	0	1 (<0.1)	0	1 (<0.1)
Sinus node dysfunction	0	1 (<0.1)	0	1 (<0.1)
Ventricular tachycardia	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.32.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Acute left ventricular failure	0	0	2 (<0.1)	2 (<0.1)
Angina pectoris	0	0	1 (<0.1)	1 (<0.1)
Bradycardia	0	0	1 (<0.1)	1 (<0.1)
Cardiac arrest	0	0	1 (<0.1)	1 (<0.1)
Coronary artery insufficiency	0	0	1 (<0.1)	1 (<0.1)
Ischaemic cardiomyopathy	0	0	1 (<0.1)	1 (<0.1)
Pulseless electrical activity	0	0	1 (<0.1)	1 (<0.1)
Ventricular arrhythmia	1 (<0.1)	0	0	1 (<0.1)
Vascular disorders	0	5 (<0.1)	8 (<0.1)	13 (<0.1)
Deep vein thrombosis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Aortic stenosis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypertension	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Peripheral arterial occlusive disease	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Aortic dissection	0	0	1 (<0.1)	1 (<0.1)
Hypotension	0	0	2 (<0.1)	2 (<0.1)
Intermittent claudication	0	0	1 (<0.1)	1 (<0.1)
Jugular vein thrombosis	0	0	1 (<0.1)	1 (<0.1)
Subclavian vein thrombosis	0	0	1 (<0.1)	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	0	13 (0.1)	11 (<0.1)	24 (<0.1)
Pleural effusion	0	3 (<0.1)	1 (<0.1)	4 (<0.1)

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Table 14.3.1.32.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pulmonary embolism	0	2 (<0.1)	5 (<0.1)	7 (<0.1)
Acute respiratory failure	0	1 (<0.1)	0	1 (<0.1)
Asthma	0	1 (<0.1)	0	1 (<0.1)
Atelectasis	0	1 (<0.1)	0	1 (<0.1)
Dyspnoea	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Dyspnoea exertional	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypoxia	0	1 (<0.1)	0	1 (<0.1)
Interstitial lung disease	0	1 (<0.1)	0	1 (<0.1)
Pneumothorax	0	1 (<0.1)	0	1 (<0.1)
Respiratory failure	0	1 (<0.1)	0	1 (<0.1)
Chronic obstructive pulmonary disease	0	0	1 (<0.1)	1 (<0.1)
Respiratory tract congestion	0	0	1 (<0.1)	1 (<0.1)
Gastrointestinal disorders	0	19 (0.2)	10 (<0.1)	29 (<0.1)
Abdominal pain	0	3 (<0.1)	0	3 (<0.1)
Gastrointestinal haemorrhage	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hiatus hernia	0	2 (<0.1)	0	2 (<0.1)
Abdominal hernia	0	1 (<0.1)	0	1 (<0.1)
Abdominal pain upper	0	1 (<0.1)	0	1 (<0.1)
Dental caries	0	1 (<0.1)	0	1 (<0.1)
Diarrhoea	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.32.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Duodenal ulcer perforation	0	1 (<0.1)	0	1 (<0.1)
Gastroesophageal reflux disease	0	1 (<0.1)	0	1 (<0.1)
Internal hernia	0	1 (<0.1)	0	1 (<0.1)
Intestinal obstruction	0	1 (<0.1)	0	1 (<0.1)
Oesophageal rupture	0	1 (<0.1)	0	1 (<0.1)
Pancreatitis	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Pancreatitis acute	0	1 (<0.1)	0	1 (<0.1)
Small intestinal obstruction	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Enterovesical fistula	0	0	1 (<0.1)	1 (<0.1)
Haematochezia	0	0	1 (<0.1)	1 (<0.1)
Ileus	0	0	2 (<0.1)	2 (<0.1)
Hepatobiliary disorders	0	3 (<0.1)	6 (<0.1)	9 (<0.1)
Cholecystitis	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Biliary colic	0	0	1 (<0.1)	1 (<0.1)
Cholecystitis acute	0	0	2 (<0.1)	2 (<0.1)
Cholelithiasis obstructive	0	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	0	2 (<0.1)	0	2 (<0.1)
Decubitus ulcer	0	1 (<0.1)	0	1 (<0.1)
Drug eruption	0	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.32.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders	0	11 (<0.1)	9 (<0.1)	20 (<0.1)
Intervertebral disc degeneration	0	2 (<0.1)	0	2 (<0.1)
Osteoarthritis	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Arthralgia	0	1 (<0.1)	0	1 (<0.1)
Arthritis	0	1 (<0.1)	0	1 (<0.1)
Back pain	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Bursitis	0	1 (<0.1)	0	1 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)	0	1 (<0.1)
Muscle spasms	0	1 (<0.1)	0	1 (<0.1)
Muscular weakness	0	1 (<0.1)	0	1 (<0.1)
Musculoskeletal chest pain	0	0	1 (<0.1)	1 (<0.1)
Pain in extremity	0	0	2 (<0.1)	2 (<0.1)
Spondylolisthesis	0	0	1 (<0.1)	1 (<0.1)
Renal and urinary disorders	0	8 (<0.1)	7 (<0.1)	15 (<0.1)
Nephrolithiasis	0	5 (<0.1)	2 (<0.1)	7 (<0.1)
Acute kidney injury	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Haematuria	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Renal failure	0	1 (<0.1)	0	1 (<0.1)
Ureterolithiasis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Urinary retention	0	1 (<0.1)	0	1 (<0.1)
Nephritis	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.32.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Pregnancy, puerperium and perinatal conditions	0	4 (<0.1)	2 (<0.1)	6 (<0.1)
Abortion spontaneous	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Pregnancy	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Reproductive system and breast disorders	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Cervical dysplasia	0	2 (<0.1)	0	2 (<0.1)
Benign prostatic hyperplasia	0	1 (<0.1)	0	1 (<0.1)
Endometriosis	0	0	1 (<0.1)	1 (<0.1)
Ovarian cyst	0	0	1 (<0.1)	1 (<0.1)
Congenital, familial and genetic disorders	0	1 (<0.1)	0	1 (<0.1)
Arnold-Chiari malformation	0	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	0	8 (<0.1)	5 (<0.1)	13 (<0.1)
Chest pain	0	5 (<0.1)	2 (<0.1)	7 (<0.1)
Asthenia	0	1 (<0.1)	0	1 (<0.1)
Gait disturbance	0	1 (<0.1)	0	1 (<0.1)
Non-cardiac chest pain	0	1 (<0.1)	0	1 (<0.1)
Chest discomfort	0	0	1 (<0.1)	1 (<0.1)
Incarcerated hernia	0	0	1 (<0.1)	1 (<0.1)
Sudden death	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.32.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations	0	2 (<0.1)	0	2 (<0.1)
Anticoagulation drug level above therapeutic	0	1 (<0.1)	0	1 (<0.1)
Platelet count decreased	0	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	1 (<0.1)	9 (<0.1)	13 (<0.1)	23 (<0.1)
Anaemia postoperative	0	2 (<0.1)	0	2 (<0.1)
Accidental overdose	0	1 (<0.1)	0	1 (<0.1)
Animal bite	0	1 (<0.1)	0	1 (<0.1)
Femur fracture	0	1 (<0.1)	0	1 (<0.1)
Limb injury	0	1 (<0.1)	0	1 (<0.1)
Post procedural hypotension	0	1 (<0.1)	0	1 (<0.1)
Rib fracture	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Stress fracture	0	1 (<0.1)	0	1 (<0.1)
Acetabulum fracture	0	0	1 (<0.1)	1 (<0.1)
Cervical vertebral fracture	0	0	1 (<0.1)	1 (<0.1)
Fibula fracture	0	0	1 (<0.1)	1 (<0.1)
Fracture displacement	0	0	1 (<0.1)	1 (<0.1)
Fractured sacrum	0	0	1 (<0.1)	1 (<0.1)
Head injury	0	0	1 (<0.1)	1 (<0.1)
Hip fracture	0	0	2 (<0.1)	2 (<0.1)
Lower limb fracture	0	0	1 (<0.1)	1 (<0.1)
Patella fracture	0	0	1 (<0.1)	1 (<0.1)
Pelvic fracture	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.32.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Poisoning	0	0	1 (<0.1)	1 (<0.1)
Post procedural haematoma	0	0	1 (<0.1)	1 (<0.1)
Stab wound	1 (<0.1)	0	0	1 (<0.1)
Tendon rupture	0	0	1 (<0.1)	1 (<0.1)
Thoracic vertebral fracture	0	0	1 (<0.1)	1 (<0.1)
Tibia fracture	0	0	1 (<0.1)	1 (<0.1)
Surgical and medical procedures	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Colostomy	0	1 (<0.1)	0	1 (<0.1)
Hip arthroplasty	0	1 (<0.1)	0	1 (<0.1)
Shoulder arthroplasty	0	1 (<0.1)	0	1 (<0.1)
Gastric bypass	0	0	1 (<0.1)	1 (<0.1)
Social circumstances	0	0	1 (<0.1)	1 (<0.1)
Physical assault	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.32.1.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects Reporting Unsolicited Adverse Events	5 (0.2)	83 (0.9)	81 (0.7)	169 (0.7)	2 (0.6)	65 (1.9)	60 (1.6)	127 (1.7)
Number of Unsolicited Adverse Events	5	99	101	205	3	91	80	174
Infections and infestations	1 (<0.1)	19 (0.2)	14 (0.1)	34 (0.1)	0	12 (0.4)	9 (0.2)	21 (0.3)
Pneumonia	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Appendicitis	0	4 (<0.1)	2 (<0.1)	6 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Sepsis	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
COVID-19	0	0	1 (<0.1)	1 (<0.1)	0	3 (<0.1)	0	3 (<0.1)
Appendicitis perforated	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	0	0	0

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Table 14.3.1.32.1.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Arthritis bacterial	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Diverticulitis	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Osteomyelitis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Appendiceal abscess	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Breast cellulitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
COVID-19 pneumonia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Cystitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Hepatic infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Medical device site joint infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Meningitis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Oesophageal candidiasis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Osteomyelitis bacterial	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Post procedural infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Staphylococcal sepsis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Wound infection	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Cellulitis	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Epididymitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Orchitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pericarditis infective	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0
Perirectal abscess	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pneumonia bacterial	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Staphylococcal bacteraemia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Streptococcal infection	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Urinary tract infection	0	0	1 (<0.1)	1 (<0.1)	0	0	2 (<0.1)	2 (<0.1)

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Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (<0.1)	6 (<0.1)	8 (<0.1)	16 (<0.1)	0	2 (<0.1)	4 (0.1)	6 (<0.1)
Castleman's disease	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Metastases to lung	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Myelodysplastic syndrome	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Oesophageal adenocarcinoma	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pancreatic carcinoma metastatic	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pancreatic carcinoma stage IV	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Prostate cancer	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Renal cancer	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Borderline mucinous tumour of ovary	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Breast cancer	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Colorectal cancer metastatic	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0
High-grade B-cell lymphoma	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0

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Table 14.3.1.32.1.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Oesophageal carcinoma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Phaeochromocytoma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Salivary gland cancer stage IV	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Thyroid cancer	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Uterine cancer	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Uterine leiomyoma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Table 14.3.1.32.1.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Blood and lymphatic system disorders	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Anaemia	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Immune thrombocytopenia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Leukocytosis	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Immune system disorders	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Anaphylactic reaction	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Endocrine disorders	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Autoimmune thyroiditis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Adrenal mass	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Endocrine disorders (Cont.)								
Goitre	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Metabolism and nutrition disorders	0	1 (<0.1)	4 (<0.1)	5 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Obesity	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Dehydration	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Diabetic ketoacidosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Gout	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Hyperglycaemia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Hyperkalaemia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Lactic acidosis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.32.1.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Psychiatric disorders	1 (<0.1)	3 (<0.1)	8 (<0.1)	12 (<0.1)	1 (0.3)	0	1 (<0.1)	2 (<0.1)
Suicidal ideation	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Depression	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	0	0
Agitation	0	0	0	0	1 (0.3)	0	0	1 (<0.1)
Bipolar I disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Delirium	0	0	0	0	1 (0.3)	0	0	1 (<0.1)
Drug dependence	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0
Intentional self-injury	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Major depression	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Post-traumatic stress disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Substance use disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Psychiatric disorders (Cont.)								
Suicide attempt	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Nervous system disorders	0	6 (<0.1)	7 (<0.1)	13 (<0.1)	0	5 (0.1)	4 (0.1)	9 (0.1)
Cerebrovascular accident	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Paraesthesia	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Amyotrophic lateral sclerosis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Brain stem infarction	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Haemorrhage intracranial	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Nervous system disorders (Cont.)								
Ischaemic cerebral infarction	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Sciatica	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Balance disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Carotid artery stenosis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Presyncope	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Seizure	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Syncope	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Transient global amnesia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Transient ischaemic attack	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Eye disorders	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Diplopia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Retinal artery occlusion	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Retinal tear	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Ear and labyrinth disorders	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vertigo	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardiac disorders	0	5 (<0.1)	5 (<0.1)	10 (<0.1)	1 (0.3)	17 (0.5)	15 (0.4)	33 (0.4)
Coronary artery disease	0	0	0	0	0	4 (0.1)	4 (0.1)	8 (0.1)
Myocardial infarction	0	1 (<0.1)	0	1 (<0.1)	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Acute myocardial infarction	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)

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Cardiac disorders (Cont.)								
Angina unstable	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Cardiac failure	0	0	0	0	0	2 (<0.1)	0	2 (<0.1)
Cardiac failure congestive	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Acute coronary syndrome	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Aortic valve incompetence	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Arrhythmia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Atrial fibrillation	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Atrial flutter	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Atrioventricular block complete	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Sinus node dysfunction	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Cardiac disorders (Cont.)								
Ventricular tachycardia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Acute left ventricular failure	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Angina pectoris	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Bradycardia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Cardiac arrest	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Coronary artery insufficiency	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Ischaemic cardiomyopathy	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Pulseless electrical activity	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Cardiac disorders (Cont.)								
Ventricular arrhythmia	0	0	0	0	1 (0.3)	0	0	1 (<0.1)
Vascular disorders	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	4 (0.1)	5 (0.1)	9 (0.1)
Deep vein thrombosis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Aortic stenosis	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypertension	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Peripheral arterial occlusive disease	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Aortic dissection	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Hypotension	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Intermittent claudication	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Vascular disorders (Cont.)								
Jugular vein thrombosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Subclavian vein thrombosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Respiratory, thoracic and mediastinal disorders	0	4 (<0.1)	6 (<0.1)	10 (<0.1)	0	9 (0.3)	5 (0.1)	14 (0.2)
Pleural effusion	0	0	0	0	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Pulmonary embolism	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Acute respiratory failure	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Asthma	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Atelectasis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Dyspnoea	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Respiratory, thoracic and mediastinal disorders (Cont.)								
Dyspnoea exertional	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypoxia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Interstitial lung disease	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Pneumothorax	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Respiratory failure	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Chronic obstructive pulmonary disease	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Respiratory tract congestion	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Gastrointestinal disorders	0	13 (0.1)	6 (<0.1)	19 (<0.1)	0	6 (0.2)	4 (0.1)	10 (0.1)
Abdominal pain	0	3 (<0.1)	0	3 (<0.1)	0	0	0	0
Gastrointestinal haemorrhage	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hiatus hernia	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Abdominal hernia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Abdominal pain upper	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Dental caries	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Diarrhoea	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Duodenal ulcer perforation	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Gastrooesophageal reflux disease	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Gastrointestinal disorders (Cont.)								
Internal hernia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Intestinal obstruction	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Oesophageal rupture	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pancreatitis	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	0	0	0
Pancreatitis acute	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Small intestinal obstruction	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Enterovesical fistula	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Haematochezia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Ileus	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

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	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Hepatobiliary disorders	0	3 (<0.1)	4 (<0.1)	7 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Cholecystitis	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Biliary colic	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Cholecystitis acute	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Cholelithiasis obstructive	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Skin and subcutaneous tissue disorders	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Decubitus ulcer	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Drug eruption	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders	0	4 (<0.1)	4 (<0.1)	8 (<0.1)	0	7 (0.2)	5 (0.1)	12 (0.2)
Intervertebral disc degeneration	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Osteoarthritis	0	0	0	0	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Arthralgia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Arthritis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Back pain	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Bursitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Chondrocalcinosis pyrophosphate	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Muscle spasms	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301320102.sas 21JUN2021 03:15

Table 14.3.1.32.1.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)								
Muscular weakness	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Musculoskeletal chest pain	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pain in extremity	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Spondylolisthesis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Renal and urinary disorders	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	7 (0.2)	4 (0.1)	11 (0.1)
Nephrolithiasis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	4 (0.1)	1 (<0.1)	5 (<0.1)
Acute kidney injury	0	0	0	0	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Haematuria	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301320102.sas 21JUN2021 03:15

Table 14.3.1.32.1.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Renal and urinary disorders (Cont.)								
Renal failure	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Ureterolithiasis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Urinary retention	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Nephritis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pregnancy, puerperium and perinatal conditions	0	4 (<0.1)	2 (<0.1)	6 (<0.1)	0	0	0	0
Abortion spontaneous	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	0	0	0
Pregnancy	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0

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MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301320102.sas 21JUN2021 03:15

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Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Reproductive system and breast disorders	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	0	0	0
Cervical dysplasia	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Benign prostatic hyperplasia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Endometriosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Ovarian cyst	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Congenital, familial and genetic disorders	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Arnold-Chiari malformation	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Table 14.3.1.32.1.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
General disorders and administration site conditions	0	5 (<0.1)	4 (<0.1)	9 (<0.1)	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Chest pain	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Asthenia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Gait disturbance	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Non-cardiac chest pain	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Chest discomfort	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Incarcerated hernia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Sudden death	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Table 14.3.1.32.1.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Investigations	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Anticoagulation drug level above therapeutic	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Platelet count decreased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Injury, poisoning and procedural complications	1 (<0.1)	4 (<0.1)	8 (<0.1)	13 (<0.1)	0	5 (0.1)	5 (0.1)	10 (0.1)
Anaemia postoperative	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Accidental overdose	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Animal bite	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Femur fracture	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Limb injury	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Post procedural hypotension	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Rib fracture	0	0	0	0	0	1 (<0.1)	1	2 (<0.1)
Stress fracture	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Acetabulum fracture	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Cervical vertebral fracture	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Fibula fracture	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Fracture displacement	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Fractured sacrum	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Head injury	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Hip fracture	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Lower limb fracture	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Patella fracture	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pelvic fracture	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Poisoning	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Post procedural haematoma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Stab wound	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0
Tendon rupture	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Thoracic vertebral fracture	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Tibia fracture	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Surgical and medical procedures	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Colostomy	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Hip arthroplasty	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Shoulder arthroplasty	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Gastric bypass	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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MedDRA version 23.0.

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Table 14.3.1.32.1.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Social circumstances	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Physical assault	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301320102.sas 21JUN2021 03:15

Table 14.3.1.33.1.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	37 (1.5)	1509 (11.9)	1457 (9.6)	3003 (9.9)
Number of Unsolicited Adverse Events	51	2202	2067	4320
Infections and infestations	9 (0.4)	479 (3.8)	462 (3.0)	950 (3.1)
Urinary tract infection	0	59 (0.5)	65 (0.4)	124 (0.4)
COVID-19	3 (0.1)	51 (0.4)	32 (0.2)	86 (0.3)
Upper respiratory tract infection	2 (<0.1)	39 (0.3)	40 (0.3)	81 (0.3)
Sinusitis	0	34 (0.3)	29 (0.2)	63 (0.2)
Rhinovirus infection	0	20 (0.2)	18 (0.1)	38 (0.1)
Viral infection	0	20 (0.2)	27 (0.2)	47 (0.2)
Tooth infection	0	17 (0.1)	14 (<0.1)	31 (0.1)
Pharyngitis streptococcal	0	13 (0.1)	4 (<0.1)	17 (<0.1)
Diverticulitis	0	12 (<0.1)	6 (<0.1)	18 (<0.1)
Herpes zoster	0	11 (<0.1)	12 (<0.1)	23 (<0.1)
Suspected COVID-19	0	11 (<0.1)	25 (0.2)	36 (0.1)
Gastroenteritis	0	10 (<0.1)	9 (<0.1)	19 (<0.1)
Otitis media	0	10 (<0.1)	3 (<0.1)	13 (<0.1)
Pneumonia	0	10 (<0.1)	6 (<0.1)	16 (<0.1)
Tooth abscess	1 (<0.1)	10 (<0.1)	13 (<0.1)	24 (<0.1)
Cellulitis	0	8 (<0.1)	12 (<0.1)	20 (<0.1)
Acute sinusitis	0	7 (<0.1)	6 (<0.1)	13 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301330101.sas 21JUN2021 03:17

Table 14.3.1.33.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Appendicitis	0	6 (<0.1)	5 (<0.1)	11 (<0.1)
Bronchitis	0	6 (<0.1)	11 (<0.1)	17 (<0.1)
Conjunctivitis	0	6 (<0.1)	6 (<0.1)	12 (<0.1)
Onychomycosis	0	6 (<0.1)	0	6 (<0.1)
Ear infection	0	5 (<0.1)	6 (<0.1)	11 (<0.1)
Localised infection	0	5 (<0.1)	3 (<0.1)	8 (<0.1)
Pharyngitis	0	5 (<0.1)	6 (<0.1)	11 (<0.1)
Sepsis	0	5 (<0.1)	4 (<0.1)	9 (<0.1)
Bacterial vaginosis	1 (<0.1)	4 (<0.1)	4 (<0.1)	9 (<0.1)
Cystitis	0	4 (<0.1)	3 (<0.1)	7 (<0.1)
Hordeolum	0	4 (<0.1)	5 (<0.1)	9 (<0.1)
Staphylococcal infection	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Viral upper respiratory tract infection	0	4 (<0.1)	6 (<0.1)	10 (<0.1)
Asymptomatic COVID-19	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Coronavirus infection	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Folliculitis	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Fungal skin infection	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Gingivitis	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Helicobacter infection	1 (<0.1)	3 (<0.1)	2 (<0.1)	6 (<0.1)
Infected bite	0	3 (<0.1)	0	3 (<0.1)
Oral herpes	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Abscess limb	0	2 (<0.1)	3 (<0.1)	5 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.33.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Appendicitis perforated	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Arthritis bacterial	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Eye infection	0	2 (<0.1)	5 (<0.1)	7 (<0.1)
Gastroenteritis bacterial	0	2 (<0.1)	0	2 (<0.1)
Gastroenteritis viral	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Infected dermal cyst	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Kidney infection	0	2 (<0.1)	0	2 (<0.1)
Osteomyelitis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Otitis externa	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Rhinitis	0	2 (<0.1)	0	2 (<0.1)
Tinea pedis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Vulvovaginal candidiasis	0	2 (<0.1)	5 (<0.1)	7 (<0.1)
Vulvovaginal mycotic infection	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Wound infection	0	2 (<0.1)	0	2 (<0.1)
Appendiceal abscess	0	1 (<0.1)	0	1 (<0.1)
Arthritis infective	0	1 (<0.1)	0	1 (<0.1)
Breast cellulitis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
COVID-19 pneumonia	0	1 (<0.1)	0	1 (<0.1)
Candida infection	0	1 (<0.1)	0	1 (<0.1)
Chlamydial infection	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chronic sinusitis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Conjunctivitis viral	0	1 (<0.1)	0	1 (<0.1)

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MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301330101.sas 21JUN2021 03:17

Table 14.3.1.33.1.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Endophthalmitis	0	1 (<0.1)	0	1 (<0.1)
Escherichia infection	0	1 (<0.1)	0	1 (<0.1)
Eyelid infection	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Fungal infection	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Furuncle	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastrointestinal bacterial overgrowth	0	1 (<0.1)	0	1 (<0.1)
Genital herpes	0	1 (<0.1)	0	1 (<0.1)
Genital herpes simplex	0	1 (<0.1)	0	1 (<0.1)
Genital infection fungal	0	1 (<0.1)	0	1 (<0.1)
Groin abscess	0	1 (<0.1)	0	1 (<0.1)
Helicobacter gastritis	0	1 (<0.1)	0	1 (<0.1)
Hepatic infection	0	1 (<0.1)	0	1 (<0.1)
Herpes simplex	0	1 (<0.1)	0	1 (<0.1)
Impetigo	0	1 (<0.1)	0	1 (<0.1)
Infected cyst	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Infectious mononucleosis	0	1 (<0.1)	0	1 (<0.1)
Influenza	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Labyrinthitis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lower respiratory tract infection	0	1 (<0.1)	0	1 (<0.1)
Medical device site joint infection	0	1 (<0.1)	0	1 (<0.1)
Meningitis	0	1 (<0.1)	0	1 (<0.1)
Nasal vestibulitis	0	1 (<0.1)	0	1 (<0.1)

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MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301330101.sas 21JUN2021 03:17

Table 14.3.1.33.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Nipple infection	0	1 (<0.1)	0	1 (<0.1)
Oesophageal candidiasis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ophthalmic herpes simplex	0	1 (<0.1)	0	1 (<0.1)
Oral candidiasis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Osteomyelitis bacterial	0	1 (<0.1)	0	1 (<0.1)
Papilloma viral infection	0	1 (<0.1)	4 (<0.1)	5 (<0.1)
Paronychia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Parotitis	0	1 (<0.1)	0	1 (<0.1)
Periorbital cellulitis	0	1 (<0.1)	0	1 (<0.1)
Pilonidal cyst	0	1 (<0.1)	0	1 (<0.1)
Post procedural infection	0	1 (<0.1)	0	1 (<0.1)
Postoperative abscess	0	1 (<0.1)	0	1 (<0.1)
Postoperative wound infection	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Pseudomonas infection	0	1 (<0.1)	0	1 (<0.1)
Pulpitis dental	0	1 (<0.1)	0	1 (<0.1)
Pyelonephritis	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Respiratory tract infection	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Root canal infection	0	1 (<0.1)	0	1 (<0.1)
Staphylococcal sepsis	0	1 (<0.1)	0	1 (<0.1)
Syphilis	0	1 (<0.1)	0	1 (<0.1)
Tinea manuum	0	1 (<0.1)	0	1 (<0.1)
Tonsillitis	0	1 (<0.1)	0	1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Trichomoniasis	0	1 (<0.1)	0	1 (<0.1)
Urethritis chlamydial	0	1 (<0.1)	0	1 (<0.1)
Uterine infection	0	1 (<0.1)	0	1 (<0.1)
Vaginal infection	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Abscess	0	0	1 (<0.1)	1 (<0.1)
Abscess neck	0	0	1 (<0.1)	1 (<0.1)
Abscess oral	0	0	1 (<0.1)	1 (<0.1)
American trypanosomiasis	0	0	1 (<0.1)	1 (<0.1)
Bacterial diarrhoea	0	0	1 (<0.1)	1 (<0.1)
Body tinea	0	0	1 (<0.1)	1 (<0.1)
Bronchitis bacterial	0	0	1 (<0.1)	1 (<0.1)
Cervicitis	0	0	1 (<0.1)	1 (<0.1)
Clostridium difficile infection	0	0	1 (<0.1)	1 (<0.1)
Diarrhoea infectious	0	0	1 (<0.1)	1 (<0.1)
Enterovirus infection	0	0	1 (<0.1)	1 (<0.1)
Epididymitis	0	0	2 (<0.1)	2 (<0.1)
Escherichia urinary tract infection	0	0	1 (<0.1)	1 (<0.1)
Gonorrhoea	0	0	1 (<0.1)	1 (<0.1)
Laryngitis viral	0	0	1 (<0.1)	1 (<0.1)
Lice infestation	1 (<0.1)	0	0	1 (<0.1)
Lip infection	0	0	1 (<0.1)	1 (<0.1)
Nasopharyngitis	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.33.1.1

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System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Necrotising fasciitis	0	0	1 (<0.1)	1 (<0.1)
Ophthalmic herpes zoster	0	0	1 (<0.1)	1 (<0.1)
Orchitis	0	0	1 (<0.1)	1 (<0.1)
Oropharyngeal candidiasis	0	0	1 (<0.1)	1 (<0.1)
Otitis media acute	0	0	2 (<0.1)	2 (<0.1)
Pericarditis infective	1 (<0.1)	0	0	1 (<0.1)
Perirectal abscess	0	0	1 (<0.1)	1 (<0.1)
Pertussis	0	0	1 (<0.1)	1 (<0.1)
Pharyngeal abscess	0	0	1 (<0.1)	1 (<0.1)
Pneumonia bacterial	0	0	1 (<0.1)	1 (<0.1)
Proctitis chlamydial	0	0	2 (<0.1)	2 (<0.1)
Respiratory syncytial virus infection	0	0	1 (<0.1)	1 (<0.1)
Sialoadenitis	0	0	1 (<0.1)	1 (<0.1)
Sinusitis bacterial	0	0	2 (<0.1)	2 (<0.1)
Skin infection	0	0	3 (<0.1)	3 (<0.1)
Staphylococcal bacteraemia	0	0	1 (<0.1)	1 (<0.1)
Streptococcal infection	0	0	1 (<0.1)	1 (<0.1)
Tinea versicolour	0	0	2 (<0.1)	2 (<0.1)
Urethritis	0	0	1 (<0.1)	1 (<0.1)
Vestibular neuronitis	0	0	1 (<0.1)	1 (<0.1)
Vestibulitis	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.33.1.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.1)	40 (0.3)	62 (0.4)	105 (0.3)
Basal cell carcinoma	0	13 (0.1)	6 (<0.1)	19 (<0.1)
Squamous cell carcinoma of skin	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Lipoma	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Melanocytic naevus	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Benign neoplasm of skin	0	1 (<0.1)	0	1 (<0.1)
Bladder neoplasm	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blepharal papilloma	0	1 (<0.1)	0	1 (<0.1)
Breast cancer	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Castleman's disease	0	1 (<0.1)	0	1 (<0.1)
Colon adenoma	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ear neoplasm malignant	0	1 (<0.1)	0	1 (<0.1)
Fibroadenoma of breast	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fibrous histiocyoma	0	1 (<0.1)	0	1 (<0.1)
Intraductal proliferative breast lesion	0	1 (<0.1)	0	1 (<0.1)
Malignant melanoma	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Metastases to lung	0	1 (<0.1)	0	1 (<0.1)
Myelodysplastic syndrome	0	1 (<0.1)	0	1 (<0.1)
Oesophageal adenocarcinoma	0	1 (<0.1)	0	1 (<0.1)
Pancreatic carcinoma	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pancreatic carcinoma metastatic	0	1 (<0.1)	0	1 (<0.1)
Pancreatic carcinoma stage IV	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.33.1.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Prostate cancer	0	1 (<0.1)	7 (<0.1)	8 (<0.1)
Prostate cancer stage I	0	1 (<0.1)	0	1 (<0.1)
Renal cancer	0	1 (<0.1)	0	1 (<0.1)
Uterine leiomyoma	1 (<0.1)	1 (<0.1)	5 (<0.1)	7 (<0.1)
Acrochordon	0	0	1 (<0.1)	1 (<0.1)
B-cell lymphoma	0	0	1 (<0.1)	1 (<0.1)
Borderline mucinous tumour of ovary	0	0	1 (<0.1)	1 (<0.1)
Colorectal cancer metastatic	1 (<0.1)	0	0	1 (<0.1)
Cutaneous T-cell lymphoma	0	0	1 (<0.1)	1 (<0.1)
Endometrial cancer	0	0	1 (<0.1)	1 (<0.1)
Eye naevus	0	0	1 (<0.1)	1 (<0.1)
High-grade B-cell lymphoma	0	0	1 (<0.1)	1 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	0	1 (<0.1)	2 (<0.1)
Lung adenocarcinoma	0	0	1 (<0.1)	1 (<0.1)
Lung neoplasm malignant	0	0	1 (<0.1)	1 (<0.1)
Lymphoma	0	0	1 (<0.1)	1 (<0.1)
Neoplasm skin	0	0	1 (<0.1)	1 (<0.1)
Oesophageal carcinoma	0	0	1 (<0.1)	1 (<0.1)
Oral fibroma	0	0	1 (<0.1)	1 (<0.1)
Papillary thyroid cancer	0	0	1 (<0.1)	1 (<0.1)
Phaeochromocytoma	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.33.1.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Salivary gland cancer stage IV	0	0	1 (<0.1)	1 (<0.1)
Skin cancer	0	0	2 (<0.1)	2 (<0.1)
Skin papilloma	0	0	1 (<0.1)	1 (<0.1)
Squamous cell carcinoma	0	0	3 (<0.1)	3 (<0.1)
Throat cancer	0	0	2 (<0.1)	2 (<0.1)
Thyroid cancer	0	0	1 (<0.1)	1 (<0.1)
Uterine cancer	0	0	1 (<0.1)	1 (<0.1)
Vocal cord neoplasm	0	0	1 (<0.1)	1 (<0.1)
Blood and lymphatic system disorders	0	24 (0.2)	18 (0.1)	42 (0.1)
Lymphadenopathy	0	12 (<0.1)	6 (<0.1)	18 (<0.1)
Anaemia	0	5 (<0.1)	3 (<0.1)	8 (<0.1)
Iron deficiency anaemia	0	2 (<0.1)	5 (<0.1)	7 (<0.1)
Hyperchromic anaemia	0	1 (<0.1)	0	1 (<0.1)
Immune thrombocytopenia	0	1 (<0.1)	0	1 (<0.1)
Leukocytosis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lymph node calcification	0	1 (<0.1)	0	1 (<0.1)
Thrombocytopenia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Haemoconcentration	0	0	1 (<0.1)	1 (<0.1)
Splenomegaly	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.33.1.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Immune system disorders	0	16 (0.1)	17 (0.1)	33 (0.1)
Seasonal allergy	0	9 (<0.1)	10 (<0.1)	19 (<0.1)
Anaphylactic reaction	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Food allergy	0	2 (<0.1)	0	2 (<0.1)
Drug hypersensitivity	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hypersensitivity	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Sarcoidosis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Allergy to arthropod sting	0	0	1 (<0.1)	1 (<0.1)
Endocrine disorders	0	14 (0.1)	25 (0.2)	39 (0.1)
Hypothyroidism	0	9 (<0.1)	15 (<0.1)	24 (<0.1)
Autoimmune thyroiditis	0	2 (<0.1)	0	2 (<0.1)
Basedow's disease	0	2 (<0.1)	0	2 (<0.1)
Thyroid mass	0	2 (<0.1)	4 (<0.1)	6 (<0.1)
Adrenal mass	0	0	1 (<0.1)	1 (<0.1)
Goitre	0	0	2 (<0.1)	2 (<0.1)
Hyperandrogenism	0	0	1 (<0.1)	1 (<0.1)
Hyperprolactinaemia	0	0	1 (<0.1)	1 (<0.1)
Hyperthyroidism	0	0	1 (<0.1)	1 (<0.1)
Hypogonadism	0	0	1 (<0.1)	1 (<0.1)
Metabolism and nutrition disorders	0	94 (0.7)	92 (0.6)	186 (0.6)
Hypercholesterolaemia	0	18 (0.1)	14 (<0.1)	32 (0.1)

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System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)				
Type 2 diabetes mellitus	0	17 (0.1)	19 (0.1)	36 (0.1)
Vitamin D deficiency	0	15 (0.1)	13 (<0.1)	28 (<0.1)
Hyperlipidaemia	0	13 (0.1)	15 (<0.1)	28 (<0.1)
Diabetes mellitus	0	6 (<0.1)	4 (<0.1)	10 (<0.1)
Gout	0	4 (<0.1)	4 (<0.1)	8 (<0.1)
Iron deficiency	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Dehydration	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Diabetes mellitus inadequate control	0	3 (<0.1)	0	3 (<0.1)
Glucose tolerance impaired	0	3 (<0.1)	8 (<0.1)	11 (<0.1)
Hyperglycaemia	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Hypokalaemia	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Vitamin B12 deficiency	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Electrolyte imbalance	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fluid overload	0	1 (<0.1)	0	1 (<0.1)
Hyperkalaemia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypertriglyceridaemia	0	1 (<0.1)	0	1 (<0.1)
Hypoglycaemia	0	1 (<0.1)	0	1 (<0.1)
Hyponatraemia	0	1 (<0.1)	0	1 (<0.1)
Lactic acidosis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Magnesium deficiency	0	1 (<0.1)	0	1 (<0.1)
Obesity	0	1 (<0.1)	0	1 (<0.1)
Postprandial hypoglycaemia	0	1 (<0.1)	0	1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)				
Type 1 diabetes mellitus	0	1 (<0.1)	0	1 (<0.1)
Diabetic ketoacidosis	0	0	1 (<0.1)	1 (<0.1)
Dyslipidaemia	0	0	1 (<0.1)	1 (<0.1)
Haemochromatosis	0	0	1 (<0.1)	1 (<0.1)
Hypercalcaemia	0	0	2 (<0.1)	2 (<0.1)
Insulin resistance	0	0	1 (<0.1)	1 (<0.1)
Metabolic acidosis	0	0	1 (<0.1)	1 (<0.1)
Vitamin C deficiency	0	0	1 (<0.1)	1 (<0.1)
Psychiatric disorders	3 (0.1)	76 (0.6)	76 (0.5)	155 (0.5)
Depression	0	29 (0.2)	27 (0.2)	56 (0.2)
Anxiety	1 (<0.1)	26 (0.2)	22 (0.1)	49 (0.2)
Insomnia	0	12 (<0.1)	10 (<0.1)	22 (<0.1)
Attention deficit hyperactivity disorder	0	9 (<0.1)	10 (<0.1)	19 (<0.1)
Suicidal ideation	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Adjustment disorder	0	1 (<0.1)	0	1 (<0.1)
Affective disorder	0	1 (<0.1)	0	1 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)	0	1 (<0.1)
Bipolar disorder	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Panic attack	0	1 (<0.1)	0	1 (<0.1)
Paranoia	0	1 (<0.1)	0	1 (<0.1)
Post-traumatic stress disorder	0	1 (<0.1)	1 (<0.1)	2 (<0.1)

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System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Schizophrenia	0	1 (<0.1)	0	1 (<0.1)
Substance abuse	0	1 (<0.1)	0	1 (<0.1)
Adjustment disorder with depressed mood	0	0	1 (<0.1)	1 (<0.1)
Agitation	1 (<0.1)	0	0	1 (<0.1)
Autism spectrum disorder	0	0	1 (<0.1)	1 (<0.1)
Bipolar I disorder	0	0	1 (<0.1)	1 (<0.1)
Delirium	1 (<0.1)	0	0	1 (<0.1)
Dissociative identity disorder	0	0	1 (<0.1)	1 (<0.1)
Drug dependence	1 (<0.1)	0	0	1 (<0.1)
Dysphemia	0	0	1 (<0.1)	1 (<0.1)
Initial insomnia	0	0	1 (<0.1)	1 (<0.1)
Intentional self-injury	0	0	1 (<0.1)	1 (<0.1)
Libido decreased	0	0	1 (<0.1)	1 (<0.1)
Major depression	0	0	1 (<0.1)	1 (<0.1)
Mental status changes	0	0	1 (<0.1)	1 (<0.1)
Mood swings	0	0	1 (<0.1)	1 (<0.1)
Substance use disorder	0	0	1 (<0.1)	1 (<0.1)
Suicide attempt	0	0	2 (<0.1)	2 (<0.1)
Thinking abnormal	1 (<0.1)	0	0	1 (<0.1)
Nervous system disorders	1 (<0.1)	103 (0.8)	92 (0.6)	196 (0.6)
Headache	0	25 (0.2)	25 (0.2)	50 (0.2)

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MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301330101.sas 21JUN2021 03:17

Table 14.3.1.33.1.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Dizziness	1 (<0.1)	14 (0.1)	4 (<0.1)	19 (<0.1)
Paraesthesia	0	9 (<0.1)	5 (<0.1)	14 (<0.1)
Migraine	0	7 (<0.1)	6 (<0.1)	13 (<0.1)
Sciatica	0	7 (<0.1)	7 (<0.1)	14 (<0.1)
Ageusia	0	5 (<0.1)	0	5 (<0.1)
Syncope	0	5 (<0.1)	2 (<0.1)	7 (<0.1)
Cerebrovascular accident	0	4 (<0.1)	5 (<0.1)	9 (<0.1)
Restless legs syndrome	0	4 (<0.1)	2 (<0.1)	6 (<0.1)
Carpal tunnel syndrome	0	3 (<0.1)	4 (<0.1)	7 (<0.1)
Trigeminal neuralgia	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Anosmia	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cervical radiculopathy	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hypoaesthesia	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Nerve compression	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Neuropathy peripheral	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Amyotrophic lateral sclerosis	0	1 (<0.1)	0	1 (<0.1)
Aphasia	0	1 (<0.1)	0	1 (<0.1)
Brain stem infarction	0	1 (<0.1)	0	1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dysgeusia	0	1 (<0.1)	0	1 (<0.1)
Haemorrhage intracranial	0	1 (<0.1)	0	1 (<0.1)
Hypogeusia	0	1 (<0.1)	0	1 (<0.1)

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Nervous system disorders (Cont.)				
Ischaemic cerebral infarction	0	1 (<0.1)	0	1 (<0.1)
Lacunar infarction	0	1 (<0.1)	0	1 (<0.1)
Loss of consciousness	0	1 (<0.1)	0	1 (<0.1)
Lumbar radiculopathy	0	1 (<0.1)	0	1 (<0.1)
Lumbosacral radiculopathy	0	1 (<0.1)	0	1 (<0.1)
Migraine with aura	0	1 (<0.1)	0	1 (<0.1)
Narcolepsy	0	1 (<0.1)	0	1 (<0.1)
Neuralgia	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Piriformis syndrome	0	1 (<0.1)	0	1 (<0.1)
Presyncope	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Seizure	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tension headache	0	1 (<0.1)	0	1 (<0.1)
Transient ischaemic attack	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tremor	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Balance disorder	0	0	1 (<0.1)	1 (<0.1)
Burning sensation	0	0	1 (<0.1)	1 (<0.1)
Carotid arteriosclerosis	0	0	1 (<0.1)	1 (<0.1)
Carotid artery aneurysm	0	0	1 (<0.1)	1 (<0.1)
Cerebral ischaemia	0	0	1 (<0.1)	1 (<0.1)
Cluster headache	0	0	1 (<0.1)	1 (<0.1)
Exertional headache	0	0	1 (<0.1)	1 (<0.1)
Hemiparesis	0	0	1 (<0.1)	1 (<0.1)

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Nervous system disorders (Cont.)				
Migraine without aura	0	0	1 (<0.1)	1 (<0.1)
Nystagmus	0	0	2 (<0.1)	2 (<0.1)
Peripheral sensory neuropathy	0	0	1 (<0.1)	1 (<0.1)
Post herpetic neuralgia	0	0	2 (<0.1)	2 (<0.1)
Shift work disorder	0	0	1 (<0.1)	1 (<0.1)
Somnolence	0	0	1 (<0.1)	1 (<0.1)
Spinal cord compression	0	0	1 (<0.1)	1 (<0.1)
Transient global amnesia	0	0	1 (<0.1)	1 (<0.1)
Eye disorders	0	33 (0.3)	27 (0.2)	60 (0.2)
Cataract	0	7 (<0.1)	8 (<0.1)	15 (<0.1)
Glaucoma	0	4 (<0.1)	0	4 (<0.1)
Blepharitis	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Conjunctival haemorrhage	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Dacryostenosis acquired	0	2 (<0.1)	0	2 (<0.1)
Diplopia	0	2 (<0.1)	0	2 (<0.1)
Eye irritation	0	2 (<0.1)	0	2 (<0.1)
Chalazion	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Conjunctivitis allergic	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dry eye	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Eye pain	0	1 (<0.1)	0	1 (<0.1)
Eyelid rash	0	1 (<0.1)	0	1 (<0.1)

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Eye disorders (Cont.)				
Macular degeneration	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Normal tension glaucoma	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Retinal artery occlusion	0	1 (<0.1)	0	1 (<0.1)
Retinal detachment	0	1 (<0.1)	0	1 (<0.1)
Retinal tear	0	1 (<0.1)	0	1 (<0.1)
Uveitis	0	1 (<0.1)	0	1 (<0.1)
Vitreous floaters	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dermatochalasis	0	0	1 (<0.1)	1 (<0.1)
Diabetic retinopathy	0	0	1 (<0.1)	1 (<0.1)
Episcleritis	0	0	1 (<0.1)	1 (<0.1)
Lacrimation increased	0	0	1 (<0.1)	1 (<0.1)
Neovascular age-related macular degeneration	0	0	1 (<0.1)	1 (<0.1)
Ocular rosacea	0	0	1 (<0.1)	1 (<0.1)
Periorbital swelling	0	0	1 (<0.1)	1 (<0.1)
Vision blurred	0	0	1 (<0.1)	1 (<0.1)
Visual impairment	0	0	1 (<0.1)	1 (<0.1)
Ear and labyrinth disorders	1 (<0.1)	28 (0.2)	27 (0.2)	56 (0.2)
Vertigo	1 (<0.1)	10 (<0.1)	14 (<0.1)	25 (<0.1)
Tinnitus	0	5 (<0.1)	4 (<0.1)	9 (<0.1)
Deafness unilateral	0	2 (<0.1)	0	2 (<0.1)
Ear canal erythema	0	2 (<0.1)	2 (<0.1)	4 (<0.1)

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Ear and labyrinth disorders (Cont.)				
Ear discomfort	0	2 (<0.1)	0	2 (<0.1)
Ear pain	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Cerumen impaction	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Deafness neurosensory	0	1 (<0.1)	0	1 (<0.1)
Ear pruritus	0	1 (<0.1)	0	1 (<0.1)
Excessive cerumen production	0	1 (<0.1)	0	1 (<0.1)
External ear inflammation	0	1 (<0.1)	0	1 (<0.1)
Meniere's disease	0	1 (<0.1)	0	1 (<0.1)
Tympanic membrane disorder	0	1 (<0.1)	0	1 (<0.1)
Tympanic membrane hyperaemia	0	1 (<0.1)	0	1 (<0.1)
Ear congestion	0	0	1 (<0.1)	1 (<0.1)
Middle ear effusion	0	0	1 (<0.1)	1 (<0.1)
Vertigo positional	0	0	2 (<0.1)	2 (<0.1)
Cardiac disorders	1 (<0.1)	58 (0.5)	48 (0.3)	107 (0.4)
Atrial fibrillation	0	7 (<0.1)	6 (<0.1)	13 (<0.1)
Coronary artery disease	0	6 (<0.1)	8 (<0.1)	14 (<0.1)
Palpitations	0	6 (<0.1)	3 (<0.1)	9 (<0.1)
Tachycardia	0	5 (<0.1)	5 (<0.1)	10 (<0.1)
Cardiac failure	0	4 (<0.1)	0	4 (<0.1)
Myocardial infarction	0	4 (<0.1)	2 (<0.1)	6 (<0.1)
Acute myocardial infarction	0	3 (<0.1)	2 (<0.1)	5 (<0.1)

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Cardiac disorders (Cont.)				
Bradycardia	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Cardiac failure congestive	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Angina pectoris	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Angina unstable	0	2 (<0.1)	0	2 (<0.1)
Arrhythmia	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Sinus tachycardia	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Supraventricular tachycardia	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Ventricular extrasystoles	0	2 (<0.1)	0	2 (<0.1)
Ventricular tachycardia	0	2 (<0.1)	0	2 (<0.1)
Acute coronary syndrome	0	1 (<0.1)	0	1 (<0.1)
Aortic valve incompetence	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Atrial flutter	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Atrioventricular block complete	0	1 (<0.1)	0	1 (<0.1)
Bifascicular block	0	1 (<0.1)	0	1 (<0.1)
Cardiac failure acute	0	1 (<0.1)	0	1 (<0.1)
Cardiovascular disorder	0	1 (<0.1)	0	1 (<0.1)
Coronary artery occlusion	0	1 (<0.1)	0	1 (<0.1)
Sinus node dysfunction	0	1 (<0.1)	0	1 (<0.1)
Acute left ventricular failure	0	0	2 (<0.1)	2 (<0.1)
Bundle branch block left	0	0	1 (<0.1)	1 (<0.1)
Bundle branch block right	0	0	1 (<0.1)	1 (<0.1)

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Cardiac disorders (Cont.)				
Cardiac disorder	0	0	1 (<0.1)	1 (<0.1)
Cardiomyopathy	0	0	1 (<0.1)	1 (<0.1)
Coronary artery insufficiency	0	0	1 (<0.1)	1 (<0.1)
Extrasystoles	0	0	1 (<0.1)	1 (<0.1)
Ischaemic cardiomyopathy	0	0	1 (<0.1)	1 (<0.1)
Left atrial enlargement	0	0	1 (<0.1)	1 (<0.1)
Mitral valve incompetence	0	0	3 (<0.1)	3 (<0.1)
Postural orthostatic tachycardia syndrome	0	0	1 (<0.1)	1 (<0.1)
Pulseless electrical activity	0	0	1 (<0.1)	1 (<0.1)
Supraventricular extrasystoles	0	0	1 (<0.1)	1 (<0.1)
Ventricular arrhythmia	1 (<0.1)	0	0	1 (<0.1)
Vascular disorders	2 (<0.1)	118 (0.9)	90 (0.6)	210 (0.7)
Hypertension	2 (<0.1)	98 (0.8)	69 (0.5)	169 (0.6)
Deep vein thrombosis	0	4 (<0.1)	3 (<0.1)	7 (<0.1)
Lymphoedema	0	3 (<0.1)	0	3 (<0.1)
Hot flush	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Aortic stenosis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Essential hypertension	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypertensive crisis	0	1 (<0.1)	0	1 (<0.1)
Hypertensive urgency	0	1 (<0.1)	0	1 (<0.1)
Hypotension	0	1 (<0.1)	4 (<0.1)	5 (<0.1)

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Vascular disorders (Cont.)				
Labile blood pressure	0	1 (<0.1)	0	1 (<0.1)
Orthostatic hypotension	0	1 (<0.1)	0	1 (<0.1)
Peripheral arterial occlusive disease	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Peripheral vascular disorder	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Peripheral venous disease	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Prehypertension	0	1 (<0.1)	0	1 (<0.1)
Raynaud's phenomenon	0	1 (<0.1)	0	1 (<0.1)
Aortic aneurysm	0	0	1 (<0.1)	1 (<0.1)
Aortic arteriosclerosis	0	0	1 (<0.1)	1 (<0.1)
Aortic dissection	0	0	1 (<0.1)	1 (<0.1)
Haematoma	0	0	2 (<0.1)	2 (<0.1)
Intermittent claudication	0	0	1 (<0.1)	1 (<0.1)
Jugular vein thrombosis	0	0	1 (<0.1)	1 (<0.1)
Phlebitis	0	0	1 (<0.1)	1 (<0.1)
Subclavian vein thrombosis	0	0	1 (<0.1)	1 (<0.1)
Vascular insufficiency	0	0	1 (<0.1)	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	2 (<0.1)	91 (0.7)	104 (0.7)	197 (0.6)
Cough	1 (<0.1)	20 (0.2)	23 (0.2)	44 (0.1)
Rhinorrhoea	0	12 (<0.1)	12 (<0.1)	24 (<0.1)
Dyspnoea	0	11 (<0.1)	12 (<0.1)	23 (<0.1)
Nasal congestion	0	11 (<0.1)	19 (0.1)	30 (<0.1)

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Respiratory, thoracic and mediastinal disorders (Cont.)				
Asthma	0	8 (<0.1)	8 (<0.1)	16 (<0.1)
Oropharyngeal pain	0	8 (<0.1)	20 (0.1)	28 (<0.1)
Epistaxis	0	5 (<0.1)	3 (<0.1)	8 (<0.1)
Sinus congestion	0	5 (<0.1)	2 (<0.1)	7 (<0.1)
Acute respiratory failure	0	3 (<0.1)	0	3 (<0.1)
Chronic obstructive pulmonary disease	0	3 (<0.1)	4 (<0.1)	7 (<0.1)
Pleural effusion	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Sleep apnoea syndrome	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Pulmonary embolism	0	2 (<0.1)	5 (<0.1)	7 (<0.1)
Pulmonary mass	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Rhinitis allergic	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Sinus pain	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Wheezing	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Allergic cough	0	1 (<0.1)	0	1 (<0.1)
Asthma exercise induced	0	1 (<0.1)	0	1 (<0.1)
Atelectasis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dry throat	0	1 (<0.1)	0	1 (<0.1)
Dyspnoea exertional	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Emphysema	0	1 (<0.1)	0	1 (<0.1)
Hypoxia	0	1 (<0.1)	0	1 (<0.1)
Interstitial lung disease	0	1 (<0.1)	0	1 (<0.1)

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Respiratory, thoracic and mediastinal disorders (Cont.)				
Lower respiratory tract congestion	0	1 (<0.1)	0	1 (<0.1)
Nasal inflammation	0	1 (<0.1)	0	1 (<0.1)
Nasal polyps	0	1 (<0.1)	0	1 (<0.1)
Nasal septum deviation	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Paranasal sinus discomfort	0	1 (<0.1)	0	1 (<0.1)
Paranasal sinus hypersecretion	0	1 (<0.1)	0	1 (<0.1)
Pharyngeal erythema	0	1 (<0.1)	0	1 (<0.1)
Pneumothorax	0	1 (<0.1)	0	1 (<0.1)
Reflux laryngitis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory disorder	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Respiratory failure	0	1 (<0.1)	0	1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	1 (<0.1)	1 (<0.1)	3 (<0.1)
Allergic sinusitis	0	0	1 (<0.1)	1 (<0.1)
Lung disorder	0	0	1 (<0.1)	1 (<0.1)
Mediastinal cyst	0	0	1 (<0.1)	1 (<0.1)
Mediastinal mass	0	0	1 (<0.1)	1 (<0.1)
Pharyngeal ulceration	0	0	1 (<0.1)	1 (<0.1)
Pulmonary fibrosis	0	0	1 (<0.1)	1 (<0.1)
Pulmonary hypertension	0	0	1 (<0.1)	1 (<0.1)
Pulmonary oedema	0	0	1 (<0.1)	1 (<0.1)
Respiratory tract congestion	0	0	2 (<0.1)	2 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Rhinalgia	0	0	1 (<0.1)	1 (<0.1)
Sinus disorder	0	0	1 (<0.1)	1 (<0.1)
Throat irritation	0	0	1 (<0.1)	1 (<0.1)
Upper-airway cough syndrome	0	0	1 (<0.1)	1 (<0.1)
Vocal cord polyp	0	0	1 (<0.1)	1 (<0.1)
Gastrointestinal disorders	5 (0.2)	139 (1.1)	117 (0.8)	261 (0.9)
Nausea	1 (<0.1)	19 (0.2)	12 (<0.1)	32 (0.1)
Gastroesophageal reflux disease	2 (<0.1)	16 (0.1)	19 (0.1)	37 (0.1)
Dental caries	0	13 (0.1)	5 (<0.1)	18 (<0.1)
Abdominal pain	0	12 (<0.1)	4 (<0.1)	16 (<0.1)
Toothache	1 (<0.1)	10 (<0.1)	3 (<0.1)	14 (<0.1)
Vomiting	0	9 (<0.1)	2 (<0.1)	11 (<0.1)
Diarrhoea	1 (<0.1)	8 (<0.1)	16 (0.1)	25 (<0.1)
Haemorrhoids	0	6 (<0.1)	2 (<0.1)	8 (<0.1)
Constipation	0	5 (<0.1)	4 (<0.1)	9 (<0.1)
Abdominal discomfort	0	3 (<0.1)	0	3 (<0.1)
Abdominal pain upper	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Hiatus hernia	0	3 (<0.1)	4 (<0.1)	7 (<0.1)
Inguinal hernia	0	3 (<0.1)	0	3 (<0.1)
Colitis	0	2 (<0.1)	0	2 (<0.1)

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MedDRA version 23.0.

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Table 14.3.1.33.1.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Dyspepsia	0	2 (<0.1)	4 (<0.1)	6 (<0.1)
Gastritis	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Gastrointestinal haemorrhage	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Large intestine polyp	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Umbilical hernia	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Abdominal hernia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Abdominal pain lower	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Abdominal tenderness	0	1 (<0.1)	0	1 (<0.1)
Anal fissure	0	1 (<0.1)	0	1 (<0.1)
Colitis microscopic	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Duodenal ulcer perforation	0	1 (<0.1)	0	1 (<0.1)
Enlarged uvula	0	1 (<0.1)	0	1 (<0.1)
Enteritis	0	1 (<0.1)	0	1 (<0.1)
Flatulence	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Food poisoning	0	1 (<0.1)	0	1 (<0.1)
Gastric ulcer	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastritis erosive	0	1 (<0.1)	0	1 (<0.1)
Gastrointestinal inflammation	0	1 (<0.1)	0	1 (<0.1)
Gastrointestinal pain	0	1 (<0.1)	0	1 (<0.1)
Haemorrhoidal haemorrhage	0	1 (<0.1)	0	1 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)	0	1 (<0.1)
Ileus paralytic	0	1 (<0.1)	0	1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Impaired gastric emptying	0	1 (<0.1)	0	1 (<0.1)
Internal hernia	0	1 (<0.1)	0	1 (<0.1)
Intestinal obstruction	0	1 (<0.1)	0	1 (<0.1)
Lip oedema	0	1 (<0.1)	0	1 (<0.1)
Mouth ulceration	0	1 (<0.1)	0	1 (<0.1)
Oesophageal rupture	0	1 (<0.1)	0	1 (<0.1)
Oral disorder	0	1 (<0.1)	0	1 (<0.1)
Pancreatitis	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Pancreatitis acute	0	1 (<0.1)	0	1 (<0.1)
Parotid gland enlargement	0	1 (<0.1)	0	1 (<0.1)
Peptic ulcer	0	1 (<0.1)	0	1 (<0.1)
Periodontal disease	0	1 (<0.1)	0	1 (<0.1)
Proctalgia	0	1 (<0.1)	0	1 (<0.1)
Pulpless tooth	0	1 (<0.1)	0	1 (<0.1)
Salivary gland calculus	0	1 (<0.1)	0	1 (<0.1)
Small intestinal obstruction	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth disorder	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tooth impacted	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Abdominal distension	0	0	1 (<0.1)	1 (<0.1)
Anal fistula	0	0	1 (<0.1)	1 (<0.1)
Barrett's oesophagus	0	0	1 (<0.1)	1 (<0.1)
Crohn's disease	0	0	2 (<0.1)	2 (<0.1)

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Gastrointestinal disorders (Cont.)				
Diverticulum	1 (<0.1)	0	1 (<0.1)	2 (<0.1)
Duodenal ulcer	0	0	1 (<0.1)	1 (<0.1)
Enterovesical fistula	0	0	1 (<0.1)	1 (<0.1)
Erosive oesophagitis	0	0	1 (<0.1)	1 (<0.1)
Faeces soft	0	0	1 (<0.1)	1 (<0.1)
Gastric polyps	0	0	1 (<0.1)	1 (<0.1)
Gastrointestinal disorder	0	0	1 (<0.1)	1 (<0.1)
Glossitis	0	0	1 (<0.1)	1 (<0.1)
Haematochezia	0	0	3 (<0.1)	3 (<0.1)
Ileus	0	0	2 (<0.1)	2 (<0.1)
Irritable bowel syndrome	0	0	2 (<0.1)	2 (<0.1)
Oral pain	0	0	1 (<0.1)	1 (<0.1)
Pancreatic failure	0	0	1 (<0.1)	1 (<0.1)
Portal hypertensive gastropathy	0	0	1 (<0.1)	1 (<0.1)
Proctitis	0	0	1 (<0.1)	1 (<0.1)
Rectal polyp	0	0	1 (<0.1)	1 (<0.1)
Rectal prolapse	0	0	1 (<0.1)	1 (<0.1)
Varices oesophageal	0	0	1 (<0.1)	1 (<0.1)
Hepatobiliary disorders	0	8 (<0.1)	15 (<0.1)	23 (<0.1)
Cholecystitis	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Cholelithiasis	0	2 (<0.1)	2 (<0.1)	4 (<0.1)

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Hepatobiliary disorders (Cont.)				
Bile duct obstruction	0	1 (<0.1)	0	1 (<0.1)
Cholangitis	0	1 (<0.1)	0	1 (<0.1)
Hepatic steatosis	0	1 (<0.1)	0	1 (<0.1)
Hepatomegaly	0	1 (<0.1)	0	1 (<0.1)
Biliary colic	0	0	1 (<0.1)	1 (<0.1)
Cholecystitis acute	0	0	2 (<0.1)	2 (<0.1)
Cholelithiasis obstructive	0	0	1 (<0.1)	1 (<0.1)
Hepatic cirrhosis	0	0	1 (<0.1)	1 (<0.1)
Hepatic lesion	0	0	2 (<0.1)	2 (<0.1)
Hyperbilirubinaemia	0	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	5 (0.2)	67 (0.5)	54 (0.4)	126 (0.4)
Rash	1 (<0.1)	7 (<0.1)	2 (<0.1)	10 (<0.1)
Urticaria	0	7 (<0.1)	5 (<0.1)	12 (<0.1)
Dermatitis contact	0	5 (<0.1)	5 (<0.1)	10 (<0.1)
Pruritus	0	5 (<0.1)	0	5 (<0.1)
Skin lesion	0	5 (<0.1)	2 (<0.1)	7 (<0.1)
Actinic keratosis	0	4 (<0.1)	4 (<0.1)	8 (<0.1)
Rosacea	0	4 (<0.1)	3 (<0.1)	7 (<0.1)
Acne	0	3 (<0.1)	4 (<0.1)	7 (<0.1)
Dermal cyst	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Decubitus ulcer	0	2 (<0.1)	0	2 (<0.1)

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Skin and subcutaneous tissue disorders (Cont.)				
Drug eruption	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Eczema	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Rash maculo-papular	0	2 (<0.1)	0	2 (<0.1)
Seborrhoeic dermatitis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Acne cystic	0	1 (<0.1)	0	1 (<0.1)
Alopecia	0	1 (<0.1)	0	1 (<0.1)
Asteatosis	0	1 (<0.1)	0	1 (<0.1)
Dermatitis allergic	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dry skin	0	1 (<0.1)	0	1 (<0.1)
Erythema nodosum	0	1 (<0.1)	0	1 (<0.1)
Lichen planus	0	1 (<0.1)	0	1 (<0.1)
Lichen sclerosus	0	1 (<0.1)	0	1 (<0.1)
Nail discolouration	0	1 (<0.1)	0	1 (<0.1)
Pain of skin	0	1 (<0.1)	0	1 (<0.1)
Pityriasis	0	1 (<0.1)	0	1 (<0.1)
Rash pruritic	0	1 (<0.1)	0	1 (<0.1)
Skin mass	0	1 (<0.1)	0	1 (<0.1)
Skin necrosis	0	1 (<0.1)	0	1 (<0.1)
Skin ulcer	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Subcutaneous emphysema	0	1 (<0.1)	0	1 (<0.1)
Urticaria papular	0	1 (<0.1)	0	1 (<0.1)
Vitiligo	0	1 (<0.1)	0	1 (<0.1)

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Skin and subcutaneous tissue disorders (Cont.)				
Dermatitis	0	0	4 (<0.1)	4 (<0.1)
Erythema	0	0	3 (<0.1)	3 (<0.1)
Fixed eruption	0	0	1 (<0.1)	1 (<0.1)
Hidradenitis	0	0	1 (<0.1)	1 (<0.1)
Ingrowing nail	0	0	3 (<0.1)	3 (<0.1)
Ingrown hair	0	0	1 (<0.1)	1 (<0.1)
Perioral dermatitis	1 (<0.1)	0	3 (<0.1)	4 (<0.1)
Precancerous skin lesion	1 (<0.1)	0	0	1 (<0.1)
Psoriasis	1 (<0.1)	0	2 (<0.1)	3 (<0.1)
Rash erythematous	0	0	2 (<0.1)	2 (<0.1)
Rash vesicular	0	0	1 (<0.1)	1 (<0.1)
Sensitive skin	1 (<0.1)	0	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	1 (<0.1)	164 (1.3)	174 (1.1)	339 (1.1)
Arthralgia	0	24 (0.2)	20 (0.1)	44 (0.1)
Osteoarthritis	0	19 (0.2)	16 (0.1)	35 (0.1)
Back pain	0	18 (0.1)	26 (0.2)	44 (0.1)
Musculoskeletal pain	0	13 (0.1)	7 (<0.1)	20 (<0.1)
Myalgia	0	11 (<0.1)	10 (<0.1)	21 (<0.1)
Pain in extremity	0	10 (<0.1)	16 (0.1)	26 (<0.1)
Muscle spasms	0	8 (<0.1)	5 (<0.1)	13 (<0.1)
Neck pain	0	8 (<0.1)	2 (<0.1)	10 (<0.1)

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Musculoskeletal and connective tissue disorders (Cont.)				
Bursitis	0	7 (<0.1)	6 (<0.1)	13 (<0.1)
Arthritis	0	5 (<0.1)	4 (<0.1)	9 (<0.1)
Osteoporosis	0	5 (<0.1)	7 (<0.1)	12 (<0.1)
Tendonitis	0	5 (<0.1)	7 (<0.1)	12 (<0.1)
Intervertebral disc degeneration	0	4 (<0.1)	0	4 (<0.1)
Trigger finger	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Musculoskeletal chest pain	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Costochondritis	0	2 (<0.1)	0	2 (<0.1)
Groin pain	0	2 (<0.1)	0	2 (<0.1)
Intervertebral disc protrusion	0	2 (<0.1)	6 (<0.1)	8 (<0.1)
Joint swelling	0	2 (<0.1)	0	2 (<0.1)
Lumbar spinal stenosis	0	2 (<0.1)	0	2 (<0.1)
Muscular weakness	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Plantar fasciitis	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Rheumatoid arthritis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Rotator cuff syndrome	0	2 (<0.1)	6 (<0.1)	8 (<0.1)
Ankle impingement	0	1 (<0.1)	0	1 (<0.1)
Ankylosing spondylitis	0	1 (<0.1)	0	1 (<0.1)
Axillary mass	0	1 (<0.1)	0	1 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)	0	1 (<0.1)
Dupuytren's contracture	0	1 (<0.1)	0	1 (<0.1)

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Musculoskeletal and connective tissue disorders (Cont.)				
Exostosis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Flank pain	0	1 (<0.1)	5 (<0.1)	6 (<0.1)
Intervertebral disc displacement	0	1 (<0.1)	0	1 (<0.1)
Joint hyperextension	0	1 (<0.1)	0	1 (<0.1)
Joint noise	0	1 (<0.1)	0	1 (<0.1)
Joint range of motion decreased	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Musculoskeletal discomfort	0	1 (<0.1)	0	1 (<0.1)
Musculoskeletal stiffness	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Myositis	0	1 (<0.1)	0	1 (<0.1)
Neck mass	0	1 (<0.1)	0	1 (<0.1)
Pain in jaw	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Patellofemoral pain syndrome	0	1 (<0.1)	0	1 (<0.1)
Polyarthrititis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Psoriatic arthropathy	0	1 (<0.1)	0	1 (<0.1)
Scleroderma	0	1 (<0.1)	0	1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vertebral lateral recess stenosis	0	1 (<0.1)	0	1 (<0.1)
Cervical spinal stenosis	0	0	1 (<0.1)	1 (<0.1)
Haemarthrosis	0	0	1 (<0.1)	1 (<0.1)
Intervertebral disc disorder	0	0	1 (<0.1)	1 (<0.1)
Myofascial pain syndrome	0	0	1 (<0.1)	1 (<0.1)

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Musculoskeletal and connective tissue disorders (Cont.)				
Osteopenia	0	0	3 (<0.1)	3 (<0.1)
Periarthritis	0	0	1 (<0.1)	1 (<0.1)
Sacroiliitis	0	0	1 (<0.1)	1 (<0.1)
Scoliosis	0	0	1 (<0.1)	1 (<0.1)
Spinal osteoarthritis	0	0	4 (<0.1)	4 (<0.1)
Spinal pain	1 (<0.1)	0	0	1 (<0.1)
Spondylitis	0	0	3 (<0.1)	3 (<0.1)
Spondylolisthesis	0	0	1 (<0.1)	1 (<0.1)
Tenosynovitis stenans	0	0	1 (<0.1)	1 (<0.1)
Torticollis	0	0	1 (<0.1)	1 (<0.1)
Renal and urinary disorders	1 (<0.1)	35 (0.3)	32 (0.2)	68 (0.2)
Nephrolithiasis	0	17 (0.1)	7 (<0.1)	24 (<0.1)
Dysuria	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Haematuria	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Acute kidney injury	0	2 (<0.1)	4 (<0.1)	6 (<0.1)
Hypertonic bladder	1 (<0.1)	2 (<0.1)	3 (<0.1)	6 (<0.1)
Ureterolithiasis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Urinary retention	0	2 (<0.1)	0	2 (<0.1)
Chronic kidney disease	0	1 (<0.1)	0	1 (<0.1)
Micturition urgency	0	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Renal and urinary disorders (Cont.)				
Pollakiuria	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Renal colic	0	1 (<0.1)	0	1 (<0.1)
Renal failure	0	1 (<0.1)	0	1 (<0.1)
Renal injury	0	1 (<0.1)	0	1 (<0.1)
Stress urinary incontinence	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bladder prolapse	0	0	1 (<0.1)	1 (<0.1)
Bladder spasm	0	0	1 (<0.1)	1 (<0.1)
Incontinence	0	0	1 (<0.1)	1 (<0.1)
Ketonuria	0	0	1 (<0.1)	1 (<0.1)
Nephritis	0	0	1 (<0.1)	1 (<0.1)
Proteinuria	0	0	1 (<0.1)	1 (<0.1)
Renal cyst	0	0	1 (<0.1)	1 (<0.1)
Renal pain	0	0	1 (<0.1)	1 (<0.1)
Urinary incontinence	0	0	2 (<0.1)	2 (<0.1)
Urine abnormality	0	0	1 (<0.1)	1 (<0.1)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	3 (<0.1)	3 (<0.1)	7 (<0.1)
Abortion spontaneous	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Pregnancy	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gestational diabetes	1 (<0.1)	0	1 (<0.1)	2 (<0.1)

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MedDRA version 23.0.

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Table 14.3.1.33.1.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders	0	33 (0.3)	37 (0.2)	70 (0.2)
Ovarian cyst	0	4 (<0.1)	3 (<0.1)	7 (<0.1)
Prostatomegaly	0	4 (<0.1)	0	4 (<0.1)
Breast mass	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Cervical dysplasia	0	3 (<0.1)	0	3 (<0.1)
Benign prostatic hyperplasia	0	2 (<0.1)	6 (<0.1)	8 (<0.1)
Breast pain	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Endometriosis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Erectile dysfunction	0	2 (<0.1)	0	2 (<0.1)
Menstruation irregular	0	2 (<0.1)	0	2 (<0.1)
Uterine polyp	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Haematospermia	0	1 (<0.1)	0	1 (<0.1)
Pelvic pain	0	1 (<0.1)	0	1 (<0.1)
Perineal disorder	0	1 (<0.1)	0	1 (<0.1)
Postmenopausal haemorrhage	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Prostatitis	0	1 (<0.1)	5 (<0.1)	6 (<0.1)
Scrotal disorder	0	1 (<0.1)	0	1 (<0.1)
Uterine cyst	0	1 (<0.1)	0	1 (<0.1)
Vaginal discharge	0	1 (<0.1)	0	1 (<0.1)
Vaginal haemorrhage	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Adnexa uteri pain	0	0	1 (<0.1)	1 (<0.1)
Dysmenorrhoea	0	0	1 (<0.1)	1 (<0.1)
Endometrial hyperplasia	0	0	1 (<0.1)	1 (<0.1)

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Reproductive system and breast disorders (Cont.)				
Endometrial thickening	0	0	1 (<0.1)	1 (<0.1)
Gynaecomastia	0	0	1 (<0.1)	1 (<0.1)
Pelvic cyst	0	0	1 (<0.1)	1 (<0.1)
Pelvic prolapse	0	0	1 (<0.1)	1 (<0.1)
Polycystic ovaries	0	0	1 (<0.1)	1 (<0.1)
Sexual dysfunction	0	0	1 (<0.1)	1 (<0.1)
Uterine haemorrhage	0	0	1 (<0.1)	1 (<0.1)
Uterine prolapse	0	0	3 (<0.1)	3 (<0.1)
Congenital, familial and genetic disorders	0	4 (<0.1)	5 (<0.1)	9 (<0.1)
Arnold-Chiari malformation	0	1 (<0.1)	0	1 (<0.1)
Congenital knee deformity	0	1 (<0.1)	0	1 (<0.1)
Thalassaemia beta	0	1 (<0.1)	0	1 (<0.1)
Type IIa hyperlipidaemia	0	1 (<0.1)	0	1 (<0.1)
Corneal dystrophy	0	0	1 (<0.1)	1 (<0.1)
Enteric duplication	0	0	1 (<0.1)	1 (<0.1)
Hydrocele	0	0	1 (<0.1)	1 (<0.1)
Type V hyperlipidaemia	0	0	2 (<0.1)	2 (<0.1)
General disorders and administration site conditions	3 (0.1)	80 (0.6)	61 (0.4)	144 (0.5)
Fatigue	1 (<0.1)	15 (0.1)	23 (0.2)	39 (0.1)

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Table 14.3.1.33.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Chest pain	1 (<0.1)	11 (<0.1)	6 (<0.1)	18 (<0.1)
Injection site pain	0	9 (<0.1)	2 (<0.1)	11 (<0.1)
Pyrexia	0	7 (<0.1)	5 (<0.1)	12 (<0.1)
Chills	0	6 (<0.1)	9 (<0.1)	15 (<0.1)
Pain	1 (<0.1)	6 (<0.1)	12 (<0.1)	19 (<0.1)
Influenza like illness	0	5 (<0.1)	1 (<0.1)	6 (<0.1)
Oedema peripheral	0	4 (<0.1)	5 (<0.1)	9 (<0.1)
Peripheral swelling	1 (<0.1)	4 (<0.1)	3 (<0.1)	8 (<0.1)
Injection site lymphadenopathy	0	3 (<0.1)	0	3 (<0.1)
Injection site swelling	0	3 (<0.1)	0	3 (<0.1)
Non-cardiac chest pain	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Injection site erythema	0	2 (<0.1)	0	2 (<0.1)
Injection site pruritus	0	2 (<0.1)	0	2 (<0.1)
Injection site rash	0	2 (<0.1)	0	2 (<0.1)
Asthenia	0	1 (<0.1)	0	1 (<0.1)
Axillary pain	0	1 (<0.1)	0	1 (<0.1)
Chest discomfort	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Cyst	0	1 (<0.1)	0	1 (<0.1)
Drug intolerance	0	1 (<0.1)	0	1 (<0.1)
Early satiety	0	1 (<0.1)	0	1 (<0.1)
Exercise tolerance decreased	0	1 (<0.1)	0	1 (<0.1)

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General disorders and administration site conditions (Cont.)				
Facial pain	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gait disturbance	0	1 (<0.1)	0	1 (<0.1)
Generalised oedema	0	1 (<0.1)	0	1 (<0.1)
Inflammation	0	1 (<0.1)	0	1 (<0.1)
Injection site discolouration	0	1 (<0.1)	0	1 (<0.1)
Injection site inflammation	0	1 (<0.1)	0	1 (<0.1)
Nodule	0	1 (<0.1)	0	1 (<0.1)
Precancerous condition	0	1 (<0.1)	0	1 (<0.1)
Swelling	0	1 (<0.1)	0	1 (<0.1)
Swelling face	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	1 (<0.1)	0	2 (<0.1)
Complication associated with device	0	0	1 (<0.1)	1 (<0.1)
Incarcerated hernia	0	0	1 (<0.1)	1 (<0.1)
Medical device site haemorrhage	0	0	1 (<0.1)	1 (<0.1)
Medical device site pain	0	0	1 (<0.1)	1 (<0.1)
Papillitis	0	0	1 (<0.1)	1 (<0.1)
Pelvic mass	0	0	1 (<0.1)	1 (<0.1)
Sudden death	0	0	1 (<0.1)	1 (<0.1)
Investigations	3 (0.1)	45 (0.4)	45 (0.3)	93 (0.3)
Blood cholesterol increased	0	5 (<0.1)	6 (<0.1)	11 (<0.1)

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Investigations (Cont.)				
Blood pressure increased	2 (<0.1)	4 (<0.1)	2 (<0.1)	8 (<0.1)
Blood testosterone decreased	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Hepatic enzyme increased	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Blood glucose increased	0	2 (<0.1)	0	2 (<0.1)
Cardiac murmur	0	2 (<0.1)	0	2 (<0.1)
Glycosylated haemoglobin increased	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Heart rate irregular	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Liver function test increased	0	2 (<0.1)	0	2 (<0.1)
Anticoagulation drug level above therapeutic	0	1 (<0.1)	0	1 (<0.1)
Blood bilirubin increased	0	1 (<0.1)	0	1 (<0.1)
Blood potassium decreased	0	1 (<0.1)	0	1 (<0.1)
Blood pressure diastolic increased	0	1 (<0.1)	0	1 (<0.1)
Blood triglycerides increased	0	1 (<0.1)	0	1 (<0.1)
Blood uric acid increased	0	1 (<0.1)	0	1 (<0.1)
Blood urine present	0	1 (<0.1)	0	1 (<0.1)
Cells in urine	0	1 (<0.1)	0	1 (<0.1)
Culture urine positive	0	1 (<0.1)	0	1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Full blood count abnormal	0	1 (<0.1)	0	1 (<0.1)
Haemoglobin decreased	1 (<0.1)	1 (<0.1)	0	2 (<0.1)
Intraocular pressure increased	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Metabolic function test abnormal	0	1 (<0.1)	0	1 (<0.1)

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Investigations (Cont.)				
Platelet count decreased	0	1 (<0.1)	0	1 (<0.1)
Progesterone decreased	0	1 (<0.1)	0	1 (<0.1)
Prostatic specific antigen increased	0	1 (<0.1)	4 (<0.1)	5 (<0.1)
Transaminases increased	0	1 (<0.1)	0	1 (<0.1)
Vitamin D decreased	0	1 (<0.1)	4 (<0.1)	5 (<0.1)
White blood cell count decreased	0	1 (<0.1)	0	1 (<0.1)
Alanine aminotransferase increased	0	0	2 (<0.1)	2 (<0.1)
Angiotensin converting enzyme increased	0	0	1 (<0.1)	1 (<0.1)
Antinuclear antibody increased	0	0	1 (<0.1)	1 (<0.1)
Antipsychotic drug level increased	0	0	1 (<0.1)	1 (<0.1)
Aspartate aminotransferase increased	0	0	2 (<0.1)	2 (<0.1)
Blood alkaline phosphatase increased	0	0	1 (<0.1)	1 (<0.1)
Blood calcium increased	0	0	1 (<0.1)	1 (<0.1)
Blood creatinine decreased	0	0	1 (<0.1)	1 (<0.1)
Blood lactic acid increased	0	0	1 (<0.1)	1 (<0.1)
Brain scan abnormal	0	0	1 (<0.1)	1 (<0.1)
Cardiac stress test abnormal	0	0	1 (<0.1)	1 (<0.1)
Cortisol decreased	0	0	1 (<0.1)	1 (<0.1)
Electrocardiogram QT prolonged	0	0	1 (<0.1)	1 (<0.1)
Heart rate increased	0	0	1 (<0.1)	1 (<0.1)
Liver function test abnormal	0	0	1 (<0.1)	1 (<0.1)
Mammogram abnormal	0	0	1 (<0.1)	1 (<0.1)

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Investigations (Cont.)				
Nitrite urine present	0	0	1 (<0.1)	1 (<0.1)
Red blood cell count decreased	0	0	1 (<0.1)	1 (<0.1)
Serum ferritin decreased	0	0	1 (<0.1)	1 (<0.1)
Smear cervix abnormal	0	0	1 (<0.1)	1 (<0.1)
Smooth muscle antibody positive	0	0	1 (<0.1)	1 (<0.1)
Urine calcium increased	0	0	1 (<0.1)	1 (<0.1)
Weight increased	0	0	3 (<0.1)	3 (<0.1)
White blood cell count increased	0	0	1 (<0.1)	1 (<0.1)
White blood cells urine positive	0	0	1 (<0.1)	1 (<0.1)
Injury, poisoning and procedural complications	3 (0.1)	179 (1.4)	163 (1.1)	345 (1.1)
Procedural pain	0	21 (0.2)	16 (0.1)	37 (0.1)
Tooth fracture	0	14 (0.1)	6 (<0.1)	20 (<0.1)
Skin laceration	0	13 (0.1)	15 (<0.1)	28 (<0.1)
Ligament sprain	0	12 (<0.1)	9 (<0.1)	21 (<0.1)
Muscle strain	0	11 (<0.1)	13 (<0.1)	24 (<0.1)
Limb injury	0	9 (<0.1)	3 (<0.1)	12 (<0.1)
Animal bite	0	8 (<0.1)	0	8 (<0.1)
Meniscus injury	0	8 (<0.1)	7 (<0.1)	15 (<0.1)
Fall	0	7 (<0.1)	9 (<0.1)	16 (<0.1)
Foot fracture	0	6 (<0.1)	6 (<0.1)	12 (<0.1)
Contusion	0	5 (<0.1)	5 (<0.1)	10 (<0.1)

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Injury, poisoning and procedural complications (Cont.)				
Hand fracture	0	5 (<0.1)	2 (<0.1)	7 (<0.1)
Stress fracture	0	5 (<0.1)	3 (<0.1)	8 (<0.1)
Fibula fracture	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Radius fracture	0	4 (<0.1)	0	4 (<0.1)
Tendon rupture	0	4 (<0.1)	1 (<0.1)	5 (<0.1)
Ankle fracture	1 (<0.1)	3 (<0.1)	2 (<0.1)	6 (<0.1)
Concussion	0	3 (<0.1)	6 (<0.1)	9 (<0.1)
Dental restoration failure	0	3 (<0.1)	0	3 (<0.1)
Epicondylitis	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Joint injury	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Lip injury	0	3 (<0.1)	0	3 (<0.1)
Upper limb fracture	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Anaemia postoperative	0	2 (<0.1)	0	2 (<0.1)
Cartilage injury	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Corneal abrasion	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Eye injury	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Femur fracture	0	2 (<0.1)	0	2 (<0.1)
Ligament rupture	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Post-traumatic pain	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Rib fracture	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Wrist fracture	0	2 (<0.1)	4 (<0.1)	6 (<0.1)

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Injury, poisoning and procedural complications (Cont.)				
Arthropod bite	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Avulsion fracture	0	1 (<0.1)	0	1 (<0.1)
Back injury	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Bite	0	1 (<0.1)	0	1 (<0.1)
Bone contusion	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Brain contusion	0	1 (<0.1)	0	1 (<0.1)
Burn oral cavity	0	1 (<0.1)	0	1 (<0.1)
Clavicle fracture	1 (<0.1)	1 (<0.1)	0	2 (<0.1)
Eyelid injury	0	1 (<0.1)	0	1 (<0.1)
Gun shot wound	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Head injury	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Iliotibial band syndrome	0	1 (<0.1)	0	1 (<0.1)
Incision site discharge	0	1 (<0.1)	0	1 (<0.1)
Incisional hernia	0	1 (<0.1)	0	1 (<0.1)
Joint dislocation	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Lisfranc fracture	0	1 (<0.1)	0	1 (<0.1)
Lumbar vertebral fracture	0	1 (<0.1)	0	1 (<0.1)
Mouth injury	0	1 (<0.1)	0	1 (<0.1)
Pneumothorax traumatic	0	1 (<0.1)	0	1 (<0.1)
Post procedural constipation	0	1 (<0.1)	0	1 (<0.1)
Post procedural fever	0	1 (<0.1)	0	1 (<0.1)

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Injury, poisoning and procedural complications (Cont.)				
Post procedural hypotension	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Post procedural pruritus	0	1 (<0.1)	0	1 (<0.1)
Procedural complication	0	1 (<0.1)	0	1 (<0.1)
Procedural nausea	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Radiation associated pain	0	1 (<0.1)	0	1 (<0.1)
Radiation skin injury	0	1 (<0.1)	0	1 (<0.1)
Road traffic accident	0	1 (<0.1)	4 (<0.1)	5 (<0.1)
Skin abrasion	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin injury	0	1 (<0.1)	0	1 (<0.1)
Spinal compression fracture	0	1 (<0.1)	0	1 (<0.1)
Subcutaneous haematoma	0	1 (<0.1)	0	1 (<0.1)
Tibia fracture	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ulna fracture	0	1 (<0.1)	0	1 (<0.1)
Wound	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Acetabulum fracture	0	0	1 (<0.1)	1 (<0.1)
Animal scratch	0	0	1 (<0.1)	1 (<0.1)
Cervical vertebral fracture	0	0	1 (<0.1)	1 (<0.1)
Chemical burn	0	0	1 (<0.1)	1 (<0.1)
Chillblains	0	0	1 (<0.1)	1 (<0.1)
Exposure to toxic agent	0	0	2 (<0.1)	2 (<0.1)
Eye contusion	0	0	1 (<0.1)	1 (<0.1)

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MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301330101.sas 21JUN2021 03:17

Table 14.3.1.33.1.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Facial bones fracture	0	0	2 (<0.1)	2 (<0.1)
Foreign body in eye	0	0	1 (<0.1)	1 (<0.1)
Foreign body ingestion	0	0	1 (<0.1)	1 (<0.1)
Fracture displacement	0	0	1 (<0.1)	1 (<0.1)
Fractured sacrum	0	0	1 (<0.1)	1 (<0.1)
Hip fracture	0	0	2 (<0.1)	2 (<0.1)
Humerus fracture	0	0	1 (<0.1)	1 (<0.1)
Injury	0	0	1 (<0.1)	1 (<0.1)
Limb crushing injury	0	0	1 (<0.1)	1 (<0.1)
Lower limb fracture	0	0	3 (<0.1)	3 (<0.1)
Muscle injury	0	0	2 (<0.1)	2 (<0.1)
Muscle rupture	0	0	1 (<0.1)	1 (<0.1)
Patella fracture	0	0	1 (<0.1)	1 (<0.1)
Pelvic fracture	0	0	1 (<0.1)	1 (<0.1)
Poisoning	0	0	1 (<0.1)	1 (<0.1)
Post procedural haematoma	0	0	1 (<0.1)	1 (<0.1)
Post procedural haemorrhage	0	0	1 (<0.1)	1 (<0.1)
Seroma	0	0	1 (<0.1)	1 (<0.1)
Soft tissue injury	0	0	1 (<0.1)	1 (<0.1)
Spinal cord injury	0	0	1 (<0.1)	1 (<0.1)
Splinter	0	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301330101.sas 21JUN2021 03:17

Table 14.3.1.33.1.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Stab wound	1 (<0.1)	0	0	1 (<0.1)
Tendon injury	0	0	1 (<0.1)	1 (<0.1)
Thermal burn	0	0	1 (<0.1)	1 (<0.1)
Thoracic vertebral fracture	0	0	1 (<0.1)	1 (<0.1)
Ulnar nerve injury	0	0	1 (<0.1)	1 (<0.1)
Vaccination complication	0	0	1 (<0.1)	1 (<0.1)
Wound dehiscence	0	0	1 (<0.1)	1 (<0.1)
Surgical and medical procedures	0	5 (<0.1)	0	5 (<0.1)
Colostomy	0	1 (<0.1)	0	1 (<0.1)
Elbow operation	0	1 (<0.1)	0	1 (<0.1)
Hip arthroplasty	0	1 (<0.1)	0	1 (<0.1)
Micrographic skin surgery	0	1 (<0.1)	0	1 (<0.1)
Shoulder arthroplasty	0	1 (<0.1)	0	1 (<0.1)
Social circumstances	0	0	1 (<0.1)	1 (<0.1)
Physical assault	0	0	1 (<0.1)	1 (<0.1)
Product issues	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Device failure	0	1 (<0.1)	0	1 (<0.1)
Device physical property issue	0	1 (<0.1)	2 (<0.1)	3 (<0.1)

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MedDRA version 23.0.

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Table 14.3.1.33.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Product issues (Cont.) Device breakage	0	0	1 (<0.1)	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301330101.sas 21JUN2021 03:17

Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	30 (1.4)	998 (10.8)	986 (8.6)	2014 (8.8)	7 (1.9)	511 (15.1)	471 (12.5)	989 (13.2)
Number of Unsolicited Adverse Events	41	1436	1382	2859	10	766	685	1461
Infections and infestations	8 (0.4)	342 (3.7)	348 (3.0)	698 (3.1)	1 (0.3)	137 (4.0)	114 (3.0)	252 (3.4)
Urinary tract infection	0	38 (0.4)	46 (0.4)	84 (0.4)	0	21 (0.6)	19 (0.5)	40 (0.5)
COVID-19	3 (0.1)	38 (0.4)	25 (0.2)	66 (0.3)	0	13 (0.4)	7 (0.2)	20 (0.3)
Upper respiratory tract infection	2 (<0.1)	30 (0.3)	36 (0.3)	68 (0.3)	0	9 (0.3)	4 (0.1)	13 (0.2)
Sinusitis	0	21 (0.2)	19 (0.2)	40 (0.2)	0	13 (0.4)	10 (0.3)	23 (0.3)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301330102.sas 21JUN2021 03:17

Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Rhinovirus infection	0	17 (0.2)	15 (0.1)	32 (0.1)	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Viral infection	0	17 (0.2)	22 (0.2)	39 (0.2)	0	3 (<0.1)	5 (0.1)	8 (0.1)
Tooth infection	0	9 (<0.1)	9 (<0.1)	18 (<0.1)	0	8 (0.2)	5 (0.1)	13 (0.2)
Pharyngitis streptococcal	0	11 (0.1)	2 (<0.1)	13 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Diverticulitis	0	7 (<0.1)	2 (<0.1)	9 (<0.1)	0	5 (0.1)	4 (0.1)	9 (0.1)
Herpes zoster	0	8 (<0.1)	8 (<0.1)	16 (<0.1)	0	3 (<0.1)	4 (0.1)	7 (<0.1)
Suspected COVID-19	0	11 (0.1)	21 (0.2)	32 (0.1)	0	0	4 (0.1)	4 (<0.1)
Gastroenteritis	0	6 (<0.1)	8 (<0.1)	14 (<0.1)	0	4 (0.1)	1 (<0.1)	5 (<0.1)
Otitis media	0	9 (<0.1)	3 (<0.1)	12 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Pneumonia	0	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	6 (0.2)	3 (<0.1)	9 (0.1)

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Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Tooth abscess	1 (<0.1)	7 (<0.1)	8 (<0.1)	16 (<0.1)	0	3 (<0.1)	5 (0.1)	8 (0.1)
Cellulitis	0	5 (<0.1)	9 (<0.1)	14 (<0.1)	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Acute sinusitis	0	7 (<0.1)	5 (<0.1)	12 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Appendicitis	0	5 (<0.1)	4 (<0.1)	9 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bronchitis	0	4 (<0.1)	10 (<0.1)	14 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Conjunctivitis	0	4 (<0.1)	5 (<0.1)	9 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Onychomycosis	0	5 (<0.1)	0	5 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Ear infection	0	4 (<0.1)	6 (<0.1)	10 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Localised infection	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Pharyngitis	0	5 (<0.1)	6 (<0.1)	11 (<0.1)	0	0	0	0

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Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Sepsis	0	3 (<0.1)	3 (<0.1)	6 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bacterial vaginosis	1 (<0.1)	4 (<0.1)	4 (<0.1)	9 (<0.1)	0	0	0	0
Cystitis	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hordeolum	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Staphylococcal infection	0	3 (<0.1)	0	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Viral upper respiratory tract infection	0	3 (<0.1)	6 (<0.1)	9 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Asymptomatic COVID-19	0	3 (<0.1)	3 (<0.1)	6 (<0.1)	0	0	0	0
Coronavirus infection	0	3 (<0.1)	3 (<0.1)	6 (<0.1)	0	0	0	0
Folliculitis	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	0	0	0

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Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Infections and infestations (Cont.)								
Fungal skin infection	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gingivitis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Helicobacter infection	1 (<0.1)	3 (<0.1)	2 (<0.1)	6 (<0.1)	0	0	0	0
Infected bite	0	3 (<0.1)	0	3 (<0.1)	0	0	0	0
Oral herpes	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Abscess limb	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	0	0	0
Appendicitis perforated	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	0	0	0
Arthritis bacterial	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eye infection	0	1 (<0.1)	4 (<0.1)	5 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastroenteritis bacterial	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Gastroenteritis viral	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Infected dermal cyst	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Kidney infection	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Osteomyelitis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Otitis externa	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Rhinitis	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Tinea pedis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Vulvovaginal candidiasis	0	1 (<0.1)	4 (<0.1)	5 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vulvovaginal mycotic infection	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301330102.sas 21JUN2021 03:17

Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Wound infection	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Appendiceal abscess	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Arthritis infective	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Breast cellulitis	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
COVID-19 pneumonia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Candida infection	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Chlamydial infection	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Chronic sinusitis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Conjunctivitis viral	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Endophthalmitis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Escherichia infection	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Eyelid infection	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fungal infection	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Furuncle	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Gastrointestinal bacterial overgrowth	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Genital herpes	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Genital herpes simplex	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Genital infection fungal	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Groin abscess	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Helicobacter gastritis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Hepatic infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Herpes simplex	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Impetigo	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Infected cyst	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Infectious mononucleosis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Influenza	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Labyrinthitis	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Lower respiratory tract infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Medical device site joint infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Meningitis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Nasal vestibulitis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Nipple infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Oesophageal candidiasis	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Ophthalmic herpes simplex	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Oral candidiasis	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Osteomyelitis bacterial	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Papilloma viral infection	0	1 (<0.1)	4 (<0.1)	5 (<0.1)	0	0	0	0

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Infections and infestations (Cont.)								
Paronychia	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Parotitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Periorbital cellulitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pilonidal cyst	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Post procedural infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Postoperative abscess	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Postoperative wound infection	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Pseudomonas infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pulpitis dental	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Infections and infestations (Cont.)								
Pyelonephritis	0	0	3 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Respiratory tract infection	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	0	0
Root canal infection	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Staphylococcal sepsis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Syphilis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Tinea manuum	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Tonsillitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Trichomoniasis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Urethritis chlamydial	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Uterine infection	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Infections and infestations (Cont.)								
Vaginal infection	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Abscess	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Abscess neck	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Abscess oral	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
American trypanosomiasis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Bacterial diarrhoea	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Body tinea	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Bronchitis bacterial	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Cervicitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Infections and infestations (Cont.)								
Clostridium difficile infection	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Diarrhoea infectious	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Enterovirus infection	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Epididymitis	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Escherichia urinary tract infection	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Gonorrhoea	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Laryngitis viral	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Lice infestation	0	0	0	0	1 (0.3)	0	0	1 (<0.1)

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Infections and infestations (Cont.)								
Lip infection	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Nasopharyngitis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Necrotising fasciitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Ophthalmic herpes zoster	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Orchitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Oropharyngeal candidiasis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Otitis media acute	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Pericarditis infective	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0
Perirectal abscess	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pertussis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Infections and infestations (Cont.)								
Pharyngeal abscess	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pneumonia bacterial	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Proctitis chlamydial	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Sialoadenitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Sinusitis bacterial	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Skin infection	0	0	2 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Staphylococcal bacteraemia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Streptococcal infection	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Infections and infestations (Cont.)								
Tinea versicolour	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Urethritis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Vestibular neuronitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Vestibulitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.1)	20 (0.2)	30 (0.3)	53 (0.2)	0	20 (0.6)	32 (0.8)	52 (0.7)
Basal cell carcinoma	0	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	9 (0.3)	3 (<0.1)	12 (0.2)

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Squamous cell carcinoma of skin	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Lipoma	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	0	0	0
Melanocytic naevus	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Benign neoplasm of skin	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Bladder neoplasm	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Blepharal papilloma	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Breast cancer	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Castleman's disease	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Colon adenoma	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Ear neoplasm malignant	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Fibroadenoma of breast	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Fibrous histiocytoma	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Intraductal proliferative breast lesion	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Malignant melanoma	0	0	0	0	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Metastases to lung	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Myelodysplastic syndrome	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Oesophageal adenocarcinoma	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pancreatic carcinoma	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Pancreatic carcinoma metastatic	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pancreatic carcinoma stage IV	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Prostate cancer	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	5 (0.1)	5 (<0.1)
Prostate cancer stage I	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Renal cancer	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Uterine leiomyoma	1 (<0.1)	1 (<0.1)	5 (<0.1)	7 (<0.1)	0	0	0	0
Acrochordon	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
B-cell lymphoma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Borderline mucinous tumour of ovary	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Colorectal cancer metastatic	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0
Cutaneous T-cell lymphoma	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Endometrial cancer	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Eye naevus	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
High-grade B-cell lymphoma	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	0	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Lung adenocarcinoma	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Lung neoplasm malignant	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Lymphoma	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Neoplasm skin	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Oesophageal carcinoma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Oral fibroma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Papillary thyroid cancer	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Phaeochromocytoma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Salivary gland cancer stage IV	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Skin cancer	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Skin papilloma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Squamous cell carcinoma	0	0	1 (<0.1)	1 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Throat cancer	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)

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MedDRA version 23.0.

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Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)								
Thyroid cancer	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Uterine cancer	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Vocal cord neoplasm	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Blood and lymphatic system disorders	0	15 (0.2)	15 (0.1)	30 (0.1)	0	9 (0.3)	3 (<0.1)	12 (0.2)
Lymphadenopathy	0	8 (<0.1)	6 (<0.1)	14 (<0.1)	0	4 (0.1)	0	4 (<0.1)
Anaemia	0	4 (<0.1)	1 (<0.1)	5 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Iron deficiency anaemia	0	1 (<0.1)	5 (<0.1)	6 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Blood and lymphatic system disorders (Cont.)								
Hyperchromic anaemia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Immune thrombocytopenia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Leukocytosis	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Lymph node calcification	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Thrombocytopenia	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Haemoconcentration	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Splenomegaly	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Immune system disorders	0	9 (<0.1)	15 (0.1)	24 (0.1)	0	7 (0.2)	2 (<0.1)	9 (0.1)
Seasonal allergy	0	3 (<0.1)	9 (<0.1)	12 (<0.1)	0	6 (0.2)	1 (<0.1)	7 (<0.1)

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Immune system disorders (Cont.)								
Anaphylactic reaction	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Food allergy	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Drug hypersensitivity	0	1 (<0.1)	1	2 (<0.1)	0	0	1	1
Hypersensitivity	0	1 (<0.1)	2	3 (<0.1)	0	0	0 (<0.1)	0 (<0.1)
Sarcoidosis	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Allergy to arthropod sting	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Endocrine disorders	0	10 (0.1)	13 (0.1)	23 (0.1)	0	4 (0.1)	12 (0.3)	16 (0.2)
Hypothyroidism	0	5 (<0.1)	9 (<0.1)	14 (<0.1)	0	4 (0.1)	6 (0.2)	10 (0.1)
Autoimmune thyroiditis	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0

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Endocrine disorders (Cont.)								
Basedow's disease	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Thyroid mass	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	3 (<0.1)	3 (<0.1)
Adrenal mass	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Goitre	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Hyperandrogenism	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Hyperprolactinaemia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Hyperthyroidism	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Hypogonadism	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Metabolism and nutrition disorders	0	58 (0.6)	57 (0.5)	115 (0.5)	0	36 (1.1)	35 (0.9)	71 (0.9)
Hypercholesterolaemia	0	9 (<0.1)	7 (<0.1)	16 (<0.1)	0	9 (0.3)	7 (0.2)	16 (0.2)
Type 2 diabetes mellitus	0	12 (0.1)	13 (0.1)	25 (0.1)	0	5 (0.1)	6 (0.2)	11 (0.1)
Vitamin D deficiency	0	13 (0.1)	10 (<0.1)	23 (0.1)	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hyperlipidaemia	0	6 (<0.1)	8 (<0.1)	14 (<0.1)	0	7 (0.2)	7 (0.2)	14 (0.2)
Diabetes mellitus	0	5 (<0.1)	2 (<0.1)	7 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Gout	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Iron deficiency	0	0	1 (<0.1)	1 (<0.1)	0	4 (0.1)	0	4 (<0.1)
Dehydration	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Diabetes mellitus inadequate control	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Metabolism and nutrition disorders (Cont.)								
Glucose tolerance impaired	0	3 (<0.1)	6 (<0.1)	9 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Hyperglycaemia	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypokalaemia	0	0	4 (<0.1)	4 (<0.1)	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Vitamin B12 deficiency	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Electrolyte imbalance	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fluid overload	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Hyperkalaemia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Hypertriglyceridaemia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Hypoglycaemia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Hyponatraemia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Metabolism and nutrition disorders (Cont.)								
Lactic acidosis	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Magnesium deficiency	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Obesity	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Postprandial hypoglycaemia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Type 1 diabetes mellitus	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Diabetic ketoacidosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Dyslipidaemia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Haemochromatosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Hypercalcaemia	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Insulin resistance	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Metabolism and nutrition disorders (Cont.)								
Metabolic acidosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Vitamin C deficiency	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Psychiatric disorders	2 (<0.1)	68 (0.7)	65 (0.6)	135 (0.6)	1 (0.3)	8 (0.2)	11 (0.3)	20 (0.3)
Depression	0	24 (0.3)	22 (0.2)	46 (0.2)	0	5 (0.1)	5 (0.1)	10 (0.1)
Anxiety	1 (<0.1)	25 (0.3)	21 (0.2)	47 (0.2)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Insomnia	0	10 (0.1)	4 (<0.1)	14 (<0.1)	0	2 (<0.1)	6 (0.2)	8 (0.1)
Attention deficit hyperactivity disorder	0	9 (<0.1)	10 (<0.1)	19 (<0.1)	0	0	0	0
Suicidal ideation	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0

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	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Psychiatric disorders (Cont.)								
Adjustment disorder	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Affective disorder	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Alcohol withdrawal syndrome	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Bipolar disorder	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Panic attack	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Paranoia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Post-traumatic stress disorder	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Schizophrenia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Substance abuse	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Psychiatric disorders (Cont.)								
Adjustment disorder with depressed mood	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Agitation	0	0	0	0	1 (0.3)	0	0	1 (<0.1)
Autism spectrum disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Bipolar I disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Delirium	0	0	0	0	1 (0.3)	0	0	1 (<0.1)
Dissociative identity disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Drug dependence	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0
Dysphemia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Psychiatric disorders (Cont.)								
Initial insomnia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Intentional self-injury	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Libido decreased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Major depression	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Mental status changes	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Mood swings	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Substance use disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Suicide attempt	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Thinking abnormal	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0

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Nervous system disorders	1 (<0.1)	74 (0.8)	59 (0.5)	134 (0.6)	0	29 (0.9)	33 (0.9)	62 (0.8)
Headache	0	22 (0.2)	18 (0.2)	40 (0.2)	0	3 (<0.1)	7 (0.2)	10 (0.1)
Dizziness	1 (<0.1)	9 (<0.1)	2 (<0.1)	12 (<0.1)	0	5 (0.1)	2 (<0.1)	7 (<0.1)
Paraesthesia	0	9 (<0.1)	2 (<0.1)	11 (<0.1)	0	0	3 (<0.1)	3 (<0.1)
Migraine	0	6 (<0.1)	5 (<0.1)	11 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sciatica	0	6 (<0.1)	6 (<0.1)	12 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ageusia	0	3 (<0.1)	0	3 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Syncope	0	4 (<0.1)	1 (<0.1)	5 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cerebrovascular accident	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Restless legs syndrome	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	3 (<0.1)	0	3 (<0.1)
Carpal tunnel syndrome	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Trigeminal neuralgia	0	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Nervous system disorders (Cont.)								
Anosmia	0	0	0	0	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cervical radiculopathy	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Hypoaesthesia	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Nerve compression	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Neuropathy peripheral	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Amyotrophic lateral sclerosis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Aphasia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Brain stem infarction	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Carotid artery stenosis	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

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MedDRA version 23.0.

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Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Nervous system disorders (Cont.)								
Dysgeusia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Haemorrhage intracranial	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Hypogeusia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Ischaemic cerebral infarction	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Lacunar infarction	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Loss of consciousness	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Lumbar radiculopathy	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Lumbosacral radiculopathy	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Migraine with aura	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Nervous system disorders (Cont.)								
Narcolepsy	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Neuralgia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Piriformis syndrome	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Presyncope	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Seizure	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Tension headache	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Transient ischaemic attack	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tremor	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Balance disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Burning sensation	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Nervous system disorders (Cont.)								
Carotid arteriosclerosis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Carotid artery aneurysm	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Cerebral ischaemia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Cluster headache	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Exertional headache	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Hemiparesis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Migraine without aura	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Nystagmus	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Peripheral sensory neuropathy	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Nervous system disorders (Cont.)								
Post herpetic neuralgia	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Shift work disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Somnolence	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Spinal cord compression	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Transient global amnesia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Eye disorders	0	17 (0.2)	13 (0.1)	30 (0.1)	0	16 (0.5)	14 (0.4)	30 (0.4)
Cataract	0	2 (<0.1)	4 (<0.1)	6 (<0.1)	0	5 (0.1)	4 (0.1)	9 (0.1)
Glaucoma	0	3 (<0.1)	0	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Blepharitis	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Eye disorders (Cont.)								
Conjunctival haemorrhage	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dacryostenosis acquired	0	0	0	0	0	2 (<0.1)	0	2 (<0.1)
Diplopia	0	0	0	0	0	2 (<0.1)	0	2 (<0.1)
Eye irritation	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Chalazion	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Conjunctivitis allergic	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dry eye	0	0	2 (<0.1)	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eye pain	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Eyelid rash	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Macular degeneration	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Normal tension glaucoma	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

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Eye disorders (Cont.)								
Retinal artery occlusion	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Retinal detachment	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Retinal tear	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Uveitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Vitreous floaters	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Dermatochalasis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Diabetic retinopathy	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Episcleritis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Lacrimation increased	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Neovascular age-related macular degeneration	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Eye disorders (Cont.)								
Ocular rosacea	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Periorbital swelling	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Vision blurred	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Visual impairment	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Ear and labyrinth disorders	1 (<0.1)	22 (0.2)	22 (0.2)	45 (0.2)	0	6 (0.2)	5 (0.1)	11 (0.1)
Vertigo	1 (<0.1)	7 (<0.1)	10 (<0.1)	18 (<0.1)	0	3 (<0.1)	4 (0.1)	7 (<0.1)
Tinnitus	0	4 (<0.1)	4 (<0.1)	8 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Deafness unilateral	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Ear canal erythema	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	0	0	0
Ear discomfort	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0

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Ear and labyrinth disorders (Cont.)								
Ear pain	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Cerumen impaction	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Deafness neurosensory	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Ear pruritus	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Excessive cerumen production	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
External ear inflammation	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Meniere's disease	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Tympanic membrane disorder	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Ear and labyrinth disorders (Cont.)								
Tympanic membrane hyperaemia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Ear congestion	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Middle ear effusion	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Vertigo positional	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Cardiac disorders	0	23 (0.2)	20 (0.2)	43 (0.2)	1 (0.3)	35 (1.0)	28 (0.7)	64 (0.9)
Atrial fibrillation	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	6 (0.2)	5 (0.1)	11 (0.1)
Coronary artery disease	0	0	2 (<0.1)	2 (<0.1)	0	6 (0.2)	6 (0.2)	12 (0.2)
Palpitations	0	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	2 (<0.1)	0	2 (<0.1)

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Cardiac disorders (Cont.)								
Tachycardia	0	3 (<0.1)	5 (<0.1)	8 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Cardiac failure	0	1 (<0.1)	0	1 (<0.1)	0	3 (<0.1)	0	3 (<0.1)
Myocardial infarction	0	1 (<0.1)	0	1 (<0.1)	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Acute myocardial infarction	0	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Bradycardia	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Cardiac failure congestive	0	0	1 (<0.1)	1 (<0.1)	0	3 (<0.1)	4 (0.1)	7 (<0.1)
Angina pectoris	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Angina unstable	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Arrhythmia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Sinus tachycardia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Cardiac disorders (Cont.)								
Supraventricular tachycardia	0	2 (<0.1)	0	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Ventricular extrasystoles	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Ventricular tachycardia	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Acute coronary syndrome	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Aortic valve incompetence	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Atrial flutter	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Atrioventricular block complete	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Cardiac disorders (Cont.)								
Bifascicular block	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Cardiac failure acute	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Cardiovascular disorder	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Coronary artery occlusion	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Sinus node dysfunction	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Acute left ventricular failure	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Bundle branch block left	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Bundle branch block right	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Cardiac disorder	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Cardiomyopathy	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Cardiac disorders (Cont.)								
Coronary artery insufficiency	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Extrasystoles	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Ischaemic cardiomyopathy	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Left atrial enlargement	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Mitral valve incompetence	0	0	0	0	0	0	3 (<0.1)	3 (<0.1)
Postural orthostatic tachycardia syndrome	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pulseless electrical activity	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Cardiac disorders (Cont.)								
Supraventricular extrasystoles	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Ventricular arrhythmia	0	0	0	0	1 (0.3)	0	0	1 (<0.1)
Vascular disorders	2 (<0.1)	73 (0.8)	48 (0.4)	123 (0.5)	0	45 (1.3)	42 (1.1)	87 (1.2)
Hypertension	2 (<0.1)	64 (0.7)	39 (0.3)	105 (0.5)	0	34 (1.0)	30 (0.8)	64 (0.9)
Deep vein thrombosis	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Lymphoedema	0	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Hot flush	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Aortic stenosis	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Essential hypertension	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Vascular disorders (Cont.)								
Hypertensive crisis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Hypertensive urgency	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Hypotension	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Labile blood pressure	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Orthostatic hypotension	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Peripheral arterial occlusive disease	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Peripheral vascular disorder	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Peripheral venous disease	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Prehypertension	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Vascular disorders (Cont.)								
Raynaud's phenomenon	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Aortic aneurysm	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Aortic arteriosclerosis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Aortic dissection	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Haematoma	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Intermittent claudication	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Jugular vein thrombosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Phlebitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Subclavian vein thrombosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Vascular insufficiency	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Respiratory, thoracic and mediastinal disorders	2 (<0.1)	57 (0.6)	75 (0.7)	134 (0.6)	0	34 (1.0)	29 (0.8)	63 (0.8)
Cough	1 (<0.1)	17 (0.2)	18 (0.2)	36 (0.2)	0	3 (<0.1)	5 (0.1)	8 (0.1)
Rhinorrhoea	0	11 (0.1)	9 (<0.1)	20 (<0.1)	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Dyspnoea	0	3 (<0.1)	9 (<0.1)	12 (<0.1)	0	8 (0.2)	3 (<0.1)	11 (0.1)
Nasal congestion	0	10 (0.1)	17 (0.1)	27 (0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Asthma	0	7 (<0.1)	6 (<0.1)	13 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Oropharyngeal pain	0	7 (<0.1)	15 (0.1)	22 (<0.1)	0	1 (<0.1)	5 (0.1)	6 (<0.1)
Epistaxis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Sinus congestion	0	5 (<0.1)	2 (<0.1)	7 (<0.1)	0	0	0	0
Acute respiratory failure	0	0	0	0	0	3 (<0.1)	0	3 (<0.1)

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Respiratory, thoracic and mediastinal disorders (Cont.)								
Chronic obstructive pulmonary disease	0	0	3 (<0.1)	3 (<0.1)	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Pleural effusion	0	0	0	0	0	3 (<0.1)	3 (<0.1)	6 (<0.1)
Sleep apnoea syndrome	0	2 (<0.1)	5 (<0.1)	7 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Pulmonary embolism	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Pulmonary mass	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Rhinitis allergic	0	0	3 (<0.1)	3 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Sinus pain	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Wheezing	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Respiratory, thoracic and mediastinal disorders (Cont.)								
Allergic cough	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Asthma exercise induced	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Atelectasis	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Dry throat	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Dyspnoea exertional	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Emphysema	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Hypoxia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Interstitial lung disease	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Respiratory, thoracic and mediastinal disorders (Cont.)								
Lower respiratory tract congestion	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Nasal inflammation	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Nasal polyps	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Nasal septum deviation	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Paranasal sinus discomfort	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Paranasal sinus hypersecretion	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pharyngeal erythema	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Respiratory, thoracic and mediastinal disorders (Cont.)								
Pneumothorax	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Reflux laryngitis	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Respiratory disorder	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	0	0
Respiratory failure	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	1 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Allergic sinusitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Lung disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Mediastinal cyst	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Mediastinal mass	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Respiratory, thoracic and mediastinal disorders (Cont.)								
Pharyngeal ulceration	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pulmonary fibrosis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Pulmonary hypertension	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Pulmonary oedema	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Respiratory tract congestion	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Rhinalgia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Sinus disorder	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Throat irritation	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Respiratory, thoracic and mediastinal disorders (Cont.)								
Upper-airway cough syndrome	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Vocal cord polyp	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Gastrointestinal disorders	3 (0.1)	102 (1.1)	77 (0.7)	182 (0.8)	2 (0.6)	37 (1.1)	40 (1.1)	79 (1.1)
Nausea	1 (<0.1)	17 (0.2)	9 (<0.1)	27 (0.1)	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Gastroesophageal reflux disease	1 (<0.1)	9 (<0.1)	11 (<0.1)	21 (<0.1)	1 (0.3)	7 (0.2)	8 (0.2)	16 (0.2)
Dental caries	0	11 (0.1)	5 (<0.1)	16 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Abdominal pain	0	11 (0.1)	4 (<0.1)	15 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Gastrointestinal disorders (Cont.)								
Toothache	1 (<0.1)	7 (<0.1)	1 (<0.1)	9 (<0.1)	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Vomiting	0	9 (<0.1)	2 (<0.1)	11 (<0.1)	0	0	0	0
Diarrhoea	1 (<0.1)	7 (<0.1)	13 (0.1)	21 (<0.1)	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Haemorrhoids	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	5 (0.1)	0	5 (<0.1)
Constipation	0	4 (<0.1)	2 (<0.1)	6 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Abdominal discomfort	0	3 (<0.1)	0	3 (<0.1)	0	0	0	0
Abdominal pain upper	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hiatus hernia	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Inguinal hernia	0	0	0	0	0	3 (<0.1)	0	3 (<0.1)
Colitis	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0

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Gastrointestinal disorders (Cont.)								
Dyspepsia	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastritis	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Gastrointestinal haemorrhage	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Large intestine polyp	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Umbilical hernia	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Abdominal hernia	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Abdominal pain lower	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Abdominal tenderness	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Anal fissure	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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MedDRA version 23.0.

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Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)								
Colitis microscopic	0	0	2 (<0.1)	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Duodenal ulcer perforation	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Enlarged uvula	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Enteritis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Flatulence	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Food poisoning	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Gastric ulcer	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Gastritis erosive	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Gastrointestinal inflammation	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Gastrointestinal disorders (Cont.)								
Gastrointestinal pain	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Haemorrhoidal haemorrhage	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Ileus paralytic	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Impaired gastric emptying	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Internal hernia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Intestinal obstruction	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Lip oedema	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Mouth ulceration	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Oesophageal rupture	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Gastrointestinal disorders (Cont.)								
Oral disorder	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pancreatitis	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	0	0	0
Pancreatitis acute	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Parotid gland enlargement	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Peptic ulcer	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Periodontal disease	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Proctalgia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Pulpless tooth	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Salivary gland calculus	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Gastrointestinal disorders (Cont.)								
Small intestinal obstruction	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Tooth disorder	0	1 (<0.1)	0	1 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Tooth impacted	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Abdominal distension	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Anal fistula	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Barrett's oesophagus	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Crohn's disease	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Diverticulum	0	0	0	0	1 (0.3)	0	1 (<0.1)	2 (<0.1)
Duodenal ulcer	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (Cont.)								
Enterovesical fistula	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Erosive oesophagitis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Faeces soft	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Gastric polyps	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Gastrointestinal disorder	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Glossitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Haematochezia	0	0	1 (<0.1)	1 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Ileus	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Irritable bowel syndrome	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Oral pain	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Gastrointestinal disorders (Cont.)								
Pancreatic failure	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Portal hypertensive gastropathy	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Proctitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Rectal polyp	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Rectal prolapse	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Varices oesophageal	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Hepatobiliary disorders	0	6 (<0.1)	8 (<0.1)	14 (<0.1)	0	2 (<0.1)	7 (0.2)	9 (0.1)
Cholecystitis	0	3 (<0.1)	4 (<0.1)	7 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

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Hepatobiliary disorders (Cont.)								
Cholelithiasis	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bile duct obstruction	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Cholangitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Hepatic steatosis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Hepatomegaly	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Biliary colic	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Cholecystitis acute	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Cholelithiasis obstructive	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Hepatic cirrhosis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Hepatic lesion	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)

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Hepatobiliary disorders (Cont.)								
Hyperbilirubinaemia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	3 (0.1)	31 (0.3)	33 (0.3)	67 (0.3)	2 (0.6)	36 (1.1)	21 (0.6)	59 (0.8)
Rash	1 (<0.1)	1 (<0.1)	2 (<0.1)	4 (<0.1)	0	6 (0.2)	0	6 (<0.1)
Urticaria	0	5 (<0.1)	2 (<0.1)	7 (<0.1)	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Dermatitis contact	0	3 (<0.1)	5 (<0.1)	8 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Pruritus	0	4 (<0.1)	0	4 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Skin lesion	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	4 (0.1)	1 (<0.1)	5 (<0.1)
Actinic keratosis	0	0	1 (<0.1)	1 (<0.1)	0	4 (0.1)	3 (<0.1)	7 (<0.1)

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Skin and subcutaneous tissue disorders (Cont.)								
Rosacea	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Acne	0	3 (<0.1)	3 (<0.1)	6 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Dermal cyst	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Decubitus ulcer	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Drug eruption	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Eczema	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rash maculo-papular	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Seborrheic dermatitis	0	0	0	0	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Acne cystic	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Alopecia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Skin and subcutaneous tissue disorders (Cont.)								
Asteatosis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Dermatitis allergic	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Dry skin	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Erythema nodosum	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Lichen planus	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Lichen sclerosus	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Nail discolouration	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Pain of skin	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pityriasis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Rash pruritic	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Skin and subcutaneous tissue disorders (Cont.)								
Skin mass	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Skin necrosis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Skin ulcer	0	0	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Subcutaneous emphysema	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Urticaria papular	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Vitiligo	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Dermatitis	0	0	3 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Erythema	0	0	2 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Fixed eruption	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Hidradenitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Skin and subcutaneous tissue disorders (Cont.)								
Ingrowing nail	0	0	2 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Ingrown hair	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Perioral dermatitis	1 (<0.1)	0	3 (<0.1)	4 (<0.1)	0	0	0	0
Precancerous skin lesion	0	0	0	0	1 (0.3)	0	0	1 (<0.1)
Psoriasis	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Rash erythematous	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Rash vesicular	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Sensitive skin	0	0	0	0	1 (0.3)	0	0	1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders	1 (<0.1)	98 (1.1)	101 (0.9)	200 (0.9)	0	66 (1.9)	73 (1.9)	139 (1.8)
Arthralgia	0	14 (0.2)	13 (0.1)	27 (0.1)	0	10 (0.3)	7 (0.2)	17 (0.2)
Osteoarthritis	0	8 (<0.1)	4 (<0.1)	12 (<0.1)	0	11 (0.3)	12 (0.3)	23 (0.3)
Back pain	0	14 (0.2)	13 (0.1)	27 (0.1)	0	4 (0.1)	13 (0.3)	17 (0.2)
Musculoskeletal pain	0	7 (<0.1)	4 (<0.1)	11 (<0.1)	0	6 (0.2)	3 (<0.1)	9 (0.1)
Myalgia	0	6 (<0.1)	7 (<0.1)	13 (<0.1)	0	5 (0.1)	3 (<0.1)	8 (0.1)
Pain in extremity	0	8 (<0.1)	13 (0.1)	21 (<0.1)	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Muscle spasms	0	6 (<0.1)	5 (<0.1)	11 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Neck pain	0	6 (<0.1)	0	6 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Bursitis	0	5 (<0.1)	1 (<0.1)	6 (<0.1)	0	2 (<0.1)	5 (0.1)	7 (<0.1)
Arthritis	0	2 (<0.1)	2 (<0.1)	4 (<0.1)	0	3 (<0.1)	2 (<0.1)	5 (<0.1)

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Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)								
Osteoporosis	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	4 (0.1)	4 (0.1)	8 (0.1)
Tendonitis	0	3 (<0.1)	6 (<0.1)	9 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Intervertebral disc degeneration	0	2 (<0.1)	0	2 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Trigger finger	0	1 (<0.1)	0	1 (<0.1)	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Musculoskeletal chest pain	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Costochondritis	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Groin pain	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0

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Musculoskeletal and connective tissue disorders (Cont.)								
Intervertebral disc protrusion	0	2 (<0.1)	5 (<0.1)	7 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Joint swelling	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Lumbar spinal stenosis	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Muscular weakness	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Plantar fasciitis	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	0	0	0
Rheumatoid arthritis	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rotator cuff syndrome	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
Ankle impingement	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (Cont.)								
Ankylosing spondylitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Axillary mass	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Dupuytren's contracture	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Exostosis	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Flank pain	0	0	4 (<0.1)	4 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Intervertebral disc displacement	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Musculoskeletal and connective tissue disorders (Cont.)								
Joint hyperextension	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Joint noise	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Joint range of motion decreased	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Musculoskeletal discomfort	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Musculoskeletal stiffness	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Myositis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Neck mass	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pain in jaw	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Musculoskeletal and connective tissue disorders (Cont.)								
Patellofemoral pain syndrome	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Polyarthrititis	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Psoriatic arthropathy	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Scleroderma	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Temporomandibular joint syndrome	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	0	0
Vertebral lateral recess stenosis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Musculoskeletal and connective tissue disorders (Cont.)								
Cervical spinal stenosis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Haemarthrosis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Intervertebral disc disorder	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Myofascial pain syndrome	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Osteopenia	0	0	0	0	0	0	3 (<0.1)	3 (<0.1)
Periarthritis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Sacroiliitis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Scoliosis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Musculoskeletal and connective tissue disorders (Cont.)								
Spinal osteoarthritis	0	0	2 (<0.1)	2 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Spinal pain	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0
Spondylitis	0	0	0	0	0	0	3 (<0.1)	3 (<0.1)
Spondylolisthesis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Tenosynovitis stenosaurs	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Torticollis	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Renal and urinary disorders	0	13 (0.1)	16 (0.1)	29 (0.1)	1 (0.3)	22 (0.6)	16 (0.4)	39 (0.5)
Nephrolithiasis	0	7 (<0.1)	4 (<0.1)	11 (<0.1)	0	10 (0.3)	3 (<0.1)	13 (0.2)

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Renal and urinary disorders (Cont.)								
Dysuria	0	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Haematuria	0	1 (<0.1)	2	3 (<0.1)	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Acute kidney injury	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hypertonic bladder	0	0	2 (<0.1)	2 (<0.1)	1 (0.3)	2 (<0.1)	1 (<0.1)	4 (<0.1)
Ureterolithiasis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Urinary retention	0	0	0	0	0	2 (<0.1)	0	2 (<0.1)
Chronic kidney disease	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Micturition urgency	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Pollakiuria	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Renal colic	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Renal and urinary disorders (Cont.)								
Renal failure	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Renal injury	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Stress urinary incontinence	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Bladder prolapse	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Bladder spasm	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Incontinence	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Ketonuria	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Nephritis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Proteinuria	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Renal cyst	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Renal and urinary disorders (Cont.)								
Renal pain	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Urinary incontinence	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Urine abnormality	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	3 (<0.1)	3 (<0.1)	7 (<0.1)	0	0	0	0
Abortion spontaneous	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Pregnancy	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Gestational diabetes	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	0	0	0	0

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Reproductive system and breast disorders	0	20 (0.2)	23 (0.2)	43 (0.2)	0	13 (0.4)	14 (0.4)	27 (0.4)
Ovarian cyst	0	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	0	0	0
Prostatomegaly	0	2 (<0.1)	0	2 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Breast mass	0	1 (<0.1)	4 (<0.1)	5 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cervical dysplasia	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Benign prostatic hyperplasia	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	1 (<0.1)	4 (0.1)	5 (<0.1)
Breast pain	0	2 (<0.1)	0	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Endometriosis	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Erectile dysfunction	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Menstruation irregular	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0

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Reproductive system and breast disorders (Cont.)								
Uterine polyp	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Haemospermia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Pelvic pain	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Perineal disorder	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Postmenopausal haemorrhage	0	0	0	0	0	1 (<0.1)	1	2 (<0.1)
Prostatitis	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Scrotal disorder	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Uterine cyst	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Vaginal discharge	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Vaginal haemorrhage	0	0	3 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Reproductive system and breast disorders (Cont.)								
Adnexa uteri pain	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Dysmenorrhoea	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Endometrial hyperplasia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Endometrial thickening	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Gynaecomastia	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Pelvic cyst	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Pelvic prolapse	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Polycystic ovaries	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Sexual dysfunction	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Uterine haemorrhage	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Reproductive system and breast disorders (Cont.)								
Uterine prolapse	0	0	1 (<0.1)	1 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Congenital, familial and genetic disorders	0	3 (<0.1)	3 (<0.1)	6 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Arnold-Chiari malformation	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Congenital knee deformity	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Thalassaemia beta	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Type IIa hyperlipidaemia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Corneal dystrophy	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Enteric duplication	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Congenital, familial and genetic disorders (Cont.)								
Hydrocele	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Type V hyperlipidaemia	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
General disorders and administration site conditions	2 (<0.1)	50 (0.5)	43 (0.4)	95 (0.4)	1 (0.3)	30 (0.9)	18 (0.5)	49 (0.7)
Fatigue	1 (<0.1)	12 (0.1)	17 (0.1)	30 (0.1)	0	3 (<0.1)	6 (0.2)	9 (0.1)
Chest pain	1 (<0.1)	2 (<0.1)	4 (<0.1)	7 (<0.1)	0	9 (0.3)	2 (<0.1)	11 (0.1)
Injection site pain	0	8 (<0.1)	2 (<0.1)	10 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Pyrexia	0	6 (<0.1)	3 (<0.1)	9 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)

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	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (Cont.)								
Chills	0	5 (<0.1)	7 (<0.1)	12 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Pain	1 (<0.1)	4 (<0.1)	9 (<0.1)	14 (<0.1)	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
Influenza like illness	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Oedema peripheral	0	0	3 (<0.1)	3 (<0.1)	0	4 (0.1)	2 (<0.1)	6 (<0.1)
Peripheral swelling	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	1 (0.3)	2 (<0.1)	0	3 (<0.1)
Injection site lymphadenopathy	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Injection site swelling	0	3 (<0.1)	0	3 (<0.1)	0	0	0	0
Non-cardiac chest pain	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)

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	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (Cont.)								
Injection site erythema	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Injection site pruritus	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Injection site rash	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Asthenia	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Axillary pain	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Chest discomfort	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Cyst	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Drug intolerance	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Early satiety	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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General disorders and administration site conditions (Cont.)								
Exercise tolerance decreased	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Facial pain	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Gait disturbance	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Generalised oedema	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Inflammation	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Injection site discolouration	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Injection site inflammation	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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General disorders and administration site conditions (Cont.)								
Nodule	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Precancerous condition	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Swelling	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Swelling face	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	0	0	0	0
Complication associated with device	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Incarcerated hernia	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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General disorders and administration site conditions (Cont.)								
Medical device site haemorrhage	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Medical device site pain	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Papillitis	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pelvic mass	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Sudden death	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Investigations	3 (0.1)	27 (0.3)	32 (0.3)	62 (0.3)	0	18 (0.5)	13 (0.3)	31 (0.4)
Blood cholesterol increased	0	4 (<0.1)	5 (<0.1)	9 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)

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	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Investigations (Cont.)								
Blood pressure increased	2 (<0.1)	4 (<0.1)	1 (<0.1)	7 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Blood testosterone decreased	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	0	0	0
Hepatic enzyme increased	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Blood glucose increased	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Cardiac murmur	0	0	0	0	0	2 (<0.1)	0	2 (<0.1)
Glycosylated haemoglobin increased	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Heart rate irregular	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Liver function test increased	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0

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Investigations (Cont.)								
Anticoagulation drug level above therapeutic	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Blood bilirubin increased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Blood potassium decreased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Blood pressure diastolic increased	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Blood triglycerides increased	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Blood uric acid increased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Blood urine present	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Cells in urine	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

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Investigations (Cont.)								
Culture urine positive	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Fibrin D dimer increased	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Full blood count abnormal	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Haemoglobin decreased	1 (<0.1)	0	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Intraocular pressure increased	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Metabolic function test abnormal	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Platelet count decreased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Progesterone decreased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Investigations (Cont.)								
Prostatic specific antigen increased	0	0	3 (<0.1)	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Transaminases increased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Vitamin D decreased	0	1 (<0.1)	3 (<0.1)	4 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
White blood cell count decreased	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Alanine aminotransferase increased	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Angiotensin converting enzyme increased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Investigations (Cont.)								
Antinuclear antibody increased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Antipsychotic drug level increased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Aspartate aminotransferase increased	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Blood alkaline phosphatase increased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Blood calcium increased	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Blood creatinine decreased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Blood lactic acid increased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Investigations (Cont.)								
Brain scan abnormal	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Cardiac stress test abnormal	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Cortisol decreased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Electrocardiogram QT prolonged	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Heart rate increased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Liver function test abnormal	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Mammogram abnormal	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Nitrite urine present	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301330102.sas 21JUN2021 03:17

Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Investigations (Cont.)								
Red blood cell count decreased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Serum ferritin decreased	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Smear cervix abnormal	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Smooth muscle antibody positive	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Urine calcium increased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Weight increased	0	0	3 (<0.1)	3 (<0.1)	0	0	0	0
White blood cell count increased	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Investigations (Cont.)								
White blood cells urine positive	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Injury, poisoning and procedural complications	3 (0.1)	113 (1.2)	121 (1.1)	237 (1.0)	0	66 (1.9)	42 (1.1)	108 (1.4)
Procedural pain	0	15 (0.2)	12 (0.1)	27 (0.1)	0	6 (0.2)	4 (0.1)	10 (0.1)
Tooth fracture	0	6 (<0.1)	5 (<0.1)	11 (<0.1)	0	8 (0.2)	1 (<0.1)	9 (0.1)
Skin laceration	0	7 (<0.1)	8 (<0.1)	15 (<0.1)	0	6 (0.2)	7 (0.2)	13 (0.2)
Ligament sprain	0	7 (<0.1)	7 (<0.1)	14 (<0.1)	0	5 (0.1)	2 (<0.1)	7 (<0.1)
Muscle strain	0	6 (<0.1)	10 (<0.1)	16 (<0.1)	0	5 (0.1)	3 (<0.1)	8 (0.1)
Limb injury	0	5 (<0.1)	3 (<0.1)	8 (<0.1)	0	4 (0.1)	0	4 (<0.1)

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Injury, poisoning and procedural complications (Cont.)								
Animal bite	0	6 (<0.1)	0	6 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Meniscus injury	0	7 (<0.1)	6 (<0.1)	13 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fall	0	4 (<0.1)	4 (<0.1)	8 (<0.1)	0	3 (<0.1)	5 (0.1)	8 (0.1)
Foot fracture	0	4 (<0.1)	5 (<0.1)	9 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Contusion	0	3 (<0.1)	3 (<0.1)	6 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hand fracture	0	4 (<0.1)	1 (<0.1)	5 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Stress fracture	0	5 (<0.1)	3 (<0.1)	8 (<0.1)	0	0	0	0
Fibula fracture	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Radius fracture	0	3 (<0.1)	0	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

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	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Injury, poisoning and procedural complications (Cont.)								
Tendon rupture	0	3 (<0.1)	1 (<0.1)	4 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Ankle fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)	4 (<0.1)	0	2 (<0.1)	0	2 (<0.1)
Concussion	0	2 (<0.1)	6 (<0.1)	8 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Dental restoration failure	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Epicondylitis	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Joint injury	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Lip injury	0	2 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Upper limb fracture	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	2 (<0.1)	2 (<0.1)	4 (<0.1)
Anaemia postoperative	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.33.1.2
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System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)								
Cartilage injury	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Corneal abrasion	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Eye injury	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Femur fracture	0	0	0	0	0	2 (<0.1)	0	2 (<0.1)
Ligament rupture	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	0	0	0
Post-traumatic pain	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Rib fracture	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Wrist fracture	0	1 (<0.1)	4 (<0.1)	5 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Arthropod bite	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0

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Injury, poisoning and procedural complications (Cont.)								
Avulsion fracture	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Back injury	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bite	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Bone contusion	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Brain contusion	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Burn oral cavity	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Clavicle fracture	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	0	0	0	0
Eyelid injury	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Gun shot wound	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

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Injury, poisoning and procedural complications (Cont.)								
Head injury	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Iliotibial band syndrome	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Incision site discharge	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Incisional hernia	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Joint dislocation	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lisfranc fracture	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Lumbar vertebral fracture	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Mouth injury	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pneumothorax traumatic	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Injury, poisoning and procedural complications (Cont.)								
Post procedural constipation	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Post procedural fever	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Post procedural hypotension	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Post procedural pruritus	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Procedural complication	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Procedural nausea	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Radiation associated pain	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Radiation skin injury	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

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Injury, poisoning and procedural complications (Cont.)								
Road traffic accident	0	0	4 (<0.1)	4 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Skin abrasion	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Skin injury	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Spinal compression fracture	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Subcutaneous haematoma	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Tibia fracture	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Ulna fracture	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Wound	0	0	2 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Acetabulum fracture	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Injury, poisoning and procedural complications (Cont.)								
Animal scratch	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Cervical vertebral fracture	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Chemical burn	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Chillblains	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Exposure to toxic agent	0	0	2 (<0.1)	2 (<0.1)	0	0	0	0
Eye contusion	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Facial bones fracture	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Foreign body in eye	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Foreign body ingestion	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Injury, poisoning and procedural complications (Cont.)								
Fracture displacement	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Fractured sacrum	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Hip fracture	0	0	0	0	0	0	2 (<0.1)	2 (<0.1)
Humerus fracture	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Injury	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Limb crushing injury	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Lower limb fracture	0	0	3 (<0.1)	3 (<0.1)	0	0	0	0
Muscle injury	0	0	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Muscle rupture	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Injury, poisoning and procedural complications (Cont.)								
Patella fracture	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pelvic fracture	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Poisoning	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Post procedural haematoma	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Post procedural haemorrhage	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Seroma	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Soft tissue injury	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Spinal cord injury	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Splinter	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

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Injury, poisoning and procedural complications (Cont.)								
Stab wound	1 (<0.1)	0	0	1 (<0.1)	0	0	0	0
Tendon injury	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Thermal burn	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Thoracic vertebral fracture	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Ulnar nerve injury	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Vaccination complication	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Wound dehiscence	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301330102.sas 21JUN2021 03:17

Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Surgical and medical procedures	0	2 (<0.1)	0	2 (<0.1)	0	3 (<0.1)	0	3 (<0.1)
Colostomy	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Elbow operation	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Hip arthroplasty	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Micrographic skin surgery	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Shoulder arthroplasty	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Social circumstances	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Physical assault	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301330102.sas 21JUN2021 03:17

Table 14.3.1.33.1.2
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Product issues	0	0	2 (<0.1)	2 (<0.1)	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Device failure	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Device physical property issue	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Device breakage	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301330102.sas 21JUN2021 03:17

Table 14.3.1.34.1.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	0	12 (<0.1)	2 (<0.1)	14 (<0.1)
Number of Unsolicited Adverse Events	0	12	2	14
Infections and infestations	0	3 (<0.1)	1 (<0.1)	4 (<0.1)
Arthritis bacterial	0	1 (<0.1)	0	1 (<0.1)
Parotitis	0	1 (<0.1)	0	1 (<0.1)
Suspected COVID-19	0	1 (<0.1)	0	1 (<0.1)
COVID-19	0	0	1 (<0.1)	1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	2 (<0.1)	0	2 (<0.1)
Pancreatic carcinoma metastatic	0	1 (<0.1)	0	1 (<0.1)
Prostate cancer	0	1 (<0.1)	0	1 (<0.1)
Immune system disorders	0	1 (<0.1)	0	1 (<0.1)
Anaphylactic reaction	0	1 (<0.1)	0	1 (<0.1)
Nervous system disorders	0	1 (<0.1)	0	1 (<0.1)
Brain stem infarction	0	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301340101.sas 21JUN2021 03:18

Table 14.3.1.34.1.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
in Open-Label Phase
Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Ear and labyrinth disorders	0	1 (<0.1)	0	1 (<0.1)
Deafness unilateral	0	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	0	0	1 (<0.1)	1 (<0.1)
Oropharyngeal pain	0	0	1 (<0.1)	1 (<0.1)
Skin and subcutaneous tissue disorders	0	1 (<0.1)	0	1 (<0.1)
Urticaria	0	1 (<0.1)	0	1 (<0.1)
Pregnancy, puerperium and perinatal conditions	0	2 (<0.1)	0	2 (<0.1)
Abortion spontaneous	0	1 (<0.1)	0	1 (<0.1)
Pregnancy	0	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	0	1 (<0.1)	0	1 (<0.1)
Chills	0	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301340101.sas 21JUN2021 03:18

Table 14.3.1.34.1.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	0	11 (0.1)	2 (<0.1)	13 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Number of Unsolicited Adverse Events	0	11	2	13	0	1	0	1
Infections and infestations	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Arthritis bacterial	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Parotitis	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Suspected COVID-19	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
COVID-19	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301340102.sas 21JUN2021 03:18

Table 14.3.1.34.1.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Pancreatic carcinoma metastatic	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Prostate cancer	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Immune system disorders	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Anaphylactic reaction	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Nervous system disorders	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Brain stem infarction	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301340102.sas 21JUN2021 03:18

Table 14.3.1.34.1.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Ear and labyrinth disorders	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Deafness unilateral	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Respiratory, thoracic and mediastinal disorders	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Oropharyngeal pain	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Skin and subcutaneous tissue disorders	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Urticaria	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.34.1.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
by Age Group in Open-Label Phase
Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pregnancy, puerperium and perinatal conditions	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Abortion spontaneous	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Pregnancy	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
General disorders and administration site conditions	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Chills	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301340102.sas 21JUN2021 03:18

Table 14.3.1.35.1.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1 (<0.1)	4 (<0.1)	7 (<0.1)	12 (<0.1)
Number of Unsolicited Adverse Events	1	6	9	16
Nervous system disorders	0	2 (<0.1)	1 (<0.1)	3 (<0.1)
Amyotrophic lateral sclerosis	0	1 (<0.1)	0	1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardiac disorders	1 (<0.1)	1 (<0.1)	4 (<0.1)	6 (<0.1)
Cardiac failure congestive	0	1 (<0.1)	0	1 (<0.1)
Acute myocardial infarction	0	0	1 (<0.1)	1 (<0.1)
Cardiac arrest	0	0	1 (<0.1)	1 (<0.1)
Myocardial infarction	0	0	1 (<0.1)	1 (<0.1)
Pulseless electrical activity	0	0	1 (<0.1)	1 (<0.1)
Ventricular arrhythmia	1 (<0.1)	0	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	0	0	1 (<0.1)	1 (<0.1)
Pulmonary embolism	0	0	1 (<0.1)	1 (<0.1)
Gastrointestinal disorders	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastrointestinal haemorrhage	0	1 (<0.1)	1 (<0.1)	2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301350101.sas 21JUN2021 03:18

Table 14.3.1.35.1.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term in Open-Label Phase Safety Set

System Organ Class Preferred Term	Placebo (N=2514) n (%)	Placebo- mRNA-1273 (N=12648) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions	0	0	1 (<0.1)	1 (<0.1)
Sudden death	0	0	1 (<0.1)	1 (<0.1)
Investigations	0	1 (<0.1)	0	1 (<0.1)
Anticoagulation drug level above therapeutic	0	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Accidental overdose	0	1 (<0.1)	0	1 (<0.1)
Head injury	0	0	1 (<0.1)	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301350101.sas 21JUN2021 03:18

Table 14.3.1.35.1.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	0	2 (<0.1)	4 (<0.1)	6 (<0.1)	1 (0.3)	2 (<0.1)	3 (<0.1)	6 (<0.1)
Number of Unsolicited Adverse Events	0	2	6	8	1	4	3	8
Nervous system disorders	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Amyotrophic lateral sclerosis	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301350102.sas 21JUN2021 03:18

Table 14.3.1.35.1.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Cardiac disorders	0	0	2 (<0.1)	2 (<0.1)	1 (0.3)	1 (<0.1)	2 (<0.1)	4 (<0.1)
Cardiac failure congestive	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Acute myocardial infarction	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Cardiac arrest	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Myocardial infarction	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Pulseless electrical activity	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Ventricular arrhythmia	0	0	0	0	1 (0.3)	0	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Pulmonary embolism	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301350102.sas 21JUN2021 03:18

Table 14.3.1.35.1.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155) n (%)	Placebo- mRNA-1273 (N=9256) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=359) n (%)	Placebo- mRNA-1273 (N=3392) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Gastrointestinal disorders	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Gastrointestinal haemorrhage	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Sudden death	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0
Investigations	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)
Anticoagulation drug level above therapeutic	0	0	0	0	0	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301350102.sas 21JUN2021 03:18

Table 14.3.1.35.1.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term by Age Group in Open-Label Phase Safety Set

System Organ Class Preferred Term	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Injury, poisoning and procedural complications	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	0
Accidental overdose	0	1 (<0.1)	0	1 (<0.1)	0	0	0	0
Head injury	0	0	1 (<0.1)	1 (<0.1)	0	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.36.1.1
Summary of Death in Open-Label Phase
Safety Set

	Placebo (N=2514)	Placebo- mRNA-1273 (N=12648)	mRNA-1273 (N=15184)	Total (N=30346)
Total Number of Deaths Due to Any Cause, n (%)	1 (<0.1)	3 (<0.1)	8 (<0.1)	12 (<0.1)
Time of Death from First Injection (Days) [1]				
Mean (SD)	127.0 (NA)	204.7 (18.15)	184.4 (40.83)	184.7 (39.14)
Median	127.0	202.0	193.5	195.0
Min, Max	127, 127	188, 224	122, 239	122, 239
Time of Death from First Injection (Days) [1], n (%)				
< 28 Days	0	0	0	0
>= 28 and < 57 Days	0	0	0	0
>= 57 and < 168 Days	1 (<0.1)	0	3 (<0.1)	4 (<0.1)
>= 168 Days	0	3 (<0.1)	5 (<0.1)	8 (<0.1)
Time of Death from PDV (Days) [2]				
Mean (SD)	9.0 (NA)	56.3 (19.60)	44.5 (26.32)	44.5 (25.76)
Median	9.0	54.0	46.5	46.5
Min, Max	9, 9	38, 77	7, 88	7, 88
Time of Death from PDV (Days) [2], n (%)				
< 28 Days	1 (<0.1)	0	2 (<0.1)	3 (<0.1)
>= 28 and < 57 Days	0	2 (<0.1)	3 (<0.1)	5 (<0.1)
>= 57 and < 168 Days	0	1 (<0.1)	3 (<0.1)	4 (<0.1)
>= 168 Days	0	0	0	0

PDV = Participant Decision Visit.

[1] Time of Death from First Injection is calculated as: Date of Death – Date of First Injection in the study.

[2] Time of Death from PDV is calculated as: Date of Death – Date of PDV.

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Table 14.3.1.36.1.2
Summary of Death by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
Total Number of Deaths Due to Any Cause, n (%)	0	2 (<0.1)	4 (<0.1)	6 (<0.1)	1 (0.3)	1 (<0.1)	4 (0.1)	6 (<0.1)
Time of Death from First Injection (Days) [1]								
Mean		213.0	199.0	203.7	127.0	188.0	169.8	165.7
(SD)		(15.56)	(23.04)	(20.47)	(NA)	(NA)	(52.80)	(45.66)
Median		213.0	208.0	208.0	127.0	188.0	159.0	159.0
Min, Max		202, 224	165, 215	165, 224	127, 127	188, 188	122, 239	122, 239
Time of Death from First Injection (Days) [1], n (%)								
< 28 Days	0	0	0	0	0	0	0	0
>= 28 and < 57 Days	0	0	0	0	0	0	0	0
>= 57 and < 168 Days	0	0	1 (<0.1)	1 (<0.1)	1 (0.3)	0	2 (<0.1)	3 (<0.1)
>= 168 Days	0	2 (<0.1)	3 (<0.1)	5 (<0.1)	0	1 (<0.1)	2 (<0.1)	3 (<0.1)
Time of Death from PDV (Days) [2]								
Mean		57.5	53.8	55.0	9.0	54.0	35.3	34.0
(SD)		(27.58)	(8.42)	(14.09)	(NA)	(NA)	(36.30)	(31.57)
Median		57.5	53.5	53.5	9.0	54.0	23.0	23.0
Min, Max		38, 77	46, 62	38, 77	9, 9	54, 54	7, 88	7, 88

PDV = Participant Decision Visit.

[1] Time of Death from First Injection is calculated as: Date of Death – Date of First Injection in the study.

[2] Time of Death from PDV is calculated as: Date of Death – Date of PDV.

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Table 14.3.1.36.1.2
Summary of Death by Age Group in Open-Label Phase
Safety Set

	>=18 and <65 Years				>=65 Years			
	Placebo (N=2155)	Placebo- mRNA-1273 (N=9256)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=359)	Placebo- mRNA-1273 (N=3392)	mRNA-1273 (N=3769)	Total (N=7520)
Time of Death from PDV (Days)								
[2], n (%)								
< 28 Days	0	0	0	0	1 (0.3)	0	2 (<0.1)	3 (<0.1)
>= 28 and < 57 Days	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
>= 57 and < 168 Days	0	1 (<0.1)	2 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
>= 168 Days	0	0	0	0	0	0	0	0

PDV = Participant Decision Visit.

[1] Time of Death from First Injection is calculated as: Date of Death – Date of First Injection in the study.

[2] Time of Death from PDV is calculated as: Date of Death – Date of PDV.

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15 Narratives of Deaths, Other Serious Adverse Events, and Certain Other Clinically Meaningful Adverse Events

Participant Number	Death	Other SAE	Severe COVID-19	AE Leading to Study Discontinuation	AE Leading to Withdrawal From IP	Pregnancy
US3002149		X				
US3002329						X
US3012073		X		X		
US3012171		X				
US3022167		X				
US3032108		X				
US3032201					X	X
US3032249		X	X			
US3032343					X	
US3042262		X				
US3042309		X				
US3052005		X				
US3052028		X				
US3052291						X
US3052312		X				
US3062079		X				
US3062102		X				
US3062118		X				
US3062157		X				
US3082122		X				
US3082221			X			
US3092176		X				
US3092238		X				
US3092259		X				
US3112043		X				
US3112113		X				
US3112119		X				
US3112173		X				
US3112221		X				
US3112262		X				
US3122083		X				
US3122090		X				
US3132004		X				
US3132046		X				
US3132138		X				
US3132149		X				

Participant Number	Death	Other SAE	Severe COVID-19	AE Leading to Study Discontinuation	AE Leading to Withdrawal From IP	Pregnancy
US3142137		X				
US3142139		X				
US3142236		X				
US3152037		X				
US3152118		X				
US3152162		X				
US3152175		X				
US3152308						X
US3152413		X				
US3152426						X
US3162068		X				
US3162072		X				
US3162090		X				
US3162139		X				
US3162238		X				
US3162290		X				
US3172028		X				
US3172040		X				
US3172119		X				
US3172211		X				
US3172250		X				
US3172374		X				
US3172406		X				
US3172469		X				
US3182065		X				
US3182114		X				
US3192575					X	
US3202025		X				
US3202042		X				
US3202057						X
US3202070		X				
US3202179		X				
US3202183		X				
US3202185		X				
US3202197		X				
US3202217		X				
US3202366		X				
US3202375	X	X		X		
US3202395		X				

Participant Number	Death	Other SAE	Severe COVID-19	AE Leading to Study Discontinuation	AE Leading to Withdrawal From IP	Pregnancy
US3212049		X				
US3212121		X				
US3212166		X				
US3212181		X				
US3212250		X				
US3222017	X	X		X		
US3222422			X			
US3222524	X	X		X		
US3232050		X				
US3232063		X				
US3232157		X			X	
US3232162		X				
US3242013		X			X	X
US3242081		X				
US3242089	X	X		X		
US3242102		X				
US3252215		X				
US3252382		X				
US3252399		X				
US3252624		X				
US3252665						X
US3262027		X				
US3262115		X				
US3262133		X				
US3262259		X				
US3272060		X				
US3272078		X				
US3272116						X
US3272291					X	
US3272315		X				
US3292128		X				
US3292149		X				
US3292158		X				
US3292172		X				
US3292173		X				
US3292259		X				
US3302105		X				
US3302310						X
US3302327						X

Participant Number	Death	Other SAE	Severe COVID-19	AE Leading to Study Discontinuation	AE Leading to Withdrawal From IP	Pregnancy
US3302455		X				
US3302465	X	X		X		
US3312006	X	X		X		
US3312008		X				
US3312093		X				
US3312224		X				
US3312379		X				
US3312434		X				
US3312465		X				
US3312551						X
US3322314		X				
US3322409						X
US3332033		X				
US3332059		X				
US3342085		X				
US3342127		X				
US3342204						X
US3342354		X				
US3352015		X				
US3352070		X				
US3352213		X				
US3352297		X				
US3352304		X				X
US3352349		X				
US3362029		X				
US3362071		X				
US3362116		X				
US3362125		X				
US3372089		X				
US3372348		X				
US3392065		X				
US3392112		X				
US3392133		X				
US3392287		X				
US3402082		X				
US3402153			X			
US3402204		X	X			
US3402225		X				
US3402232		X				

Participant Number	Death	Other SAE	Severe COVID-19	AE Leading to Study Discontinuation	AE Leading to Withdrawal From IP	Pregnancy
US3402288		X				
US3402420		X				
US3412022		X				
US3412030		X				
US3412059		X				
US3412151	X	X		X		
US3412200		X				
US3412246		X				
US3412262		X				
US3412296		X				
US3412337		X				
US3422101		X				
US3422280						X
US3432023		X				
US3432094		X				
US3432120		X				
US3432240		X				
US3432380		X	X			
US3432497		X				
US3432574						X
US3432580						X
US3432617		X				
US3432641						X
US3442074	X	X		X		
US3442087		X				
US3462097		X				
US3462244		X				X
US3462364		X				
US3462421		X				X
US3472020					X	
US3482005			X			
US3482240		X				
US3482302			X			
US3492061						X
US3492078		X				
US3492107		X				
US3492228						X
US3492273		X				
US3502125		X				

Participant Number	Death	Other SAE	Severe COVID-19	AE Leading to Study Discontinuation	AE Leading to Withdrawal From IP	Pregnancy
US3512082		X				
US3512248		X			X	
US3522082		X				
US3522112		X				
US3522128		X				
US3522173		X				
US3522274		X				
US3522299		X				
US3522666		X				
US3522696		X				
US3522709		X				
US3532170		X				
US3532276		X				
US3542029		X				
US3542030		X				
US3542053		X				
US3542061		X				
US3542131		X				
US3542332		X				
US3552005		X				
US3552010		X				
US3552232		X				
US3552240		X				
US3552355		X				
US3552386		X				
US3552412						X
US3562228		X				
US3562229		X				
US3572027						X
US3572076		X				X
US3572170		X				
US3572251	X	X		X		
US3572330		X				
US3582102		X				
US3582154						X
US3592061		X				
US3592238		X				
US3602123		X				
US3602154		X				

Participant Number	Death	Other SAE	Severe COVID-19	AE Leading to Study Discontinuation	AE Leading to Withdrawal From IP	Pregnancy
US3612005		X				
US3612060		X				
US3622032						X
US3622142		X	X			
US3622160		X				
US3622206		X				
US3622282		X				
US3632052		X				
US3632075		X				
US3642076		X				
US3642081		X				
US3642217		X				
US3652038						X
US3662023			X			
US3662032		X				
US3662049		X				
US3662101		X				
US3662116		X				
US3672183					X	
US3672187		X				
US3672255		X				
US3682134		X				
US3682163		X				
US3682178						X
US3682211					X	
US3702040		X			X	
US3702046	X	X		X		
US3712096		X				
US3712174		X				
US3722025						X
US3722158		X				
US3722215		X				
US3722247						X
US3732023		X				
US3742034		X				
US3742137		X				
US3742148		X				
US3742153		X				
US3742225		X				

Participant Number	Death	Other SAE	Severe COVID-19	AE Leading to Study Discontinuation	AE Leading to Withdrawal From IP	Pregnancy
US3742229		X				
US3742301		X				
US3742384		X				
US3742463						X
US3752010		X				
US3752088					X	
US3752184		X				
US3752385						X
US3752402		X				
US3762023		X				
US3762120		X				
US3762131		X				
US3762286						X
US3772007		X				
US3772017						X
US3772041		X				
US3772252		X	X			
US3782014		X				
US3782028		X				
US3782162		X				
US3792012		X				
US3792016		X				
US3802074		X				
US3802120			X			
US3802168		X				
US3812081		X				
US3812229		X				
US3822088		X				
US3822181		X				
US3822342		X				
US3822443	X					
US3822465		X				
US3832071		X				
US3832176		X				
US3852015		X				
US3852177		X				
US3862007		X				
US3862020		X				
US3862099		X				

Participant Number	Death	Other SAE	Severe COVID-19	AE Leading to Study Discontinuation	AE Leading to Withdrawal From IP	Pregnancy
US3862110		X				
US3862128		X				
US3862144		X				
US3872083		X				
US3872187		X				
US3892032		X				
US3892042		X				
US3892054		X				
US3902051		X				
US3902060		X				
US3912046		X			X	
US3912076		X			X	
US3912113						X
US3922043		X				
US3922088		X				
US3932147	X	X		X		
US3942064		X				
US3942072		X				
US3942121		X				
US3942151		X				
US3952052		X				
US3952173		X				
US3962005		X				
US3972064		X				
US3972129			X			
US3972186		X				
US3982013		X				
US3982014		X				
US3982028		X				
US3982112		X				
US3982147		X				
US3982169		X				
US3982194		X				
US3982269		X				
US3992024			X			
US3992037		X				

Abbreviations: AE=adverse event; IP=investigational product; SAE=serious adverse event.

Participant Number: US300-2329 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 28 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 30 Oct 2020 (Study Day 33)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	27 Dec 2020 (Study Day 91) - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US300-2329, a 33-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Oct 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 28 Jan 2021. The participant was unblinded on 28 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	28 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	30 Oct 2020 (Study Day 33)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 18 Feb 2021 (Study Day 144), the participant had a positive pregnancy test. The participant reported using ethinylestradiol/levonorgestrel as a means of contraception. The first day of the participant's last menstrual period was on 22 Dec 2020 (Study Day 86). The estimated date of conception was 27 Dec 2020 (Study Day 91) and the estimated due date was 02 Oct 2021 (Study Day 370). The participant had minor bleeding, but their doctor was not concerned about it.

On 22 Feb 2021 (Study Day 148), an ultrasound showed a small hematoma between the uterus and placenta, everything else looked good.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-026458	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Penicillin allergy	1992 - Ongoing
Drug hypersensitivity	Augmentin allergy	2014 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; levonorgestrel	2017 - Ongoing	Contraception
Paracetamol	31 Oct 2020 (Study Day 34) - 31 Oct 2020 (Study Day 34)	Injection Site Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US303-2201 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 12 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: 21 Jan 2021 (Study Day 163)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Exposure during pregnancy/Exposure during pregnancy	Pregnancy, AE leading to withdrawal from study vaccine	Grade 1/mild	Not related	01 Feb 2021 (Study Day 174) – 26 Feb 2021 (Study Day 199)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US303-2201, a 38-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Jan 2021. The participant was unblinded on 21 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 21 Jan 2021 (Study Day 163). The second dose was not administered.

Event Details

On 01 Feb 2021 (Study Day 174), 173 days after the first dose in Part A/11 days after the first dose in Part B and 144 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 1/mild non-serious adverse event of pregnancy. The IP dose was withdrawn due to the pregnancy. The event of pregnancy lasted for 26 days, after which it was considered to be recovered/resolved on 26 Feb 2021 (Study Day 199). The investigator assessed the event of pregnancy to be not related to the IP.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 18 Feb 2021 (Study Day 191).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	12 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	10 Sep 2020 (Study Day 30)	Negative
Choriogonadotropin Beta	21 Jan 2021 (Study Day 163)	Negative
Choriogonadotropin Beta	18 Feb 2021 (Study Day 191)	Positive
Choriogonadotropin Beta	16 Apr 2021 (Study Day 248)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 18 Feb 2021 (Study Day 191), the participant had a positive urine pregnancy test. The participant reported using condoms and levonorgestrel as dual means of contraception. The first day of the participant's last menstrual period was on 30 Jan 2021 (Study Day 172). The estimated date of conception was 01 Feb 2021 (Study Day 174), and the estimated due date was unknown. On 18 Feb 2021 (Study Day 191), the participant was at their visit for the second dose of mRNA-1273 and had a positive pregnancy test. The participant did not know they were pregnant. They were only able to guess at estimated date of conception. The participant was instructed to follow up after their first doctor's appointment.

Study IP was withdrawn as a result of the drug exposure during pregnancy.

The outcome of the event, drug exposure during pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure during pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-015701	Pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies-no medication taken	1990 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	13 Oct 2020 (Study Day 63) - 13 Oct 2020 (Study Day 63)	Seasonal Influenza Prophylaxis
Levonorgestrel	01 Feb 2021 (Study Day 174) - 01 Feb 2021 (Study Day 174)	Pregnancy
Levonorgestrel	03 Feb 2021 (Study Day 176) - 03 Feb 2021 (Study Day 176)	Pregnancy

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pregnancy	Grade 1/mild	Not related	01 Feb 2021 (Study Day 174) - 26 Feb 2021 (Study Day 199)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US305-2291 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 21 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 18 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 14 Jan 2021 (Study Day 147)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Maternal exposure during pregnancy/Maternal exposure during pregnancy	Pregnancy	Not applicable	Not applicable	14 Jan 2021 (Study Day 147) - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US305-2291, a 40-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 14 Jan 2021 (Study Day 147). The second dose was not administered.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 09 Feb 2021 (Study Day 173).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	21 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	18 Sep 2020 (Study Day 29)	Negative
Choriogonadotropin Beta	14 Jan 2021 (Study Day 147)	Negative
Choriogonadotropin Beta	09 Feb 2021 (Study Day 173)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 09 Feb 2021 (Study Day 173), the participant had a positive home pregnancy test. The first day of the participant's last menstrual period was on 31 Dec 2020 (Study Day 133). The estimated date of conception was 14 Jan 2021 (Study Day 147), and the estimated due date was 06 Oct 2021 (Study Day 412). There were no problems with the pregnancy reported. The participant was using intrauterine device for contraception.

On 11 Feb 2021 (Study Day 175), the participant had a pregnancy confirmation visit with obstetrics and gynecology.

Study IP was discontinued as a result of the pregnancy.

The outcome of the event, maternal exposure during pregnancy, was not reported.

The investigator's assessment of the relationship between the event of maternal exposure during pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012538	Maternal exposure during pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendectomy	Appendix removal	1996 - 1996
Drug hypersensitivity	Allergy: opiates	1996 - Ongoing
Caesarean section	C-section	2000 - 2000
Cholecystectomy	Cholecystectomy	2005 - 2005
Cholelithiasis	Gallstones	2005 - 2005
Caesarean section	C-section	2007 - 2007
Caesarean section	C-section	2010 - 2010
Caesarean section	C-section	2014 - 2014
Seasonal allergy	Allergy: seasonal	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Botulinum toxin type a	Not reported - Ongoing	Migraines
Fluticasone propionate	Apr 2020 - Ongoing	Seasonal Allergies

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US314-2236 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 19 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 12 Jan 2021 (Study Day 147)
Second Dose of Vaccine in Part B: 18 Feb 2021 (Study Day 184)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Paraesthesia/Left Arm Paresthesia	SAE	Grade 3/severe	Related	20 Jan 2021 (Study Day 155) – 22 Jan 2021 (Study Day 157)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US314-2236, a 41-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 12 Jan 2021 (Study Day 147). The second dose was administered in the left arm on 18 Feb 2021 (Study Day 184).

Event Details

On 20 Jan 2021 (Study Day 155), 154 days after the first dose in Part A/8 days after the first dose in Part B and 126 days after the second dose in Part A/29 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of paraesthesia. The IP dose was delayed due to the left arm paresthesia. The event of left arm paresthesia lasted for 3 days, after which it was considered to be recovered/resolved on 22 Jan 2021 (Study Day 157). The investigator assessed the event of paraesthesia to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 20 Jan 2021 (Study Day 155), the participant experienced a serious adverse event of paresthesia (left arm) that was considered medically significant. On an unreported date, the participant presented for an unscheduled visit due to swelling, redness, and tenderness at the

injection site. Possible treatment with steroids or antibiotics was discussed; however, the participant declined starting treatment at that time. No treatment was given for the event.

On 21 Jan 2021 (Study Day 156), the participant went to the emergency department (ED) due to left side pain (detailed location not specified) and paresthesia. The outcome of the ED visit was not reported by the investigator. The participant was not hospitalized overnight and was discharged from the hospital the same day.

Study IP dose was delayed in response to the event.

The outcome of the event, paresthesia (left arm), was reported as resolved on 22 Jan 2021 (Study Day 157).

On 18 Feb 2021 (Study Day 184), the participant received the second dose of mRNA-1273 and was treated prophylactically with antihistamines prior to dosing.

The investigator assessed the event, paresthesia (left arm), as related to study IP or study procedure. The investigator's rationale for assessing the event as related was because the event occurred within 24 hours of receiving the first dose of investigational IP, same laterality of dose, and it was assessed by the ED as a histamine response.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005991	Paresthesia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Acne	Acne	Not reported - Ongoing
Oral herpes	Simplex herpes on lip	1980 - Ongoing
Hypothyroidism	Hypothyroidism	1996 - Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Obsessive-compulsive disorder	Ocd	2005 - Ongoing
Astigmatism	Astigmatism, bilateral	2010 - Ongoing
Myopia	Nearsighted, bilateral	2010 - Ongoing
Migraine	Migraines	2015 - Ongoing
Epistaxis	Nose bleeds	Mar 2018 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nephrolithiasis	Kidney stones	Mar 2020 - Mar 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	1996 - Ongoing	Hypothyroidism
Medroxyprogesterone acetate	1998 - Ongoing	Birth Control
Levocetirizine dihydrochloride	2000 - Ongoing	Seasonal Allergies
Liothyronine sodium	2002 - Ongoing	Hypothyroidism
Amphetamine aspartate; amphetamine sulfate; dexamphetamine saccharate; dexamphetamine sulfate	2005 - Ongoing	Obsessive Compulsive Disorder
Vitamin b12 nos	2014 - Ongoing	General Health
Spironolactone	2015 - Ongoing	Acne
Botulinum toxin type a	2018 - Ongoing	Migraines

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US315-2308 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 20 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 21 Sep 2020 (Study Day 33)
First Dose of Vaccine in Part B: 12 Feb 2021 (Study Day 177)
Second Dose of Vaccine in Part B: 09 Mar 2021 (Study Day 202)
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	25 Apr 2021 (Study Day 249) – Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US315-2308, a 34-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Feb 2021. The participant was unblinded on 14 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 12 Feb 2021 (Study Day 177). The second dose was administered in the left arm on 09 Mar 2021 (Study Day 202).

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	20 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	21 Sep 2020 (Study Day 33)	Negative
Choriogonadotropin Beta	12 Feb 2021 (Study Day 177)	Negative
Choriogonadotropin Beta	09 Mar 2021 (Study Day 202)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 30 Apr 2021 (Study Day 250), the participant had a positive serum pregnancy test that confirmed pregnancy. The first day of the participant's last menstrual period was on 01 Apr 2021 (Study Day 225), the estimated date of conception was not provided, and the estimated due date was 06 Jan 2022 (Study Day 505). The participant reported using a barrier form of contraception from January 2021 to 01 Apr 2021 (Study Day 225). They and their partner were not utilizing any form of contraception during April 2021.

On 17 May 2021 (Study Day 271), the participant reported their pregnancy to the site. They had had no problems and was to establish care with their obstetrician.

On 21 May 2021 (Study Day 275), an additional pregnancy test was performed that was positive.

Action taken with study IP in response to the event was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-139389	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Mild intermittent asthma	1991 - Ongoing
Seasonal allergy	Seasonal allergies	1991 - Ongoing
Allergy to animal	Cat allergy	2004 - Ongoing
Migraine with aura	Visual migraines	2013 - Ongoing
Astigmatism	Bilateral astigmatism	2016 - Ongoing
Dry eye	Bilateral dry eye	2016 - Ongoing
Myopia	Bilateral nearsightedness	2016 - Ongoing
Cellulitis	Cellulitis left wrist	Feb 2020 - Feb 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1991 - Ongoing	Asthma
Drospirenone; ethinylestradiol	2018 - Ongoing	Pregnancy Prophylaxis
Fexofenadine	2018 - Ongoing	Seasonal Allergies
Triamcinolone acetonide	2018 - Ongoing	Seasonal Allergies
Vaccinium macrocarpon	2018 - Ongoing	Nutritional Supplement
Nitrofurantoin	31 Aug 2020 (Study Day 12) - 04 Sep 2020 (Study Day 16)	Urinary Tract Infection
Paracetamol	24 Sep 2020 (Study Day 36) - 24 Sep 2020 (Study Day 36)	Post Procedure Pain
Replacement crown tooth #15*	24 Sep 2020 (Study Day 36) - 24 Sep 2020 (Study Day 36)	Other, Replacement Of Old Hardware
Hydrocortisone	27 Sep 2020 (Study Day 39) - 02 Oct 2020 (Study Day 44)	Papular Rash - Glabella
Diphenhydramine	13 Oct 2020 (Study Day 55) - 18 Nov 2020 (Study Day 91)	Seasonal Allergies
Cetirizine hydrochloride	19 Nov 2020 (Study Day 92) - 30 Nov 2020 (Study Day 103)	Seasonal Allergies
Fluticasone propionate	27 Nov 2020 (Study Day 100) - 30 Nov 2020 (Study Day 103)	Seasonal Allergic Rhinitis
Paracetamol	10 Mar 2021 (Study Day 203) - 14 Mar 2021 (Study Day 207)	Injection Site Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Erythema	Grade 2/moderate	Related	09 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 207)
Injection Site Pain	Grade 2/moderate	Related	09 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 207)
Injection Site Swelling	Grade 2/moderate	Related	09 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 207)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US315-2426 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 02 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 30 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 08 Jan 2021 (Study Day 99)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Exposure during pregnancy/Exposure during pregnancy	Pregnancy	Not applicable	Not applicable	08 Jan 2021 (Study Day 99) - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US315-2426, a 32-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 02 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 30 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 08 Jan 2021. The participant was unblinded on 08 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 08 Jan 2021 (Study Day 99). The second dose was not administered.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 10 Feb 2021 (Study Day 132).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	02 Oct 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	30 Oct 2020 (Study Day 29)	Negative
Choriogonadotropin Beta	08 Jan 2021 (Study Day 99)	Negative
Choriogonadotropin Beta	10 Feb 2021 (Study Day 132)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 05 Feb 2021 (Study Day 127), the participant had a positive pregnancy test, with their last menstrual period occurring on 28 Dec 2020 (Study Day 88); the estimated conception date is unreported, and the estimated due date is in September 2021.

On 10 Feb 2021 (Study Day 132), during an unscheduled visit, a human chorionic gonadotropin test was performed which was positive.

Study IP was discontinued as a result of the pregnancy.

The outcome of the event, exposure during pregnancy, was not reported.

The investigator's assessment of the relationship between the event of exposure during pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012928	Exposure during pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraines	2010 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2017 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2020 - Ongoing
Iron deficiency anaemia	Iron deficiency anemia	01 Sep 2020 (Study Day -31) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	1997 - Ongoing	Migraines
Vitamin d nos	Jan 2020 - Ongoing	Vitamin D Deficiency
Vitamins nos	Jan 2020 - Ongoing	Nutritional Supplement
Ascorbic acid	28 Sep 2020 (Study Day -4) - Ongoing	Nutritional Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Linum usitatissimum seed oil	28 Sep 2020 (Study Day -4) - Ongoing	Nutritional Supplement
Pantoprazole	27 Jan 2021 (Study Day 118) - Ongoing	Worsening Gerd
Vitamin d nos	27 Jan 2021 (Study Day 118) - Ongoing	Vitamin D Deficiency
Vitamins, other combinations	27 Jan 2021 (Study Day 118) - Ongoing	Iron Deficiency Anemia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gastroesophageal Reflux Disease	Grade 2/moderate	Not related	27 Jan 2021 (Study Day 118) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US320-2057 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 07 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 28)
First Dose of Vaccine in Part B: 05 Jan 2021 (Study Day 152)
Second Dose of Vaccine in Part B: 02 Feb 2021 (Study Day 180)
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	15 Mar 2021 (Study Day 221) - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2057, a 30-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 05 Jan 2021. The participant was unblinded on 05 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 05 Jan 2021 (Study Day 152). The second dose was administered in the left arm on 02 Feb 2021 (Study Day 180).

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	07 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	03 Sep 2020 (Study Day 28)	Negative
Choriogonadotropin Beta	05 Jan 2021 (Study Day 152)	Negative
Choriogonadotropin Beta	02 Feb 2021 (Study Day 180)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

In early March 2021, the participant reported that their etonogestrel implant was removed.

On 13 Apr 2021 (Study Day 250), the participant had a positive urine pregnancy test. The first day of the participant's last menstrual period was in early March 2021, the estimated date of conception was 15 Mar 2021 (Study Day 221), and the estimated due date was 20 Dec 2021 (Study Day 501). The participant had yet to see an obstetrician/gynecologist for additional testing or ultrasound confirmation of the pregnancy.

Action taken with study IP in response to the event was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-076880	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Corrective lens user	Glasses/contacts	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Urticaria	Lyrica causes hives	2012 - Ongoing
Anxiety	Anxiety	2018 - Ongoing
Depression	Depression	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluoxetine hydrochloride	2018 - Ongoing	Depression
Trazodone	Jun 2018 - Ongoing	Anxiety
Ibuprofen	13 Aug 2020 (Study Day 7) - 13 Aug 2020 (Study Day 7)	Headache

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	09 Sep 2020 (Study Day 34) - 14 Sep 2020 (Study Day 39)	Upper Respiratory Infection
Paracetamol	09 Sep 2020 (Study Day 34) - 14 Sep 2020 (Study Day 39)	Upper Respiratory Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US320-2375 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine: 01 Sep 2020 (Study Day 1)
Second Dose of Vaccine: 05 Oct 2020 (Study Day 35)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Sudden Death/Sudden Death (Unknown Cause)*	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	04 Apr 2021 (Study Day 216) – 04 Apr 2021 (Study Day 216)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

* According to information from the Safety database, the preferred term was "Drug intoxication" and the verbatim term was "combined drug intoxication (methamphetamine, diphenhydramine)".

Participant US320-2375, a 56-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 05 Oct 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 01 Feb 2021. The participant was unblinded on 01 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 04 Apr 2021 (Study Day 216), 215 days after the first dose in Part A and 181 days after the second dose in Part A of the IP, the participant experienced a Grade 5 serious adverse event of sudden death. Action taken with the IP was not applicable. The event of sudden death (unknown cause) was fatal on 04 Apr 2021 (Study Day 216). The investigator assessed the event of sudden death to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 04 Apr 2021 (Study Day 216), the participant experienced a serious adverse event of sudden death. The participant's spouse reported the participant's death to the site on 05 Apr 2021 (Study Day 217).

The participant had complained of nausea and feeling ill a bit earlier on 03 Apr 2021 (Study Day 215), so they went to bed and were later found deceased on the bed in a prone position. The medic who responded declared the participant deceased at the scene. At the scene, the participant had been moved supine on the floor for assessment and there were no visible signs of trauma. The participant's spouse reported that foul play was ruled out, with a probable cause of death due to cardiac arrest or abdominal aortic aneurysm, but neither was confirmed.

The toxicology results using high performance liquid chromatography/tandem mass spectrometry, was positive for 4-anilino-N-phenethyl-piperidine, cotinine, diphenhydramine 390 ng/mL (limit 50 ng/mL), amphetamine 68 ng/mL (limit 5.0 ng/mL), and methamphetamine 55 ng/mL (limit 5.0 ng/mL).

The participant died on 04 Apr 2021 (Study Day 216). The medical examiner confirmed the cause of death was combined drug intoxication (methamphetamine, diphenhydramine), with accident as the manner of death.

Action taken with study IP in response to the event was not applicable, as the participant had already received both scheduled doses.

The investigator assessed the event, sudden death (unknown cause), as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-068077	Sudden death

Study Completion/Discontinuation

On 04 Apr 2021 (Study Day 216), the participant discontinued from the study due to death. On 04 Apr 2021 (Study Day 216), the participant died due to adverse event. A full autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Caesarean section	C-section #1	1985 - 1985
Caesarean section	C-section #2	1994 - 1994
Postmenopause	Postmenopausal	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	28 Sep 2020 (Study Day 28) - 20 Nov 2020 (Study Day 81)	Upper Respiratory Infection Of Unknown Cause

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 1/mild	Not related	28 Sep 2020 (Study Day 28) - 30 Sep 2020 (Study Day 30)
Upper Respiratory Tract Infection	Grade 1/mild	Not related	09 Nov 2020 (Study Day 70) - 20 Nov 2020 (Study Day 81)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US322-2017 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 06 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardiac Arrest/Cardiac Arrest	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	04 Feb 2021 (Study Day 183) – 04 Feb 2021 (Study Day 183)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2017, a 72-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 28 Jan 2021. The participant was unblinded on 28 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 04 Feb 2021 (Study Day 183), 182 days after the first dose in Part A and 154 days after the second dose in Part A of the IP, the participant experienced a Grade 5 serious adverse event of cardiac arrest. The IP dose was not changed due to cardiac arrest. The event of cardiac arrest was considered to be fatal on 04 Feb 2021 (Study Day 183). The investigator assessed the event of cardiac arrest to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 04 Feb 2021 (Study Day 183), the participant experienced a fatal serious adverse event of cardiac arrest.

On 24 Feb 2021 (Study Day 203), the participant's spouse notified the site about the participant's death.

Action taken with the study IP was not applicable in response to the event, as the participant had already received both scheduled doses.

The participant died on 04 Feb 2021 (Study Day 183). The cause of death was reported as cardiac arrest. It was unknown whether an autopsy was performed.

The investigator assessed the event, cardiac arrest, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-022176	Cardiac arrest

Study Completion/Discontinuation

On 04 Feb 2021 (Study Day 183), the participant discontinued from the study due to death. On 04 Feb 2021 (Study Day 183), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cholecystitis	Cholecystitis	Not reported - 01 Jan 2010 (Study Day -3870)
Postmenopause	Postmenopausal	Not reported - Ongoing
Coronary artery disease	Coronary artery disease	01 Jan 2009 (Study Day -4235) - Ongoing
Stent placement	Stent placement	01 Jan 2009 (Study Day -4235) - 01 Jan 2009 (Study Day -4235)
Cholecystectomy	Cholecystectomy	01 Jan 2010 (Study Day -3870) - 01 Jan 2010 (Study Day -3870)
Stent placement	Stent placement	10 Jan 2010 (Study Day -3861) - 10 Jan 2010 (Study Day -3861)
Endarterectomy	Endarterectomy	10 Jan 2011 (Study Day -3496) - 10 Jan 2011 (Study Day -3496)
Nonalcoholic fatty liver disease	Non-alcoholic fatty liver disease	01 Apr 2018 (Study Day -858) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

No prior or concomitant medications or procedures were reported.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US322-2524 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 05 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Oct 2020 (Study Day 35)
First Dose of Vaccine in Part B: 17 Jan 2021 (Study Day 135)
Second Dose of Vaccine in Part B: 14 Feb 2021 (Study Day 163)
Reason for Narrative: Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chest Pain/Chest Pain	SAE	Grade 2/ moderate	Not related	01 Mar 2021 (Study Day 178) – 03 Mar 2021 (Study Day 180)	Recovered/ resolved
Anticoagulation Drug Level Above Therapeutic/Supra Therapeutic INR	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	12 Mar 2021 (Study Day 189) – 12 Mar 2021 (Study Day 189)	Fatal
Cardiac Failure Congestive/Congestive Heart Failure	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	12 Mar 2021 (Study Day 189) – 12 Mar 2021 (Study Day 189)	Fatal
Gastrointestinal Haemorrhage/ Gastrointestinal Bleed	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	12 Mar 2021 (Study Day 189) – 12 Mar 2021 (Study Day 189)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2524, a 79-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 05 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was Not reported. The participant proceeded to Part B, the Open-Label Observational Phase, on 17 Jan 2021. The participant was unblinded on 17 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 17 Jan 2021 (Study Day 135). The second dose was administered in the left arm on 14 Feb 2021 (Study Day 163).

Event Details

On 01 Mar 2021 (Study Day 178), 177 days after the first dose in Part A/43 days after the first dose in Part B and 143 days after the second dose in Part A/15 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of chest pain.

Action taken with the IP was not applicable. The event of chest pain lasted for 3 days, after which it was considered to be recovered/resolved on 03 Mar 2021 (Study Day 180). The investigator assessed the event of chest pain to be not related to the IP.

On 12 Mar 2021 (Study Day 189), 188 days after the first dose in Part A/54 days after the first dose in Part B and 154 days after the second dose in Part A/26 days after the second dose in Part B of the IP, the participant experienced a Grade 5 serious adverse event of anticoagulation drug level above therapeutic. Action taken with the IP was not applicable. The event of supra therapeutic INR was considered to be fatal on 12 Mar 2021 (Study Day 189). The investigator assessed the event of anticoagulation drug level above therapeutic to be not related to the IP.

On 12 Mar 2021 (Study Day 189), 188 days after the first dose in Part A/54 days after the first dose in Part B and 154 days after the second dose in Part A/26 days after the second dose in Part B of the IP, the participant experienced a Grade 5 serious adverse event of cardiac failure congestive. Action taken with the IP was not applicable. The event of congestive heart failure was considered to be fatal on 12 Mar 2021 (Study Day 189). The investigator assessed the event of cardiac failure congestive to be not related to the IP.

On 12 Mar 2021 (Study Day 189), 188 days after the first dose in Part A/54 days after the first dose in Part B and 154 days after the second dose in Part A/26 days after the second dose in Part B of the IP, the participant experienced a Grade 5 serious adverse event of gastrointestinal haemorrhage. Action taken with the IP was not applicable. The event of gastrointestinal bleed was considered to be fatal on 12 Mar 2021 (Study Day 189). The investigator assessed the event of gastrointestinal haemorrhage to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 01 Mar 2021 (Study Day 178), the participant experienced a serious adverse event (SAE) of chest pain. On the same day, the participant presented to the emergency department with midsternal nonradiating chest pain with dyspnea for about an hour. The participant reported jolts of pain at times in their chest along with pressure, intermittent sharp stabbing pains, tightness, heaviness, and squeezing in chest that lasted a few hours. The participant denied radiation of pain, palpitations, chills, fever, or cough. The participant reported lower extremity swelling for 2 days and that the shortness of breath got worse with movement. The participant reported becoming significantly weaker over the last 24 hours and experiencing chest pain with shortness of breath and was admitted to the hospital with a slightly elevated troponin on a telemetry unit. The participant reported that taking glyceryl trinitrate PO from home and that rest helped partially relieve the pain. A chest x-ray revealed no acute abnormalities. The participant rated their level of pain as 7 out of 10. A 12-lead electrocardiogram (ECG) showed the participant had a ventricular paced rhythm. The participant was treated with glyceryl trinitrate PO and furosemide IV. The participant also had pedal edema with a temperature of 98°F, heart rate 62 beats per minute (bpm),

respirations 16 breaths/min, oxygen saturation 100%, and blood pressure 158/84 mm Hg. Laboratory test results included activated partial thromboplastin time 49.1 seconds (reference range 22.4 to 38.6 seconds), creatine 1.34 mg/dL (reference range 0.60 to 1.20 mg/dL), thyroid stimulating hormone 4.84 μ IU/mL (reference range 0.27 to 4.20 μ IU/mL), brain natriuretic peptide 4265 pg/mL (reference range 0 to 1800 pg/mL), hematocrit 35.7% (reference range 42.0 to 52.0%), hemoglobin 12 g/dL (reference range 14.0 to 18.0 g/dL), international normalized ratio (INR) 2.7 (reference range 0.8 to 1.2), platelets $120 \times 10^3/\mu$ L (reference range 130 to $400 \times 10^3/\mu$ L), prothrombin 27.1 seconds (reference range 11.5 to 14.9 seconds), red blood cell count (RBC) $3.79 \times 10^6/\mu$ L (reference range 4.70 to $6.10 \times 10^6/\mu$ L), and troponin 45 ng/L (reference range ≤ 22 ng/L).

On 02 Mar 2021 (Study Day 179), an echocardiogram showed mild concentric ventricular hypertrophy with an ejection fraction of 55 to 60% and mild valvular abnormalities. Cardiology was consulted as well. The diagnostic impression was decompensated congestive heart failure exacerbation, abnormal cardiac markers without any clinical signs of acute coronary syndrome, chronic atrial fibrillation, and pacemaker. The plan of care included adding metoprolol PO, strict intake and output, daily weight measurements, low sodium diet, and 1200 mL fluid restriction. Laboratory test results included creatine 1.32 mg/dL, glucose 101 mg/dL (reference range 70 to 99 mg/dL), hematocrit 36.6%, hemoglobin 12.5 g/dL, INR 2, platelets $123 \times 10^3/\mu$ L, prothrombin 21.7 seconds, RBC $3.95 \times 10^6/\mu$ L, and troponin 44 ng/L.

On 03 Mar 2021 (Day 180), the participant was cleared by cardiology and discharged from the hospital. The participant's discharge diagnoses included chest pain, chronic atrial fibrillation, coagulopathy, dyslipidemia, elevated brain natriuretic peptide, elevated troponin, essential hypertension, pedal edema, stage 3 kidney disease, and type 2 myocardial infarction. The participant's vital signs were temperature 97.5°F, heart rate 61 bpm, respirations 16 breaths/min, oxygen saturation 99%, and blood pressure 141/77 mm Hg. Laboratory test results included creatine 1.33 mg/dL, glucose 104 mg/dL, hematocrit 35.1%, hemoglobin 11.7 g/dL, INR 1.7, platelets $127 \times 10^3/\mu$ L, prothrombin 18.9 seconds, and RBC $3.71 \times 10^6/\mu$ L. It was reported that the slight elevation in troponin could have been from the participant's chronic kidney disease. The participant was instructed to resume activities as tolerated and to follow up with their doctor in 4 days. Treatment included hydrocodone for pain; amlodipine, metoprolol, and furosemide for hypertension; and acetylsalicylic acid for blood thinner (all PO). Additionally, the participant was started on donepezil for dementia, finasteride for benign prostatic hypertrophy, ropinirole for tremors, sildenafil for erectile function, and alendronate for osteoporosis.

On 04 Mar 2021 (Day 181), laboratory results included creatine 1.44 mg/dL, glucose 96 mg/dL, hematocrit 36.3%, hemoglobin 12.1 g/dL, INR 1.7, platelets $144 \times 10^3/\mu$ L, prothrombin 19.4 seconds, and RBC $3.86 \times 10^6/\mu$ L.

On 12 Mar 2021 (Day 189), the participant experienced SAEs of anticoagulation drug level above therapeutic, cardiac failure congestive, and gastrointestinal hemorrhage. The participant's spouse reported that the participant was taken via ambulance to the hospital, where they were admitted and ultimately died on the same day. An autopsy was not performed.

Action taken with study drug in response to the events was not applicable, as the participant had already received both scheduled doses.

The event of chest pain was reported as resolved on 03 Mar 2021 (Study Day 180).

The events of anticoagulation drug level above therapeutic, cardiac failure congestive, and gastrointestinal hemorrhage were reported as fatal on 12 Mar 2021 (Day 189). Per the death certificate, the primary cause of death was supra therapeutic INR. The secondary cause of death was gastrointestinal bleed. The tertiary cause of death was congestive heart failure.

The investigator assessed the events, anticoagulation drug level above therapeutic, cardiac failure congestive, and gastrointestinal hemorrhage, and chest pain, as not related to study IP and not related to study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-032086	Chest pain
MOD-2021-032086	Anticoagulation drug level above therapeutic
MOD-2021-032086	Cardiac failure congestive
MOD-2021-032086	Gastrointestinal hemorrhage

Study Completion/Discontinuation

On 12 Mar 2021 (Study Day 189), the participant discontinued from the study due to death. On 12 Mar 2021 (Study Day 189), the participant died due to adverse events. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Benign prostatic hyperplasia	Benign prostatic hypertrophy	Not reported - Ongoing
Coronary artery disease	Coronary artery disease	Not reported - Ongoing
Depression	Depression	Not reported - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	Not reported - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	Not reported - Ongoing
Hypertension	Hypertension	Not reported - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Intervertebral disc degeneration	Degenerative disk disease	Not reported - Ongoing
Neuropathy peripheral	Neuropathy	Not reported - Ongoing
Osteoporosis	Osteoporosis	Not reported - Ongoing
Food allergy	Allergies, shellfish	1960 - Ongoing
Obesity	Severe obesity	2012 - Ongoing
Atrial fibrillation	Atrial fibrillation	2013 - Ongoing
Cardiac pacemaker insertion	Pacemaker placement	2013 - 2013

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	Not reported - Ongoing	Hypertension
Ascorbic acid; vitamin b complex	Not reported - Ongoing	Supplement
Atorvastatin	Not reported - Ongoing	Hypercholesterolemia
Calcium citrate; vitamin d nos	Not reported - Ongoing	Supplement
Citalopram	Not reported - Ongoing	Depression
Colecalciferol	Not reported - Ongoing	Supplement
Docusate sodium	Not reported - Ongoing	Supplement
Gabapentin	Not reported - Ongoing	Neuropathy
Glyceryl trinitrate	Not reported - Ongoing	Atrial Fibrillation
Hydralazine	Not reported - Ongoing	Coronary Artery Disease
Iron	Not reported - Ongoing	Supplement
Lactulose	Not reported - Ongoing	Intermittent Constipation
Pantoprazole	Not reported - Ongoing	Gastroesophageal Reflux Disease
Paracetamol	Not reported - Ongoing	Back Pain
Prednisone	Not reported - Ongoing	Low Corticosteroid Level
Tamsulosin	Not reported - Ongoing	Benign Prostatic Hypertrophy
Warfarin sodium	Not reported - Ongoing	Blood Thinner
Tamsulosin	03 Feb 2021 (Study Day 152) - Ongoing	Bph
Chest xr*	01 Mar 2021 (Study Day 178) - 01 Mar 2021 (Study Day 178)	Adverse Event
Echocardiogram*	02 Mar 2021 (Study Day 179) - 02 Mar 2021 (Study Day 179)	Adverse Event
Acetylsalicylic acid	03 Mar 2021 (Study Day 180) - Ongoing	Blood Thinner
Alendronate sodium	03 Mar 2021 (Study Day 180) - Ongoing	Osteoporosis
Amlodipine	03 Mar 2021 (Study Day 180) - Ongoing	Htn
Donepezil	03 Mar 2021 (Study Day 180) - Ongoing	Dementia
Finasteride	03 Mar 2021 (Study Day 180) - Ongoing	Bph
Furosemide	03 Mar 2021 (Study Day 180) - Ongoing	Hypertension
Hydrocodone	03 Mar 2021 (Study Day 180) - Ongoing	Pain
Metoprolol	03 Mar 2021 (Study Day 180) - Ongoing	Htn

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ropinirole	03 Mar 2021 (Study Day 180) - Ongoing	Tremors
Sildenafil	03 Mar 2021 (Study Day 180) - Ongoing	Erectile Dysfunction
Warfarin	03 Mar 2021 (Study Day 180) - Ongoing	A-Fib

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US324-2013 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 06 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 26 Jan 2021 (Study Day 174)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy, SAE, AE leading to IP withdrawal

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure during pregnancy/ Drug exposure before pregnancy	Pregnancy	Not applicable	Not related	28 Jan 2021 (Study Day 176) - 17 Mar 2021 (Study Day 224)	Recovered/ resolved
Abortion Spontaneous/ Spontaneous Abortion	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	17 Mar 2021 (Study Day 224) – 17 Mar 2021 (Study Day 224)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US324-2013, a 33-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 26 Jan 2021. The participant was unblinded on 26 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 26 Jan 2021 (Study Day 174). The second dose was not administered.

Event Details

On 17 Mar 2021 (Study Day 224), 223 days after the first dose in Part A/50 days after the first dose in Part B and 195 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 4 serious adverse event of abortion spontaneous. The IP dose was withdrawn due to the spontaneous abortion. The event of spontaneous abortion lasted for 1 day, after which it was considered to be recovered/resolved on 17 Mar 2021 (Study Day 224). The investigator assessed the event of abortion spontaneous to be not related to the IP.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 11 Mar 2021 (Study Day 218).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	06 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	03 Sep 2020 (Study Day 29)	Negative
Choriogonadotropin Beta	26 Jan 2021 (Study Day 174)	Negative
Choriogonadotropin Beta	11 Mar 2021 (Study Day 218)	Positive
Choriogonadotropin Beta	19 Apr 2021 (Study Day 257)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 05 Feb 2021 (Study Day 184), the participant had a positive urine pregnancy test. The participant was not using birth control or other means of contraception. The first day of the participant's last menstrual period was on 04 Jan 2021 (Study Day 152). The estimated date of conception was 28 Jan 2021 (Study Day 176) and the estimated due date was November 2021. On 22 Feb 2021 (Study Day 201), the participant saw their obstetrics and gynecology (OBGYN) physician and their urine pregnancy test was positive. The participant had small amount of vaginal bleeding occurring only once approximately 3 weeks prior to the OBGYN visit. On 11 Mar 2021 (Study Day 218), the participant had a positive urine pregnancy test.

On 17 Mar 2021 (Study Day 224), the participant experienced a serious adverse event of spontaneous abortion. On the same day, the participant began having heavy uterine bleeding and went to the emergency department (ED). The participant reported waking up that morning and noticed a lot of blood in the bed and every time they went to the bathroom, they had large blood clots come out along with heavy vaginal bleeding. The participant reported using 2 pads every hour since once the bleeding started. The participant reported feeling lightheaded and dizzy and denied trauma, chest pain, shortness of breath, nausea, or vomiting. The participant experienced a spontaneous abortion and was slightly hypotensive and tachycardic upon arrival to the ED. Initial vital signs included blood pressure (BP) 104/70 mm Hg, pulse 112 beats per minute (bpm), respirations 20 breaths/minute, and oxygen saturation 98%. Initial laboratory test results included white blood cell count (WBC) $9.80 \times 10^3/\mu\text{L}$ (reference range 3.40 to $10.80 \times 10^3/\mu\text{L}$), hemoglobin 12.3 g/dL (reference range 11.4 to 16.0 g/dL), hematocrit 36.2% (reference range 34.0 to 47.0%) and quantitative human chorionic gonadotropin (HCG) was 12,527 mIU/mL (reference range 0.1 to 5.0 mIU/mL). The participant was approximately 10 weeks pregnant at the time and there were no reported prior problems. The OBGYN was consulted for plan of care. The

participant's ultrasound showed no visual of intrauterine gestational sac, the endometrium appeared thickened and heterogeneous, a hyperechoic area potentially representing blood products within the lower uterine segment measuring $2.6 \times 2.1 \times 2.3$ cm, and no ovarian torsion was noted. The initial vaginal examination showed moderate amount of vaginal bleeding and clots. The second vaginal examination 2 hours after 1 dose of misoprostol PO showed bleeding but slightly improved from initial examination. The third vaginal examination 3 hours after misoprostol showed that the bleeding had stopped. The participant received another dose of misoprostol PO, 4 hours after first dose for a total of 2 doses of misoprostol PO. Additional treatment for the event included ketorolac IV and sodium chloride IV. No surgical procedures were performed. The participant's vital signs at time of discharge from ED were BP 104/59 mm Hg, respirations 18 breaths per minute, temperature 98.6°F, pulse 94 bpm, and oxygen saturation 98%. Final laboratory results included WBC $12.70 \times 10^3/\mu\text{L}$, hemoglobin 10.4 g/dL, and hematocrit 31.4%. The participant did not stay in the hospital despite being told they could be admitted if needed. The participant was discharged home from the ED on the same day in stable condition. The clinical impression was incomplete miscarriage.

On 19 Apr 2021 (Study Day 257), the participant had a negative urine pregnancy test. The study IP was withdrawn in response to the event.

The event, spontaneous abortion, was reported as resolved on 17 Mar 2021 (Study Day 224).

The investigator assessed the event, spontaneous abortion, as not related to study IP and not related to study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-038583	Drug exposure before pregnancy
MOD-2020-038583	Spontaneous abortion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No prior or concomitant medications or procedures were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	22 Feb 2021 (Study Day 201) - Ongoing	Supplement For Pregnancy
Ketorolac	17 Mar 2021 (Study Day 224) - 17 Mar 2021 (Study Day 224)	Spontaneous Abortion
Misoprostol	17 Mar 2021 (Study Day 224) - 17 Mar 2021 (Study Day 224)	Spontaneous Abortion
Sodium chloride	17 Mar 2021 (Study Day 224) - 17 Mar 2021 (Study Day 224)	Spontaneous Abortion

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US324-2089 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 14 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 25 Jan 2021 (Study Day 165)
Second Dose of Vaccine in Part B: 23 Feb 2021 (Study Day 194)
Reason for Narrative: Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Accidental Overdose/Inadvertent Drug Overdose	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	02 Mar 2021 (Study Day 201) – 04 Mar 2021 (Study Day 203)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US324-2089, a 30-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 25 Jan 2021. The participant was unblinded on 25 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 25 Jan 2021 (Study Day 165). The second dose was administered in the left arm on 23 Feb 2021 (Study Day 194).

Event Details

On 02 Mar 2021 (Study Day 201), 200 days after the first dose in Part A/36 days after the first dose in Part B and 172 days after the second dose in Part A/7 days after the second dose in Part B of the IP, the participant experienced a Grade 5 serious adverse event of accidental overdose. Action taken with the IP was not applicable. The event of inadvertent drug overdose lasted for 3 days, after which it was considered to be fatal on 04 Mar 2021 (Study Day 203). The investigator assessed the event of accidental overdose to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 02 Mar 2021 (Study Day 201), the participant experienced a fatal serious adverse event of accidental overdose.

On 04 Mar 2021 (Study Day 203), the participant's sibling contacted the site to advise that the participant had died on the same day due to a drug overdose. They did not receive any treatment or medical intervention.

Action taken with study IP in response to the event of accidental overdose was not applicable, as the participant had already received both scheduled doses.

The event, accidental overdose, was reported as fatal, and the participant died on 04 Mar 2021 (Study Day 203). An autopsy was performed, but the autopsy report was not received by the investigator. The death certificate noted injury occurred on 02 Mar 2021 (Study Day 201) with approximate interval between onset and death of minutes to hours and an inadvertent drug overdose with cause of death listed as fentanyl, xylazine, and cocaine toxicity.

The investigator assessed the event, accidental overdose, as not related to study IP and study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-045526	Accidental overdose

Study Completion/Discontinuation

On 04 Mar 2021 (Study Day 203), the participant discontinued from the study due to death. On 04 Mar 2021 (Study Day 203), the participant died due to adverse event. An autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Oral herpes	Herpes simplex virus 2, oral	2010 - Ongoing
Hypothyroidism	Hypothyroidism	2014 - Ongoing
Intra-uterine contraceptive device insertion	Intrauterine device placement	2015 - 2015
Bipolar disorder	Bipolar	2016 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit disorder	2017 - Ongoing
Obesity	Obesity	2017 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	2018 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2018 - Ongoing
Allergy to arthropod bite	Allergy-ant bites	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Valaciclovir hydrochloride	2010 - Ongoing	Herpes Simplex Virus 2, Oral
Levothyroxine	2014 - Ongoing	Hypothyroidism
Levonorgestrel	2015 - Ongoing	Birth Control
Aripiprazole	2016 - Ongoing	Bipolar
Amphetamine aspartate; amphetamine sulfate; dexamphetamine saccharate; dexamphetamine sulfate	2017 - Ongoing	Attention Deficit Disorder
Clonidine	2018 - Ongoing	Anxiety
Vitamin d nos	2018 - Ongoing	Vitamin D Deficiency
Botulinum toxin type a	2019 - Ongoing	Cosmetic
Diphenhydramine hydrochloride	Mar 2019 - Mar 2019	Ant Allergy
Epinephrine	Mar 2019 - Mar 2019	Ant Allergy
Ibuprofen	12 Dec 2020 (Study Day 121) - 19 Dec 2020 (Study Day 128)	Upper Respiratory Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US325-2665 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 14 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 11 Nov 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	06 Mar 2021 (Study Day 144) - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2665, a 29-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 14 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 11 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 07 Jan 2021. The participant was unblinded on 07 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	14 Oct 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	11 Nov 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On an unreported day in March 2021, the participant had a positive home pregnancy test. The first day of the participant's last menstrual period was 19 Feb 2021 (Study Day 129), the estimated date of conception was 06 Mar 2021 (Study Day 144), and the estimated due date was 29 Nov 2021

(Study Day 412). The participant was not using any form of contraception. In April 2021, an ultrasound was performed by the participant's obstetrician/gynecologist and was normal.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-179394	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Polycystic ovaries	Polycystic ovarian syndrome	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	14 Oct 2020 (Study Day 1) - 14 Oct 2020 (Study Day 1)	Headache
Metformin	22 Oct 2020 (Study Day 9) - Ongoing	Polycystic Ovarian Syndrome
Paracetamol	12 Nov 2020 (Study Day 30) - 12 Nov 2020 (Study Day 30)	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US327-2116 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 12 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Sep 2020 (Study Day 34)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	18 Mar 2021 (Study Day 219) - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US327-2116, a 28-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 20 Jan 2021. The participant was unblinded on 20 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	12 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	14 Sep 2020 (Study Day 34)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 18 Mar 2021 (Study Day 219), the participant had a positive urine pregnancy test. The first day of the participant's last menstrual period, the estimated date of conception, and the estimated due date were all unreported.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-163002	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone propionate	2018 - Ongoing	Seasonal Allergies
Levocetirizine dihydrochloride	2018 - Ongoing	Seasonal Allergies
Desogestrel; ethinylestradiol	12 Aug 2020 (Study Day 1) - 06 Jan 2021 (Study Day 148)	Contraception

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US330-2310 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 20 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Sep 2020 (Study Day 28)
First Dose of Vaccine in Part B: 26 Jan 2021 (Study Day 160)
Second Dose of Vaccine in Part B: 24 Feb 2021 (Study Day 189)
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pregnancy/Pregnancy	Pregnancy	Not applicable	Not applicable	Not reported - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US330-2310, a 33-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 26 Jan 2021. The participant was unblinded on 26 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 26 Jan 2021 (Study Day 160). The second dose was administered in the left arm on 24 Feb 2021 (Study Day 189).

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	20 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	16 Sep 2020 (Study Day 28)	Negative
Choriogonadotropin Beta	26 Jan 2021 (Study Day 160)	Negative
Choriogonadotropin Beta	24 Feb 2021 (Study Day 189)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On an unreported date in 2021, the participant had a positive pregnancy test. The participant reported using oral contraception.

Action taken with study IP in response to the event was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, pregnancy, was not reported.

The investigator's assessment of the relationship between the event of pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-047494	Pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Norethisterone	Mar 2019 - Ongoing	Oral Contraceptive
Influenza vaccine	10 Oct 2020 (Study Day 52) - 10 Oct 2020 (Study Day 52)	Vaccine
Ibuprofen	01 Nov 2020 (Study Day 74) - 05 Nov 2020 (Study Day 78)	Headache (COVID Symptom)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US330-2327 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 21 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 18 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 26 Jan 2021 (Study Day 159)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	16 Feb 2021 (Study Day 180) – Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US330-2327, a 33-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 26 Jan 2021. The participant was unblinded on 26 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 26 Jan 2021 (Study Day 159). The second dose was not administered.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 26 Feb 2021 (Study Day 190).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	21 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	18 Sep 2020 (Study Day 29)	Negative
Choriogonadotropin Beta	26 Jan 2021 (Study Day 159)	Negative
Choriogonadotropin Beta	26 Feb 2021 (Study Day 190)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 16 Feb 2021 (Study Day 180), the participant had a positive home pregnancy test. The participant was not using any form of contraception. The estimated due date was 25 Oct 2021 (Study Day 431). The participant stated that they had not visited an obstetrician-gynecologist (OBGYN) but had an upcoming appointment in March 2021.

On 17 Feb 2021 (Study Day 181), the participant contacted the site and said they wanted to proceed with obtaining the second dose of study IP. They were informed that due to their pregnancy, this was not possible.

On 26 Feb 2021 (Study Day 190), the participant had a positive urine pregnancy test.

On 10 Mar 2021 (Study Day 202), the participant received a dose of the Moderna COVID-19 vaccination on their left arm at an outside facility after obtaining consent from their OBGYN.

On 15 Mar 2021 (Study Day 207), an ultrasound result was normal.

Study IP was discontinued as a result of the pregnancy.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-015218	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

No prior or concomitant medications or procedures were reported.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US330-2465 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 29 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 27 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/Myocardial Infarction	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	29 Jan 2021 (Study Day 123) – 29 Jan 2021 (Study Day 123)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US330-2465, a 69-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 29 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 27 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 29 Jan 2021 (Study Day 123), 122 days after the first dose in Part A and 94 days after the second dose in Part A of the IP, the participant experienced a Grade 5 serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction was considered to be fatal on 29 Jan 2021 (Study Day 123). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 29 Jan 2021 (Study Day 123), the participant experienced a fatal serious adverse event of myocardial infarction (MI). The participant's family member called the site and reported that the participant had a MI, which led to their death.

On 19 Mar 2021 (Study Day 172), the site reported that they had reached out to the participant's family member several times and were unable to obtain any further information. The participant's family member stated that they were unable to obtain the medical or death records.

Action taken with the study IP was not applicable in response to the event, as the participant had already received both scheduled doses.

The participant died on 29 Jan 2021 (Study Day 123). The cause of death was reported as MI. It was unknown whether an autopsy was performed.

The investigator assessed the event, MI, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-006070	Myocardial infarction

Study Completion/Discontinuation

On 29 Jan 2021 (Study Day 123), the participant discontinued from the study due to death. On 29 Jan 2021 (Study Day 123), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Chronic obstructive pulmonary disease	Copd	2007 - Ongoing
Hypertension	Hypertension	2012 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	2012 - Ongoing
Benign prostatic hyperplasia	Benign prostate hyperplasia	2014 - Ongoing
Polyuria	Polyuria	2015 - Ongoing
Prostate cancer	Prostate cancer	2016 - 2016

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tamsulosin hydrochloride	2014 - Ongoing	Bph
Fesoterodine	2015 - Ongoing	Polyuria

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glipizide	2015 - Ongoing	Diabetes Mellitus Type 2
Lisinopril	2015 - Ongoing	Hypertension
Paracetamol	01 Oct 2020 (Study Day 3) - 01 Oct 2020 (Study Day 3)	Injection Pain
Paracetamol	28 Oct 2020 (Study Day 30) - 28 Oct 2020 (Study Day 30)	Injection Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US331-2006 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 10 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 07 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Myocardial Infarction/Acute Myocardial Infarction	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	09 Mar 2021 (Study Day 212) – 09 Mar 2021 (Study Day 212)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2006, a 62-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 07 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Jan 2021. The participant was unblinded on 21 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 09 Mar 2021 (Study Day 212), 211 days after the first dose in Part A and 183 days after the second dose in Part A of the IP, the participant experienced a Grade 5 serious adverse event of acute myocardial infarction. Action taken with the IP was not applicable. The event of acute myocardial infarction was considered to be fatal on 09 Mar 2021 (Study Day 212). The investigator assessed the event of acute myocardial infarction to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 09 Mar 2021 (Study Day 212), the participant experienced a fatal serious adverse event of acute myocardial infarction. Their spouse reported that they woke up and found that the participant had died during the night; the participant was pronounced dead by emergency medical services at 07:26. The participant had a history of hypertension and bradycardia, reportedly followed by their primary care provider.

Action taken with the study IP was not applicable in response to the event, as the participant had already received both scheduled doses.

The participant died on 09 Mar 2021 (Study Day 212). On 10 Mar 2021 (Study Day 213), an autopsy was performed that revealed the cause of death as hypertensive and atherosclerotic cardiovascular disease.

The investigator assessed the event, acute myocardial infarction, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-066920	Acute myocardial infarction

Study Completion/Discontinuation

On 09 Mar 2021 (Study Day 212), the participant discontinued from the study due to death. On 09 Mar 2021 (Study Day 212), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Athletic heart syndrome	Athletis bradycardia	1980 - Ongoing
Hand fracture	Fracture of middle finger	1982 - 1982
White coat hypertension	White coat hypertension	10 Aug 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	1988 - Ongoing	Health Maintenance
Fish oil	2015 - Ongoing	Health Maintenance
Influenza vaccine	22 Oct 2020 (Study Day 74) - 22 Oct 2020 (Study Day 74)	Seasonal Influenza Vaccine

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Blood Pressure Systolic Increased	Grade 3/severe	Not related	10 Aug 2020 (Study Day 1) - 07 Sep 2020 (Study Day 29)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US331-2551 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Oct 2020 (Study Day 31)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	14 Jan 2021 (Study Day 129) - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2551, a 28-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 28 Dec 2020. The participant was unblinded on 28 Dec 2020 and had already received both doses of mRNA-1273 in Part A.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	08 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	08 Oct 2020 (Study Day 31)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 25 Jan 2021 (Study Day 140), the participant had a positive urine pregnancy test. The first day of the participant's last menstrual period was 03 Jan 2021 (Study Day 118), the estimated date of conception was 14 Jan 2021 (Study Day 129), and the estimated due date was 10 Oct 2021 (Study Day 398). The participant stopped using ethinylestradiol/etonogestrel after their last menstrual

period. They had 2 normal ultrasounds at 5 weeks and 6 weeks due to accessibility, not due to any complications.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-018657	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dysmenorrhoea	Dysmenorrhea	2006 - Ongoing
Anxiety	Anxiety	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2006 - Jan 2021	Dysmenorrhea
Ethinylestradiol; etonogestrel	May 2020 - 02 Jan 2021 (Study Day 117)	Pregnancy Prophylaxis
Paracetamol	09 Oct 2020 (Study Day 32) - 09 Oct 2020 (Study Day 32)	Fever
Influenza vaccine	23 Oct 2020 (Study Day 46) - 23 Oct 2020 (Study Day 46)	Seasonal Influenza Prophylaxis
Sertraline hydrochloride	22 Dec 2020 (Study Day 106) - Ongoing	Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US332-2409 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 02 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 05 Nov 2020 (Study Day 35)
First Dose of Vaccine in Part B: 18 Jan 2021 (Study Day 109)
Second Dose of Vaccine in Part B: 12 Feb 2021 (Study Day 134)
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Exposure during pregnancy/Exposure during pregnancy	Pregnancy	Not applicable	Not applicable	28 Jan 2021 (Study Day 119) – Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US332-2409, a 31-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 02 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 05 Nov 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 18 Jan 2021. The participant was unblinded on 18 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 18 Jan 2021 (Study Day 109). The second dose was administered in the left arm on 12 Feb 2021 (Study Day 134).

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	02 Oct 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	05 Nov 2020 (Study Day 35)	Negative
Choriogonadotropin Beta	18 Jan 2021 (Study Day 109)	Negative
Choriogonadotropin Beta	12 Feb 2021 (Study Day 134)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 18 Feb 2021 (Study Day 140), the participant had a positive urine home pregnancy test. The first day of the participant's last menstrual period was 14 Jan 2021 (Study Day 105), the estimated

date of conception was 28 Jan 2021 (Study Day 119), and the estimated due date was 21 Oct 2021 (Study Day 385). The participant was using barrier method of condom with spermicide as contraception during study participation, and the pregnancy was not planned. They reported doing well physically and had normal symptoms such as bloating, breast tenderness, increased urination, and fatigue. The participant had scheduled a medical appointment with primary care physician for referral to obstetrics and gynecology on 01 Mar 2021 (Study Day 151).

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, exposure during pregnancy, was not reported.

The investigator's assessment of the relationship between the event of exposure during pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-018807	Exposure during pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Food allergy	Seafood allergy (itching)	2013 - Ongoing
Headache	Headaches	2016 - Ongoing
Myalgia	Exercise induced muscle aches	2016 - Ongoing
Urticaria	Aspirin allergy (hives generalized)	2016 - Ongoing
Acne	Facial acne	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	Jan 2020 - Ongoing	Supplement
Naproxen	04 Oct 2020 (Study Day 3) - 04 Oct 2020 (Study Day 3)	Muscle Aches

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Aciclovir	19 Oct 2020 (Study Day 18) - 23 Oct 2020 (Study Day 22)	Shingles
Nortriptyline	19 Oct 2020 (Study Day 18) - Ongoing	Shingles
Valaciclovir	19 Oct 2020 (Study Day 18) - 26 Oct 2020 (Study Day 25)	Shingles
Amoxicillin; clavulanic acid	23 Oct 2020 (Study Day 22) - 02 Nov 2020 (Study Day 32)	Dog Bite
Diphtheria vaccine toxoid; pertussis vaccine; tetanus vaccine toxoid	23 Oct 2020 (Study Day 22) - 23 Oct 2020 (Study Day 22)	Preventative Healthcare
Ibuprofen	23 Oct 2020 (Study Day 22) - 26 Oct 2020 (Study Day 25)	Dog Bite
Ketorolac	23 Oct 2020 (Study Day 22) - 26 Oct 2020 (Study Day 25)	Dog Bite
Mupirocin	23 Oct 2020 (Study Day 22) - 01 Dec 2020 (Study Day 61)	Dog Bite
Guaifenesin	07 Nov 2020 (Study Day 37) - 12 Nov 2020 (Study Day 42)	Symptomatic COVID-19
Ibuprofen	15 Nov 2020 (Study Day 45) - Ongoing	Headaches
Prednisone	09 Jan 2021 (Study Day 100) - 15 Jan 2021 (Study Day 106)	Tennis Elbow
Paracetamol	18 Feb 2021 (Study Day 140) - Ongoing	Abdominal Cramps (Pregnancy)
Vitamins nos	26 Feb 2021 (Study Day 148) - Ongoing	Pregnancy
Simeticone	08 Mar 2021 (Study Day 158) - Ongoing	Pregnancy
Ondansetron	14 Mar 2021 (Study Day 164) - Ongoing	Nausea/Vomiting

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US334-2204 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 26 Oct 2020 (Study Day 49)
First Dose of Vaccine in Part B: 12 Jan 2021 (Study Day 127)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	18 Jan 2021 (Study Day 133) - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2204, a 34-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 26 Oct 2020 (Study Day 49). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 12 Jan 2021 (Study Day 127). The second dose was not administered.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	08 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	26 Oct 2020 (Study Day 49)	Negative
Choriogonadotropin Beta	12 Jan 2021 (Study Day 127)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 05 Feb 2021 (Study Day 151), the participant had a positive pregnancy test. The first day of the participant's last menstrual period was 01 Jan 2021 (Study Day 116), the estimated date of conception was 18 Jan 2021 (Study Day 133), and the estimated due date was not reported. The

participant reported using a cervical cap for contraception. The participant reported that a follow-up appointment would be scheduled with obstetrics and gynecology in 2 weeks.

Study IP dosing was discontinued in response to the pregnancy.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012098	Drug exposure before pregnancy

Study Completion/Discontinuation

On 10 Feb 2021 (Study Day 156), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Pectus excavatum	Pectus excavatum	1985 - Ongoing
Seasonal allergy	Seasonal allergies	1990 - Ongoing
Acne	Acne	2000 - Ongoing
Headache	Headaches	2000 - Ongoing
Restrictive pulmonary disease	Restrictive lung disease due pectus excavation	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2000 - Ongoing	Seasonal Allergies
Loratadine	2000 - Ongoing	Seasonal Allergies
Influenza vaccine	10 Nov 2020 (Study Day 64) - 10 Nov 2020 (Study Day 64)	Influenza Prophylaxis
Other viral vaccines	09 Feb 2021 (Study Day 155) - 09 Feb 2021 (Study Day 155)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US335-2304 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 29 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 13 Feb 2021 (Study Day 166)
Second Dose of Vaccine in Part B: 20 Mar 2021 (Study Day 201)
Reason for Narrative: Pregnancy, SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not related	31 Mar 2021 (Study Day 212) – 09 Apr 2021 (Study Day 221)	Recovered/resolved
Abortion Spontaneous/Miscarriage	SAE	Grade 4	Not related	09 Apr 2021 (Study Day 221) – 09 Apr 2021 (Study Day 221)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US335-2304, a 33-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 13 Feb 2021. The participant was unblinded on 13 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 13 Feb 2021 (Study Day 166). The second dose was administered in the left arm on 20 Mar 2021 (Study Day 201).

Event Details

On 09 Apr 2021 (Study Day 221), 220 days after the first dose in Part A/55 days after the first dose in Part B and 192 days after the second dose in Part A/20 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of abortion spontaneous. Action taken with the IP was not applicable. The event of miscarriage was considered to be recovered/resolved on 09 Apr 2021 (Study Day 221). The investigator assessed the event of abortion spontaneous to be not related to the IP.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	01 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	29 Sep 2020 (Study Day 29)	Negative
Choriogonadotropin Beta	13 Feb 2021 (Study Day 166)	Negative
Choriogonadotropin Beta	20 Mar 2021 (Study Day 201)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 31 Mar 2021 (Study Day 212), the participant had a positive home urine pregnancy test. The participant reported using condoms with spermicide as a method of contraception. The first day of the participant's last menstrual period was 24 Feb 2021 (Study Day 177), the estimated date of conception was unreported and the estimated due date was not applicable.

On 09 Apr 2021 (Study Day 221), the participant experienced a serious adverse event of abortion spontaneous which was considered as medically significant. On an unspecified date, the participant was contacted and reported having a miscarriage on 09 Apr 2021 (Study Day 221). The participant started having bleeding and pain and went to the emergency department (ED). Laboratory test results for human chorionic gonadotropin (HCG) quantitative in blood was $>1.5 \times 10^4$ (no units and reference range reported), and beta HCG quantitative retest was $>2.39991 \times 10^5$. An ultrasound showed subchorionic hemorrhage. A miscarriage was confirmed at that time. Treatment included cephalexin, ibuprofen and paracetamol (all PO) for abdominal pain. No COVID-19 testing was performed during the ED visit. The participant was in the hospital for about 12 hours.

Action taken with study IP in response to the event (abortion spontaneous) was not applicable, as the participant had already received both scheduled doses.

The event, abortion spontaneous, was reported as resolved on 09 Apr 2021 (Study Day 221).

The investigator assessed the event, abortion spontaneous, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the pregnancy and serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-077024	Drug exposure before pregnancy
MOD-2021-077024	Abortion spontaneous

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Somnambulism	Somnambulism	(b) (6) 1987 - Ongoing
Asthma	Moderate asthma	1990 - Ongoing
Headache	Headaches	1995 - Ongoing
Seasonal allergy	Seasonal allergies	1995 - Ongoing
Acne	Acne	2000 - 2005
Mammoplasty	Surgery - breast augmentation	2005 - 2005
Gastroesophageal reflux disease	Acid reflux	2006 - Ongoing
Skin cosmetic procedure	Facial cosmetic procedure in forehead	01 Jan 2014 (Study Day -2435) - 01 Jan 2014 (Study Day -2435)
Depression	Depression	Jun 2014 - Nov 2014
Caesarean section	Surgery - c-section	06 Oct 2015 (Study Day -1792) - 06 Oct 2015 (Study Day -1792)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1990 - Ongoing	Asthma
Cetirizine	1995 - Ongoing	Seasonal Allergies
Ibuprofen	08 Sep 2020 (Study Day 8) - 08 Sep 2020 (Study Day 8)	Headache
Paracetamol	08 Sep 2020 (Study Day 8) - 08 Sep 2020 (Study Day 8)	Headache
Ciprofloxacin	20 Oct 2020 (Study Day 50) - 03 Nov 2020 (Study Day 64)	Urinary Tract Infection
Nitrofurantoin	10 Dec 2020 (Study Day 101) - 20 Dec 2020 (Study Day 111)	Urinary Tract Infection
Ibuprofen	13 Dec 2020 (Study Day 104) - 03 Jan 2021 (Study Day 125)	COVID 19
Pantoprazole	20 Jan 2021 (Study Day 142) - Ongoing	Acid Reflux
Ibuprofen	13 Feb 2021 (Study Day 166) - 14 Feb 2021 (Study Day 167)	Fever
Paracetamol	13 Feb 2021 (Study Day 166) - 14 Feb 2021 (Study Day 167)	Pain At Injection Arm
Ibuprofen	19 Feb 2021 (Study Day 172) - Ongoing	Headache
Paracetamol	19 Feb 2021 (Study Day 172) - Ongoing	Headache

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	20 Mar 2021 (Study Day 201) - 26 Mar 2021 (Study Day 207)	Body Chills
Paracetamol	20 Mar 2021 (Study Day 201) - 26 Mar 2021 (Study Day 207)	Headache
Paracetamol	20 Mar 2021 (Study Day 201) - 26 Mar 2021 (Study Day 207)	Pain At Injection Site

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 2/moderate	Related	19 Feb 2021 (Study Day 172) - 26 Feb 2021 (Study Day 179)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US337-2089 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 11 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: 18 Jan 2021 (Study Day 161)
Second Dose of Vaccine in Part B: 15 Feb 2021 (Study Day 189)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Muscular Weakness/Muscle Weakness Lower Extremities	SAE	Grade 3/ severe	Related	16 Feb 2021 (Study Day 190) – 17 Feb 2021 (Study Day 191)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US337-2089, a 74-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 18 Jan 2021. The participant was unblinded on 18 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 18 Jan 2021 (Study Day 161). The second dose was administered in the left arm on 15 Feb 2021 (Study Day 189).

Event Details

On 16 Feb 2021 (Study Day 190), 189 days after the first dose in Part A/29 days after the first dose in Part B and 160 days after the second dose in Part A/1 day after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of muscular weakness. Action taken with the IP was not applicable. The event of muscle weakness lower extremities lasted for 2 days, after which it was considered to be recovered/resolved on 17 Feb 2021 (Study Day 191). The investigator assessed the event of muscular weakness to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 15 Feb 2021 (Study Day 189), in the evening, the participant experienced fever and generalized fatigue, and sustained a minor fall because of extremity weakness.

On 16 Feb 2021 (Study Day 190), at 02:50, the participant experienced a serious adverse event of muscular weakness in the lower extremities. The participant reported fever of greater than 102°F and urinary retention starting in the middle of the night. The participant went to the emergency department (ED) due to severe muscle weakness of the lower extremities as they were unable to stand. The investigator contacted the ED physician attending to the participant. The participant was afebrile in the ED, their urinary retention resolved, but they still had weakness in both lower extremities and difficulty walking. The participant denied experiencing chest pain, shortness of breath, loss of consciousness, cough, or any other symptoms other than generalized weakness and fever. The participant also denied experiencing any side effects with their first dose. The participant was admitted for observation only and overnight monitoring. Testing for the event and COVID-19 testing were not performed. Treatment included paracetamol PO for fever.

On 17 Feb 2021 (Study Day 191), the participant was discharged in stable condition with recommendation to follow-up as an outpatient. The participant was recommended to visit an ED if symptoms worsened.

Action taken with study IP in response to the event was not applicable, as the participant had already received both scheduled doses.

The event, muscular weakness, was resolved on 17 Feb 2021 (Study Day 191).

The investigator assessed the event, muscular weakness, as related to study IP and related to study procedure. There were no underlying or predisposing risk factors associated with the event.

The sponsor assessed the event, muscle weakness lower extremities, as related to study IP and not related to study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014796	Muscular weakness

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cartilage injury	Torn cartilage right knee	1968 - 1968
Knee arthroplasty	Arthroplasty right knee	1968 - 1968
Intervertebral disc protrusion	Herniated disc cervical spine	1989 - 1989
Osteoarthritis	Generalized osteoarthritis	1990 - Ongoing
Obesity	Obesity	1994 - 1994
Vasectomy	Vasectomy	1994 - 1994
Spinal fusion surgery	Cervical fusion	1995 - 1995
Dermatitis	Bilateral upper extremity dermatoses	2000 - Ongoing
Osteoarthritis	Osteoarthritis right shoulder	2005 - Ongoing
Joint debridement	Arthroscopic debridement right shoulder	2012 - 2012
Hyperlipidaemia	Hyperlipidemia	2017 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2018 - Ongoing
Neuropathy peripheral	Peripheral neuropathy	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrocortisone	2005 - Ongoing	Bilateral Upper Extremity Dermatitis
Simvastatin	2017 - Ongoing	Hyperlipidemia
Paracetamol	2018 - Ongoing	Generalized Arthritis
Pneumococcal vaccine	2018 - 2018	Pneumonia Prophylaxis/Prevention
Omeprazole	Aug 2018 - Ongoing	Gastroesophageal Reflux Disease
Gabapentin	2019 - Ongoing	Peripheral Neuropathy
Influenza vaccine	Sep 2019 - Sep 2019	Influenza Prophylaxis/Prevention
Biopsy basal cell carcinoma - right shoulder lateral*	18 Aug 2020 (Study Day 8) - 18 Aug 2020 (Study Day 8)	Adverse Event
Biopsy squamous cell carcinoma - left posterior upper arm*	18 Aug 2020 (Study Day 8) - 18 Aug 2020 (Study Day 8)	Adverse Event
Basal cell carcinoma excision - right shoulder lateral.*	08 Sep 2020 (Study Day 29) - 08 Sep 2020 (Study Day 29)	Adverse Event
Excision squamous cell carcinoma - left posterior upper arm.*	08 Sep 2020 (Study Day 29) - 08 Sep 2020 (Study Day 29)	Adverse Event
Influenza vaccine	25 Sep 2020 (Study Day 46) - 25 Sep 2020 (Study Day 46)	Influenza Prophylaxis/Prevention
Paracetamol	16 Feb 2021 (Study Day 190) - Ongoing	Pyrexia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pyrexia	Grade 2/moderate	Related	16 Feb 2021 (Study Day 190) - 16 Feb 2021 (Study Day 190)
Urinary Retention	Grade 1/mild	Related	16 Feb 2021 (Study Day 190) - 16 Feb 2021 (Study Day 190)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US341-2151 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 06 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Aortic Stenosis/ Worsening Of Aortic Stenosis	SAE	Grade 2/ moderate	Not related	05 Feb 2021 (Study Day 184) – Ongoing	Not recovered/ not resolved
Cerebrovascular Accident/Stroke	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	31 Mar 2021 (Study Day 238) – 02 Apr 2021 (Study Day 240)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2151, a 71-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Jan 2021. The participant was unblinded on 04 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 05 Feb 2021 (Study Day 184), 183 days after the first dose in Part A and 155 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of aortic stenosis. Action taken with the IP was not applicable. The event of worsening of aortic stenosis was considered to be ongoing. The investigator assessed the event of aortic stenosis to be not related to the IP.

On 31 Mar 2021 (Study Day 238), 237 days after the first dose in Part A and 209 days after the second dose in Part A of the IP, the participant experienced a Grade 5 serious adverse event of cerebrovascular accident. Action taken with the IP was not applicable. The event of stroke lasted

for 3 days, after which it was considered to be fatal on 02 Apr 2021 (Study Day 240). The investigator assessed the event of cerebrovascular accident to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 05 Feb 2021 (Study Day 184), the participant experienced a serious adverse event (SAE) of aortic stenosis. An echocardiogram showed that aortic stenosis had worsened from moderate to severe.

On 23 Feb 2021 (Study Day 202), the participant reported that their scheduled left shoulder joint replacement was postponed due to echocardiogram findings.

On 04 Mar 2021 (Study Day 211), the participant consulted a cardiologist. An aortic valve replacement (AVR) procedure was tentatively scheduled for 31 Mar 2021 (Study Day 238).

On 31 Mar 2021 (Study Day 238), the participant experienced a fatal SAE of cerebrovascular accident (CVA). On the same day, the participant was admitted in the hospital and underwent AVR surgery. Following surgery, the participant experienced a stroke while hospitalized. A postoperative assessment showed no motor response on right upper extremity/right lower extremity and left facial droop. A code stroke was called at 17:00. A computerized tomography (CT) scan of the head without contrast showed hypoattenuation in the distribution of the left middle cerebral artery (LMCA), compatible with acute ischemia, with no significant vasogenic edema or mass effect. A CT angiography showed a large area of hypoperfusion in the LMCA territory with a central ischemic core of 57 mL and a 73-mL penumbra. The participant was transferred to another facility for neurological evaluation and underwent a diagnostic cerebral angiogram, with mechanical aspiration thrombectomy of LMCA. The LMCA remained partially occluded. A portable chest x-ray at 22:04 showed mild bibasilar opacities and trace pleural effusion. Relevant laboratory test results showed amylase 14 U/L (reference range 16 to 117 U/L), potassium 5.4 mmol/L (reference range 3.5 to 5.3 mmol/L), glucose 157 mg/dL (reference range 70 to 100 mg/dL), calcium 7.4 mg/dL (reference range 8.6 to 10.3), white blood cell (WBC) count $15.6 \times 10^3/\mu\text{L}$ (reference range 3.8 to $10.8 \times 10^3/\mu\text{L}$), red blood cell count (RBC) count $2.99 \times 10^6/\mu\text{L}$ (reference range 4.2 to $5.80 \times 10^6/\mu\text{L}$), hemoglobin 9.8 g/dL (reference range 13.2 to 17.1 g/dL), hematocrit 28.7% (reference range 38.6 to 50.0%), platelets $120 \times 10^3/\mu\text{L}$ (reference range 140 to $400 \times 10^3/\mu\text{L}$), creatinine kinase 306 U/L (reference range 30 to 223 U/L), free serum calcium 4.15 mg/dL (reference range 4.40 to 5.40 mg/dL), alkaline phosphatase 24 U/L (reference range 36 to 126 U/L), total protein 4.8 g/dL (reference range 6.4 to 8.9 g/dL), albumin 3.3 g/dL (reference range 3.6 to 5.7 g/dL), plasma lactate 2.9 mmol/L (reference range 0.5 to 2.2 mmol/L), international normalized ratio 1.4 (reference range 0.9 to 1.1), venous blood bicarbonate 20 mmol/L (reference range 24 to 28 mmol/L), base excess venous blood -6.4 mmol/L (reference range -2.0 to 3.0 mmol/L), reduced hemoglobin 41.6% (reference range 0.0 to 5.0%), arterial base excess -8 mmol/L (reference range -2.0 to 3.0 mmol/L), arterial blood bicarbonate 21 mmol/L

(reference range 22 to 26 mmol/L), lactate 3.33 mmol/L (reference range 0.5 to 2.2 mmol/L), and arterial pH 7.30 (reference range 7.35 to 7.45). A neurosurgeon was consulted to consider surgical intervention. The participant's family decided against hemicraniotomy and decided to pursue comfort care. Additional treatment included dextrose IV, fentanyl IV, glycopyrrolate IV, midazolam IV, morphine IV, mupirocin intranasal, amiodarone IV, acetylsalicylic acid PO, atorvastatin PO, heparin SC, magnesium sulfate IV, nicardipine IV, 3% sodium chloride, and vasopressin IV. The diagnoses present on admission included status post AVR, LMCA CVA, hypertension, hyperlipidemia, and obstructive sleep apnea.

On 01 Apr 2021 (Study Day 239), a head CT scan without contrast showed interval evolution of the large LMCA stroke with findings of significant cerebral edema to include a new rightward midline shift of 7 mm and likely subfalcine herniation, with no evidence of intracranial hemorrhage. A portable chest x-ray at 05:19 showed increased bibasilar atelectasis, an endotracheal tube projected within 2 cm of the tracheal carina. A portable chest x-ray at 12:55 showed the tip of the feeding tube projected over the distal one-third of the esophagus, otherwise no change, and it was noted that the left side of the chest was not completely imaged on the radiograph. A portable chest x-ray at 12:56 demonstrated the tip of feeding tube in the gastric body. A portable chest x-ray at 15:14 showed the feeding tube tip overlaid on the esophagus, and a subsequent radiograph demonstrated advancement into the stomach and persistent left greater than right bibasilar parenchymal disease. The participant's SARS-CoV-2 nucleic acid amplification test via nasopharyngeal swab collected on 31 Mar 2021 (Study Day 238) had a result of not detected. Relevant laboratory test results showed arterial partial pressure of oxygen (PO₂) 64 mm Hg (reference range 80 to 100 mm Hg), arterial oxyhemoglobin percent 91.3% (reference range 95% to 98%), arterial base excess -2.1 mmol/L at 12:15 and -4 mmol/L at 01:21, arterial carbon dioxide content 22 mmol/L (reference range 23 to 27 mmol/L), WBC $16.5 \times 10^3/\mu\text{L}$, RBC $3.03 \times 10^6/\mu\text{L}$, hemoglobin 9.7 g/dL, hematocrit 29.3%, platelets $137 \times 10^3/\mu\text{L}$, creatinine 1.31 mg/dL (reference range 0.6 to 1.3 mg/dL), glucose 157 mg/dL, calcium 8.1 mg/dL, alkaline phosphatase 25 U/L, total protein 5.2 g/dL, blood lactate 4.4 mmol/L, thromboelastogram activated clotting time 121 seconds (reference range 86.0 to 118.0 seconds), venous blood reduced hemoglobin 48.8%, chloride 111 mmol/L (reference range 99 to 110 mmol/L), point-of-care lactate 3.74 mmol/L (reference range 0.5 to 2.2 mmol/L), and oxygen saturation 90% (reference range 95% to 98%).

On 02 Apr 2021 (Study Day 240), the participant's portable chest x-ray result showed low lung volumes with mildly increased left basilar parenchymal opacities. Relevant laboratory test results showed WBC $18.8 \times 10^3/\mu\text{L}$, RBC $2.70 \times 10^6/\mu\text{L}$, hemoglobin 9.0 g/dL, hematocrit 25.9%, platelets $105 \times 10^3/\mu\text{L}$, chloride 112 mmol/L, calcium 8.0 mg/dL, albumin 3.3 g/dL, venous blood reduced hemoglobin 34.6%, glucose 148 mg/dL, oxygen saturation 90%, and arterial PO₂

54 mm Hg. Blood pressure was noted as 168/79 mm Hg. The participant was given comfort care only and allowed to die peacefully on 02 Apr 2021 (Study Day 240).

Action taken with study IP in response to the event was not applicable, as the participant had already received both scheduled doses.

The event, CVA, was reported as fatal on 02 Apr 2021 (Study Day 240). The event, aortic stenosis, was reported as not resolved at the time of death. The cause of death was a CVA and brain herniation secondary to LMCA CVA.

The investigator assessed the events, aortic stenosis and CVA, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-065720	Aortic stenosis
MOD-2021-065720	Cerebrovascular accident

Study Completion/Discontinuation

On 02 Apr 2021 (Study Day 240), the participant discontinued from the study due to death. On 02 Apr 2021 (Study Day 240), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2010 - Ongoing
Osteoarthritis	Osteoarthritis - both knees, left shoulder	2013 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2016 - Ongoing
Aortic stenosis	Heart murmur (aortic stenosis)	2017 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Losartan	2010 - Ongoing	Hypertension
Irbesartan	2017 - Ongoing	Hypertension
Rosuvastatin	2017 - Ongoing	Hyperlipidemia
Paracetamol	07 Aug 2020 (Study Day 2) - 07 Aug 2020 (Study Day 2)	Solicited Injection Site Pain
Echocardiogram*	05 Feb 2021 (Study Day 184) - 05 Feb 2021 (Study Day 184)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US342-2280 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 15 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Oct 2020 (Study Day 32)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not related	05 Mar 2021 (Study Day 172) - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US342-2280, a 37-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 15 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 16 Oct 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on Not reported. The participant was unblinded on 14 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	15 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	16 Oct 2020 (Study Day 32)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 09 Apr 2021 (Study Day 207), the participant had a positive urine pregnancy test. The first day of the participant's last menstrual period was 28 Feb 2021 (Study Day 167). The estimated date of conception was 05 Mar 2021 (Study Day 172), and the estimated due date was 04 Dec 2021 (Study

Day 446). An ultrasound performed on 27 Apr 2021 (Study Day 225) confirmed a single intrauterine pregnancy.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-101952	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rhinitis allergic	Allergic rhinitis	2012 - Ongoing
Acne	Acne	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; norethisterone acetate	2012 - Ongoing	Birth Control
Fexofenadine hydrochloride	2018 - Ongoing	Allergic Rhinitis
Tretinoin	2020 - Ongoing	Acne
Ibuprofen	17 Oct 2020 (Study Day 33) - 19 Oct 2020 (Study Day 35)	Headache/Body Aches/Pain At Injection Site
Influenza vaccine	13 Nov 2020 (Study Day 60) - 13 Nov 2020 (Study Day 60)	Health Maintenance

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US343-2574 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 29 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 27 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 18 Jan 2021 (Study Day 112)
Second Dose of Vaccine in Part B: 16 Feb 2021 (Study Day 141)
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not related	18 Mar 2021 (Study Day 171) - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2574, a 34-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 29 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 27 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 18 Jan 2021. The participant was unblinded on 18 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 18 Jan 2021 (Study Day 112). The second dose was administered in the left arm on 16 Feb 2021 (Study Day 141).

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	29 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	27 Oct 2020 (Study Day 29)	Negative
Choriogonadotropin Beta	18 Jan 2021 (Study Day 112)	Negative
Choriogonadotropin Beta	16 Feb 2021 (Study Day 141)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 18 Mar 2021 (Study Day 171), the participant had a positive pregnancy test. The first day of the participant's last menstrual period was 01 Feb 2021 (Study Day 126). The participant had a physician's appointment scheduled.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The event, drug exposure before pregnancy, was reported as not reported.

The investigator assessed the event, drug exposure before pregnancy, as not applicable to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-058863	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2010 - Ongoing	General Health

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US343-2580 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 01 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 05 Nov 2020 (Study Day 36)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	28 Mar 2021 (Study Day 179) - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2580, a 43-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 01 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 05 Nov 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 19 Jan 2021. The participant was unblinded on 19 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	01 Oct 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	05 Nov 2020 (Study Day 36)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 26 Apr 2021 (Study Day 208), the participant had a positive urine pregnancy test. The first day of the participant's last menstrual period was 14 Mar 2021 (Study Day 165), the estimated date of conception was 28 Mar 2021 (Study Day 179), and the estimated due date was 28 Dec 2021 (Study Day 454).

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The event, drug exposure before pregnancy, was reported as not reported.

The investigator assessed the event, drug exposure before pregnancy, as not applicable to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-099652	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma (mild)	1980 - Ongoing
Hypertension	Htn	1995 - Ongoing
Hypersensitivity	Environmental allergies	2006 - Ongoing
Depression	Depression	2018 - Ongoing
Insomnia	Insomnia	2018 - Ongoing
Gastroesophageal reflux disease	Gerd	2019 - Ongoing
Eczema	Eczema (right middle digit)	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1980 - Ongoing	Asthma
Cetirizine hydrochloride	2006 - Ongoing	Environmental Allergies
Amlodipine	2008 - Ongoing	Htn
Losartan	2008 - Ongoing	Htn
Biotin	2010 - Ongoing	Hair Growth
Vitamins nos	2015 - Ongoing	General Health (Prophylaxis)
Bupropion hydrochloride	2018 - Ongoing	Depression
Temazepam	2018 - Ongoing	Insomnia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	2019 - Ongoing	Gerd
Betamethasone dipropionate	15 Oct 2020 (Study Day 15) - Ongoing	Eczema
Biotin; keratin	31 Oct 2020 (Study Day 31) - Ongoing	Hair Growth
Paracetamol	06 Nov 2020 (Study Day 37) - 06 Nov 2020 (Study Day 37)	Headaches And Muscle Aches

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US343-2641 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 22 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 25 Nov 2020 (Study Day 35)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	21 Apr 2021 (Study Day 182) - 14 May 2021 (Study Day 205)	Recovered/resolved
Abortion spontaneous/Miscarriage	Pregnancy	Not applicable	Not related	24 Apr 2021 (Study Day 182) - 14 May 2021 (Study Day 205)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2641, a 40-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 22 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 25 Nov 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 08 Jan 2021. The participant was unblinded on 08 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	22 Oct 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	25 Nov 2020 (Study Day 35)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 21 Apr 2021 (Study Day 182), the participant had a positive urine pregnancy test. The first day of the participant's last menstrual period was 14 Mar 2021 (Study Day 144), the estimated date of

conception was not reported, and the estimated due date was 19 Dec 2021 (Study Day 424). The participant reported that they were taking oral contraceptive pills inconsistently.

On 24 Apr 2021 (Study Day 185), the participant experienced a spontaneous abortion at approximately 5 weeks gestation. On that date, the participant had heavy menses, nausea, and pelvic cramping. They were examined by an obstetrician/gynecologist (OBGYN); no further testing was required. Treatment for the event included tramadol PO and an unreported antiemetic PO.

On an unreported date in May 2021, the participant stopped having vaginal bleeding.

On 14 May 2021 (Study Day 205), the participant was feeling well and was due to follow up with their OBGYN.

Action taken with study IP in response to the drug exposure before pregnancy and abortion spontaneous was not applicable, as the participant had already received both scheduled doses.

The events, drug exposure before pregnancy and spontaneous abortion, were reported as resolved on 14 May 2021 (Study Day 205).

The investigator assessed the events, drug exposure before pregnancy and spontaneous abortion, as not related to study IP and procedure.

Additional Information From the Safety Database

Additional details for the pregnancy and spontaneous abortion are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-134701	Drug exposure before pregnancy
MOD-2021-134701	Abortion spontaneous

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Intermittent headaches	2000 - Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing
Carpal tunnel syndrome	Carpal tunnel	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Naproxen sodium	2000 - Ongoing	Headache
Loratadine	2015 - Ongoing	Seasonal Allergies
Salbutamol	2015 - Ongoing	Seasonal Allergies
Ethinylestradiol; norethisterone acetate	Apr 2020 - Ongoing	Birth Control
Ibuprofen	26 Oct 2020 (Study Day 5) - 26 Oct 2020 (Study Day 5)	Headache
Paracetamol	25 Nov 2020 (Study Day 35) - 26 Nov 2020 (Study Day 36)	Injection Site Pain And Muscle Aches
Omeprazole	27 Nov 2020 (Study Day 37) - 27 Nov 2020 (Study Day 37)	Dyspepsia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US344-2074 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 25 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 22 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 19 Jan 2021 (Study Day 148)
Second Dose of Vaccine in Part B: 22 Feb 2021 (Study Day 182)
Reason for Narrative: Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cerebrovascular Accident/Ischemic Cerebrovascular Accident (CVA) (HCC)	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	02 Apr 2021 (Study Day 221) – 06 Apr 2021 (Study Day 225)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US344-2074, a 61-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 19 Jan 2021. The participant was unblinded on 19 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 19 Jan 2021 (Study Day 148). The second dose was administered in the left arm on 22 Feb 2021 (Study Day 182).

Event Details

On 02 Apr 2021 (Study Day 221), 220 days after the first dose in Part A/73 days after the first dose in Part B and 192 days after the second dose in Part A/39 days after the second dose in Part B of the IP, the participant experienced a Grade 5 serious adverse event of cerebrovascular accident. Action taken with the IP was not applicable. The event of ischemic cerebrovascular accident (CVA) (hcc) lasted for 5 days, after which it was considered to be fatal on 06 Apr 2021 (Study Day 225). The investigator assessed the event of cerebrovascular accident to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 02 Apr 2021 (Study Day 221), the participant experienced an SAE of cerebrovascular accident (CVA) and was hospitalized.

On 06 Apr 2021 (Study Day 225), the participant died.

Action taken with study IP in response to the event was not applicable, as the participant had already received both scheduled doses.

The event, CVA, was reported as fatal on 06 Apr 2021 (Study Day 225). The cause of death was reported as stroke.

The investigator assessed the event, CVA, as not related to study IP and not related to study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-069290	Cerebrovascular accident

Study Completion/Discontinuation

On 06 Apr 2021 (Study Day 225), the participant discontinued from the study due to death. On 06 Apr 2021 (Study Day 225), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2009 - Ongoing
Hot flush	Hot flashes	2012 - Ongoing
Postmenopause	Post menopausal	2012 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2013 - Ongoing
Hypertension	Hypertension	2014 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	2009 - Ongoing	Type II Diabetes
Budesonide; formoterol fumarate	2013 - Ongoing	Copd
Hydrochlorothiazide; olmesartan medoxomil	Feb 2020 - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nausea	Grade 1/mild	Related	26 Jan 2021 (Study Day 155) - 10 Feb 2021 (Study Day 170)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US346-2244 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine: 19 Aug 2020 (Study Day 1)
Second Dose of Vaccine: 16 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy, SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pregnancy/Pregnancy On Study	Pregnancy, SAE	Grade 1/ mild	Not related	12 Apr 2021 (Study Day 237) – Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US346-2244, a 27-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 22 Jan 2021. The participant was unblinded on 22 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 12 Apr 2021 (Study Day 237), 236 days after the first dose in Part A and 208 days after the second dose in Part A of the IP, the participant experienced a Grade 1/mild serious adverse event of pregnancy. Action taken with the IP was not applicable. The outcome of the event was unknown. The investigator assessed the event of pregnancy to be not related to the IP.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	19 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	16 Sep 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 22 Dec 2020 (Study Day 126), the participant had their intrauterine device removed. The device was in place during enrollment and for greater than 3 months following second dose on 16 Sep 2020 (Study Day 29).

On 12 Apr 2021 (Study Day 237), the participant had a positive pregnancy test. The first day of the participant's last menstrual period was on 05 Mar 2021 (Study Day 199). The estimated date of conception was 11 Mar 2021 (Study Day 205), and the estimated due date was 22 Dec 2021 (Study Day 491). The participant noticed an absence of regular menstrual period, increased frequency of urination, and a distended abdomen, and went to see primary care provider on this same day.

Action taken with the study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator assessed the event, drug exposure before pregnancy, as not related to the study IP or study procedure.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-078770	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	2008 - Ongoing
Depression	Depression	2008 - Ongoing
Raynaud's phenomenon	Raynaud syndrome	2011 - Ongoing
Seasonal allergy	Seasonal allergic rhinitis	2012 - Ongoing
Drug hypersensitivity	Drug allergy to sulfa medications	2018 - Ongoing
Herpes simplex	Hsv-1	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Desvenlafaxine succinate	2018 - Ongoing	Anxiety/Depression
Valaciclovir hydrochloride	2018 - Ongoing	Hsv-1
Bupropion hydrochloride	May 2020 - 01 Oct 2020 (Study Day 44)	Anxiety/Depression
Paracetamol	19 Aug 2020 (Study Day 1) - 20 Aug 2020 (Study Day 2)	Injection Site Pain/ Headache
Paracetamol	16 Sep 2020 (Study Day 29) - 17 Sep 2020 (Study Day 30)	Injection Site Pain/ Headache
Bupropion hydrochloride	02 Oct 2020 (Study Day 45) - 18 Oct 2020 (Study Day 61)	Depression/Anxiety
Loperamide hydrochloride	03 Dec 2020 (Study Day 107) - 03 Dec 2020 (Study Day 107)	Gastroenteritis, Diarrhea

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	31 Oct 2020 (Study Day 74) - 06 Nov 2020 (Study Day 80)
Gastroenteritis	Grade 2/moderate	Not related	03 Dec 2020 (Study Day 107) - 19 Dec 2020 (Study Day 123)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US346-2421 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 07 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 13 Jan 2021 (Study Day 127)
Second Dose of Vaccine in Part B: 12 Feb 2021 (Study Day 157)
Reason for Narrative: Pregnancy, SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pregnancy/ Pregnancy On The Study	Pregnancy	Grade 1/ mild	Not related	21 Jan 2021 (Study Day 135) – 23 Jan 2021 (Study Day 137)	Recovered/ resolved
Abortion Spontaneous/ Miscarriage	SAE	Grade 2/ moderate	Related	23 Jan 2021 (Study Day 137) – 23 Jan 2021 (Study Day 137)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US346-2421, a 28-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 13 Jan 2021. The participant was unblinded on 13 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 13 Jan 2021 (Study Day 127). The second dose was administered in the left arm on 12 Feb 2021 (Study Day 157).

Event Details

On 21 Jan 2021 (Study Day 135), 134 days after the first dose in Part A/8 days after the first dose in Part B and 106 days after the second dose in Part A/22 days before the second dose in Part B of the IP, the participant experienced a Grade 1/mild serious adverse event of pregnancy. The IP dose was not changed due to the pregnancy on the study. The event of pregnancy on the study lasted for 3 days, after which it was considered to be recovered/resolved on 23 Jan 2021 (Study Day 137). The investigator assessed the event of pregnancy to be not related to the IP.

On 23 Jan 2021 (Study Day 137), 136 days after the first dose in Part A/10 days after the first dose in Part B and 108 days after the second dose in Part A/20 days before the second dose in Part B of

the IP, the participant experienced a Grade 2/moderate serious adverse event of abortion spontaneous. The IP dose was not changed due to the miscarriage. The event of miscarriage lasted for 1 days, after which it was considered to be recovered/resolved on 23 Jan 2021 (Study Day 137). The investigator assessed the event of abortion spontaneous to be related to the IP.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	09 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	07 Oct 2020 (Study Day 29)	Negative
Choriogonadotropin Beta	13 Jan 2021 (Study Day 127)	Negative
Choriogonadotropin Beta	12 Feb 2021 (Study Day 157)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 21 Jan 2021 (Study Day 135), the participant performed a pregnancy test at home when their next menstrual cycle (expected to start on or around 16 to 18 Jan 2021 [Study Days 130 to Study Day 132]) had not started, the result of the pregnancy test was positive. The participant's last menstrual period started on approximately 16 Dec 2020 (Day 99) and they reported regular menses.

On 23 Jan 2021 (Study Day 137), the participant experienced a serious adverse event of spontaneous abortion and started bleeding. The participant initially thought that they might be starting their next menses; however, the participant noticed that there were clots along with normal bleeding. The participant continued to bleed for next 6 days. On 29 Jan 2021 (Study Day 143), the participant's bleeding stopped. The participant had not taken any additional pregnancy tests but believed that they had a miscarriage and were no longer pregnant. The participant reported minimal symptoms and felt stable. The participant had not seen their physician but was scheduled to be seen. The events of pregnancy and miscarriage were considered to be medically significant.

No action was taken with the study IP in response to the events as the participant had already received both doses.

The participant informed the investigator about the pregnancy and abortion spontaneous and was in between doses. The investigator confirmed that the participant was okay to continue in the study.

The event, pregnancy on the study, was reported as resolved on 23 Jan 2021 (Study Day 137). The event, spontaneous abortion, was reported as resolved on the same day.

The investigator assessed the event, pregnancy on the study, as not related to the study drug. The investigator assessed the event, spontaneous abortion, as related to the study drug due to temporal relationship. The investigator assessed both the events as not related to the study procedure.

According to the sponsor, the event of abortion spontaneous was considered not related to the study IP in disagreement with the investigator's assessment. The participant had not taken an additional pregnancy test or seen a physician.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010409	Pregnancy
MOD-2021-010409	Abortion spontaneous

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

No prior or concomitant medications or procedures were reported.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US349-2061 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 05 Oct 2020 (Study Day 32)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/ Drug exposure before pregnancy	Pregnancy	Not applicable	Not related	14 Feb 2021 (Study Day 164) - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2061, a 30-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 05 Oct 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 20 Jan 2021. The participant was unblinded on 20 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	04 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	05 Oct 2020 (Study Day 32)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 09 Mar 2021 (Study Day 187), the participant had a positive urine pregnancy test. The first day of the participant's last menstrual period was on 31 Jan 2021 (Study Day 150). The estimated date of conception was 14 Feb 2021 (Study Day 164) and the estimated due date was 14 Nov 2021 (Study Day 437). There have been no issues to report with the pregnancy.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The event, drug exposure before pregnancy, was reported as not reported.

The investigator assessed the event, drug exposure before pregnancy, as not applicable to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-063450	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2012 - Ongoing
Depression	Depression	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	2012 - Ongoing	Gastroesophageal Reflux Disease
Levonorgestrel	2014 - 22 Feb 2021 (Study Day 172)	Contraception
Ibuprofen	05 Sep 2020 (Study Day 2) - 05 Sep 2020 (Study Day 2)	Injection Site Pain
Ibuprofen	06 Oct 2020 (Study Day 33) - 07 Oct 2020 (Study Day 34)	Pain At Injection Site

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US349-2228 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 22 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 22 Oct 2020 (Study Day 31)
First Dose of Vaccine in Part B: 26 Jan 2021 (Study Day 127)
Second Dose of Vaccine in Part B: 24 Feb 2021 (Study Day 156)
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not related	07 Feb 2021 (Study Day 139) – 07 Feb 2021 (Study Day 139)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2228, a 30-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 22 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 22 Oct 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 26 Jan 2021. The participant was unblinded on 26 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 26 Jan 2021 (Study Day 127). The second dose was administered in the left arm on 24 Feb 2021 (Study Day 156).

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	22 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	22 Oct 2020 (Study Day 31)	Negative
Choriogonadotropin Beta	26 Jan 2021 (Study Day 127)	Negative
Choriogonadotropin Beta	24 Feb 2021 (Study Day 156)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 04 Feb 2021 (Study Day 136), an intrauterine device was removed as the participant desired to become pregnant.

On 08 Mar 2021 (Study Day 168), the participant had a positive pregnancy test. The first day of the participant's last menstrual period was on 07 Feb 2021 (Study Day 139).

The estimated date of conception was 07 Feb 2021 (Study Day 139), and the estimated due date was 14 Nov 2021 (Study Day 419). An obstetrician visit was scheduled on 12 Apr 2021 (Study Day 203).

On 18 May 2021 (Study Day 239), the participant reported no complaints regarding this pregnancy and reported feeling well.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The event, drug exposure before pregnancy, was reported as not reported.

The investigator assessed the event, drug exposure before pregnancy, as not applicable to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-050578	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Acne	Acne	2005 - Ongoing
Headache	Menstrual headaches	2005 - Ongoing
Polycystic ovaries	Polycystic ovary syndrome	2005 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Copper	2017 - 04 Feb 2021 (Study Day 136)	Pregnancy Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	01 Jan 2018 (Study Day -995) - Ongoing	Insulin Resistance, Secondary To Polycystic Ovary Syndrome
Ibuprofen	26 Sep 2020 (Study Day 5) - 26 Sep 2020 (Study Day 5)	Headache
Ibuprofen	27 Oct 2020 (Study Day 36) - 27 Oct 2020 (Study Day 36)	Headache
Isotretinoin	01 Nov 2020 (Study Day 41) - 01 Dec 2020 (Study Day 71)	Acne
Vitamins nos	08 Mar 2021 (Study Day 168) - Ongoing	Vitamin Supplement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US355-2240 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 29 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 01 Oct 2020 (Study Day 34)
First Dose of Vaccine in Part B: 07 Jan 2021 (Study Day 132)
Second Dose of Vaccine in Part B: 04 Feb 2021 (Study Day 160)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Autoimmune Thyroiditis/ Hashimoto's Disease	SAE	Grade 2/ moderate	Related	02 Feb 2021 (Study Day 158) – Not reported	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2240, a 39-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 29 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 07 Jan 2021. The participant was unblinded on 07 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 07 Jan 2021 (Study Day 132). The second dose was administered in the left arm on 04 Feb 2021 (Study Day 160).

Event Details

On 02 Feb 2021 (Study Day 158), 157 days after the first dose in Part A/26 days after the first dose in Part B and 124 days after the second dose in Part A/2 days before the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of autoimmune thyroiditis. The IP dose was not changed due to the Hashimoto's disease. The event of Hashimoto's disease was considered to be ongoing. The investigator assessed the event of autoimmune thyroiditis to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 02 Feb 2021 (Study Day 158), the participant experienced a serious adverse event of autoimmune thyroiditis. The participant had routine laboratory tests performed through a primary care physician and was found to have a high thyroid stimulating hormone (TSH) of 8.613 µIU/mL

(no reference range provided). The participant developed symptoms of hair loss and joint aches and was diagnosed with Hashimoto's disease. The participant had a family history of Hashimoto's disease in a parent and sibling. Treatment for the event included levothyroxine PO.

On 16 Feb 2021 (Study Day 172), the participant had a phone visit with an endocrinologist. The participant reported no fatigue, cold intolerance, or constipation.

On 23 Feb 2021 (Study Day 179), an ultrasound of the thyroid showed multinodular enlarged thyroid with hyperemia. The right thyroid nodule was 1.5 cm. Given the clinical history, concern for Hashimoto's thyroiditis was raised.

On 04 Mar 2021 (Study Day 188), an ultrasound-guided thyroid biopsy was performed. Microscopic examination of the prepared smears from right thyroid nodule showed abundant mixed lymphoid population, no colloid material, and rare thyroid follicular cells arranged in sheets. The flow cytometry studies showed no evidence of B-cell or T-cell lymphoma. Cytopathology results demonstrated chronic lymphocytic thyroiditis.

On an unreported date, laboratory test results showed that the participant was thyroid peroxidase antibody positive. The participant's TSH remained elevated.

On 23 Mar 2021 (Study Day 207), the participant contacted the endocrinology office and reported continued symptoms of fatigue and muscle pain. The participant was advised it could take a few weeks of increased dose of medication to see improvements in symptoms and was encouraged a healthy lifestyle and hydration.

No action was taken with the study IP in response to the event.

The event, autoimmune thyroiditis, was reported as resolving at the time of the report.

The investigator assessed the event, autoimmune thyroiditis, as related to study IP and not related to study procedure.

The sponsor considered the event to be not related to study IP and noted the participant's family history of Hashimoto's in a parent and sibling which may remain as confounders.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-056751	Autoimmune thyroiditis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headaches	Not reported - Ongoing
Wrist fracture	Left wrist fracture	1993 - 1993
Appendectomy	Appendectomy	1999 - 1999
Concussion	Concussion	2000 - 2000
Back pain	Lower back pain	2007 - Ongoing
Eczema	Eczema	2010 - Ongoing
Basal cell carcinoma	Basal cell carcinoma	2013 - 2013
Basal cell carcinoma	Basal cell carcinoma	2018 - 2018
Mueller-Weiss syndrome	Muller weiss disease	2018 - Ongoing
Tinnitus	Tinnitus bilateral	2018 - Ongoing
Sciatica	Bilateral sciatica	01 Nov 2018 (Study Day -667) - Ongoing
Seasonal allergy	Seasonal allergies	2019 - Ongoing
Vasectomy	Vasectomy	20 Dec 2019 (Study Day -253) - 20 Dec 2019 (Study Day -253)
Ligament sprain	Left ankle sprain	Jul 2020 - Jul 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Naproxen	2012 - Ongoing	Low Back Pain
Cetirizine hydrochloride	Jul 2019 - Ongoing	Seasonal Allergies
Vitamin d nos	Jun 2020 - Ongoing	Health
Ketorolac tromethamine	03 Aug 2020 (Study Day -26) - 03 Aug 2020 (Study Day -26)	Left Ankle Sprain
Influenza vaccine	15 Sep 2020 (Study Day 18) - 15 Sep 2020 (Study Day 18)	Influenza Prophylaxis
Acetylsalicylic acid; paracetamol; caffeine;	07 Oct 2020 (Study Day 40) - 07 Oct 2020 (Study Day 40)	Headache
Mometasone	20 Oct 2020 (Study Day 53) - 22 Oct 2020 (Study Day 55)	Eczema
Levothyroxine sodium	03 Feb 2021 (Study Day 159) - 18 Mar 2021 (Study Day 202)	Hashimoto's Disease
Needle aspiration of thyroid nodule*	04 Mar 2021 (Study Day 188) - 04 Mar 2021 (Study Day 188)	Adverse Event
Levothyroxine sodium	19 Mar 2021 (Study Day 203) - Ongoing	Hashimoto's Disease

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Rhinorrhoea	Grade 1/mild	Related	11 Jan 2021 (Study Day 136) - 14 Jan 2021 (Study Day 139)
Cough	Grade 1/mild	Related	14 Jan 2021 (Study Day 139) - 14 Jan 2021 (Study Day 139)
Fatigue	Grade 1/mild	Related	16 Jan 2021 (Study Day 141) - 22 Jan 2021 (Study Day 147)
Nasal Congestion	Grade 1/mild	Related	16 Jan 2021 (Study Day 141) - 22 Jan 2021 (Study Day 147)
Thyroid Mass	Grade 2/moderate	Related	16 Feb 2021 (Study Day 172) - Ongoing
Tendonitis	Grade 2/moderate	Not related	20 Feb 2021 (Study Day 176) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US355-2412 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/ Drug exposure before pregnancy	Pregnancy	Not applicable	Not related	17 Feb 2021 (Study Day 160) - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2412, a 29-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	11 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	09 Oct 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 05 Mar 2021 (Study Day 176), the participant had a positive pregnancy test. The first day of the participant's last menstrual period was on 02 Feb 2021 (Study Day 155). The estimated date of conception was 17 Feb 2021 (Study Day 160) and the estimated due date was 09 Nov 2021 (Study Day 425). On 08 Mar 2021 (Study Day 179), the participant reported that they were 5 weeks pregnant.

Action taken with study IP in response to the drug exposure before pregnancy was not applicable, as the participant had already received both scheduled doses.

The event, drug exposure before pregnancy, was reported as not reported.

The investigator assessed the event, drug exposure before pregnancy, as not applicable to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-037814	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headaches	2000 - Ongoing
Myopia	Myopia	2000 - Ongoing
Migraine	Migraines	2010 - Ongoing
Retinal degeneration	Bilateral lattice degeneration	2018 - Ongoing
Acne	Acne	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2000 - Ongoing	Headache
Levonorgestrel	07 Oct 2019 (Study Day -340) - 06 Jan 2021 (Study Day 118)	Contraception
Adapalene	02 Oct 2020 (Study Day 22) - Ongoing	Acne
Paracetamol	09 Oct 2020 (Study Day 29) - 09 Oct 2020 (Study Day 29)	Body Aches
Ibuprofen	10 Oct 2020 (Study Day 30) - 10 Oct 2020 (Study Day 30)	Body Aches
Naproxen	15 Oct 2020 (Study Day 35) - 15 Oct 2020 (Study Day 35)	Migraine

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	15 Oct 2020 (Study Day 35) - 15 Oct 2020 (Study Day 35)	Migraine
Influenza vaccine	27 Oct 2020 (Study Day 47) - 27 Oct 2020 (Study Day 47)	Influenza Prophylaxis
Vitamins nos	07 Jan 2021 (Study Day 119) - Ongoing	Health Promotion

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US357-2027 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 19 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 23 Sep 2020 (Study Day 36)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Maternal exposure before pregnancy/Maternal exposure before pregnancy	Pregnancy	Not applicable	Not related	01 Mar 2021 (Study Day 195) - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US357-2027, a 31-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 26 Jan 2021. The participant was unblinded on 26 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	19 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	23 Sep 2020 (Study Day 36)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 20 Mar 2021 (Study Day 214), the participant had a positive pregnancy test. The participant's first day of the last menstrual period was reported as 26 Feb 2021 (Study Day 192). The estimated date of conception was reported as 01 Mar 2021 (Study Day 195), and the estimated due date was reported as 23 Nov 2021 (Study Day 462). The participant did not use any form of contraception. The participant started taking prenatal vitamins PO since 01 Mar 2021 (Study Day 195). On 21

May 2021 (Study Day 276), the participant reported to a safety nurse that they were 13 weeks pregnant.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The event, maternal exposure before pregnancy, was reported as not reported.

The investigator assessed the event, maternal exposure before pregnancy, as not applicable to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-179053	Maternal exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Attention deficit hyperactivity disorder	Adhd	Jun 2019 - Ongoing
Gastroesophageal reflux disease	Gerd	Sep 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; norgestimate	Jan 2019 - Ongoing	Oral Contraception
Lisdexamfetamine mesilate	01 Jun 2019 (Study Day -445) - Ongoing	Adhd
Pantoprazole sodium sesquihydrate	01 Sep 2019 (Study Day -353) - Ongoing	Gerd
Ibuprofen	19 Aug 2020 (Study Day 1) - 22 Aug 2020 (Study Day 4)	Pain At Injection Site
Influenza vaccine	09 Sep 2020 (Study Day 22) - 09 Sep 2020 (Study Day 22)	Prophylaxis
Sertraline hydrochloride	14 Oct 2020 (Study Day 57) - Ongoing	Antidepressant
Clonazepam	09 Nov 2020 (Study Day 83) - Ongoing	Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US357-2076 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 24 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 22 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: 25 Feb 2021 (Study Day 186)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Maternal exposure before pregnancy Pregnancy/ Pregnancy	Pregnancy	Not applicable	Not applicable	08 Apr 2021 (Study Day 228) – 16 Apr 2021 (Study Day 236)	Recovered/ resolved
Abortion induced/elective pregnancy termination	Pregnancy	Not reported	Not related	08 Apr 2021 (Study Day 228) – 16 Apr 2021 (Study Day 236)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US357-2076, a 19-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 25 Feb 2021. The participant was unblinded on 26 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 25 Feb 2021 (Study Day 186). The second dose was not administered.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 08 Apr 2021 (Study Day 228).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	24 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	22 Sep 2020 (Study Day 30)	Negative

Test Name	Test Date	Result
Choriogonadotropin Beta	25 Feb 2021 (Study Day 186)	Negative
Choriogonadotropin Beta	08 Apr 2021 (Study Day 228)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 08 Apr 2021 (Study Day 228), the participant reported to the site for the second administration of study IP and had a positive urine pregnancy test. A repeat urine pregnancy test confirmed the positive result. The first day of the participant's last menstrual period was on 08 Mar 2021 (Study Day 197). The estimated date of conception was 14 Mar 2021 (Study Day 203), and the estimated due date was 13 Dec 2021 (Study Day 477). The participant disclosed that they had not been taking birth control pills and did not consult their gynecologist or report this to the investigator. The second dose of study IP was not administered. The participant was advised to follow-up with their physician.

Study IP was withdrawn as a result of the event.

On 26 Apr 2021 (Study Day 246), the participant had an elective early pregnancy termination at 10 weeks gestation with mifepristone PO on 16 Apr 2021 (Study Day 236) and misoprostol PO on 17 Apr 2021 (Study Day 237) with no complications.

The outcome of the event, abortion induced, was reported as resolved on 26 Apr 2021 (Study Day 246).

The investigator assessed the event, abortion induced, as not related to the study IP or study procedure.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-073432	Maternal exposure before pregnancy
MOD-2021-073432	Abortion induced

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; ferrous fumarate; norethisterone acetate	Jan 2020 - Ongoing	Contraceptive
Ibuprofen	25 Aug 2020 (Study Day 2) - 25 Aug 2020 (Study Day 2)	Headache
Anti allergic agents	03 Sep 2020 (Study Day 11) - Ongoing	Allergies

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pruritus	Grade 1/mild	Related	26 Feb 2021 (Study Day 187) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US357-2251 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 06 Oct 2020 (Study Day 27)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Head Injury/Head Trauma Due To Fall	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	03 Apr 2021 (Study Day 206) – 03 Apr 2021 (Study Day 206)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US357-2251, a 41-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 06 Oct 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 02 Feb 2021. The participant was unblinded on 02 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 03 Apr 2021 (Study Day 206), 205 days after the first dose in Part A and 179 days after the second dose in Part A of the IP, the participant experienced a Grade 5 serious adverse event of head injury. Action taken with the IP was not applicable. The event of head trauma due to fall was considered to be fatal on 03 Apr 2021 (Study Day 206). The investigator assessed the event of head injury to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 03 Apr 2021 (Study Day 206), the participant experienced a fatal serious adverse event of head injury (head trauma due to fall).

On 14 Apr 2021 (Study Day 217), the safety call nurse contacted the participant for an eDiary reminder. The participant's family member reported that the participant fainted and hit their head.

The participant was taken to the hospital where they died of blunt head trauma. The participant's family member stated that the participant was not sick and did not know why they fainted.

Action taken with IP in response to the event was not applicable, as the participant had already received both scheduled doses.

The participant died on 03 Apr 2021 (Study Day 206). The cause of death was reported as head injury, alcohol intoxication, accidental fall down the stairs, and cardiopulmonary arrest. No autopsy was performed.

The investigator assessed the event, head injury, as not related to IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-077015	Head injury

Study Completion/Discontinuation

On 03 Apr 2021 (Study Day 206), the participant discontinued from the study due to death. On 03 Apr 2021 (Study Day 206), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	Jul 2008 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	01 Jul 2008 (Study Day -4454) - Ongoing	Hypertension
Insulin aspart	01 Jul 2020 (Study Day -71) - Ongoing	Diabetes Mellitus Type 2
Empagliflozin; linagliptin	15 Jul 2020 (Study Day -57) - Ongoing	Diabetes Mellitus Type 2
Paracetamol	10 Nov 2020 (Study Day 62) - 30 Nov 2020 (Study Day 82)	Pain For Finger Amputation
Gabapentin	11 Nov 2020 (Study Day 63) - 24 Nov 2020 (Study Day 76)	Pain In Amputated Finger

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	24 Feb 2021 (Study Day 168) - Ongoing	High Cholesterol
Candesartan cilexetil	24 Feb 2021 (Study Day 168) - Ongoing	Hypertension
Lansoprazole	24 Feb 2021 (Study Day 168) - Ongoing	Reflux

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gastroesophageal Reflux Disease	Grade 1/mild	Not related	02 Feb 2021 (Study Day 146) - Ongoing
Blood Cholesterol Increased	Grade 1/mild	Not related	24 Feb 2021 (Study Day 168) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US358-2154 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 18 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Oct 2020 (Study Day 27)
First Dose of Vaccine in Part B: 05 Mar 2021 (Study Day 169)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	30 Apr 2021 (Study Day) – Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US358-2154, a 29-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 18 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 14 Oct 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 05 Mar 2021. The participant was unblinded on 03 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 05 Mar 2021 (Study Day 169). The second dose was not administered.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	18 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	14 Oct 2020 (Study Day 27)	Negative
Choriogonadotropin Beta	05 Mar 2021 (Study Day 169)	Negative
Choriogonadotropin Beta	05 Apr 2021 (Study Day 200)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 30 Apr 2021 (Study Day 225), the participant had a positive pregnancy test. The first day of the participant's last menstrual period was 31 Mar 2021 (Study Day 195), and the estimated due

date was 05 Jan 2022 (Study Day 475). The participant's first prenatal appointment with provider was scheduled for June 2021.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-119585	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headache	Not reported - Ongoing
Myalgia	Muscle pain from activity (generalized)	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	2006 - Ongoing
Cervical dysplasia	Cervical dysphasia	2010 - Ongoing
Human papilloma virus test positive	Human papilloma virus test positive	2010 - 16 Oct 2018 (Study Day -703)
Drug hypersensitivity	Sulfite allergy	2015 - Ongoing
Urticaria	Hives	2015 - Ongoing
Botulinum toxin injection	Botox injection (upper lip)	21 Aug 2020 (Study Day -28) - 21 Aug 2020 (Study Day -28)
Dermal filler injection	Juvederm (upper and lower lip)	04 Sep 2020 (Study Day -14) - 11 Sep 2020 (Study Day -7)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	Not reported - Ongoing	Headache Or Muscle Pain From Activity
Sodium chloride	Not reported - Ongoing	Seasonal Allergies
Ethinylestradiol; etonogestrel	2014 - 30 Nov 2020 (Study Day 74)	Birth Control
Fluticasone propionate	2015 - Ongoing	Seasonal Allergies
Cetirizine	14 Jul 2018 (Study Day -797) - Ongoing	Seasonal Allergies
Vitamins nos	Jul 2020 - 01 Jan 2021 (Study Day 106)	Health Maintenance
Oxymetazoline	14 Oct 2020 (Study Day 27) - 15 Oct 2020 (Study Day 28)	Nasal Congestion
Zinc acetate; zinc gluconate	22 Oct 2020 (Study Day 35) - 23 Oct 2020 (Study Day 36)	Nasal Congestion
Ibuprofen	02 Nov 2020 (Study Day 46) - 04 Nov 2020 (Study Day 48)	Gingival Inflammation From Braces Bracket. Right Upper Tooth #3
Chlorhexidine gluconate	05 Nov 2020 (Study Day 49) - Ongoing	Gingival Inflammation Due To Braces Bracket Right Upper Tooth #3
Influenza vaccine	09 Dec 2020 (Study Day 83) - 09 Dec 2020 (Study Day 83)	Health Maintenance

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US362-2032 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 17 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 07 Jan 2021 (Study Day 144)
Second Dose of Vaccine in Part B: 08 Feb 2021 (Study Day 176)
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pregnancy/Pregnancy	Pregnancy	Grade 1/mild	Not related	18 Jan 2021 (Study Day 155) – Ongoing	Not recovered/Not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US362-2032, a 33-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 07 Jan 2021. The participant was unblinded on 07 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 07 Jan 2021 (Study Day 144). The second dose was administered in the left arm on 08 Feb 2021 (Study Day 176).

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 04 Feb 2021 (Study Day 172).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	17 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	14 Sep 2020 (Study Day 29)	Negative
Choriogonadotropin Beta	07 Jan 2021 (Study Day 144)	Negative
Choriogonadotropin Beta	04 Feb 2021 (Study Day 172)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 18 Jan 2021 (Study Day 155), the participant had a positive urine pregnancy test. The first day of the participant's last menstrual period was on 12 Dec 2020 (Study Day 118). The estimated date of conception was 24 Dec 2020 (Study Day 130) and the estimated due date was 18 Sep 2021 (Study Day 398). The participant reported having a positive pregnancy test soon after their first dose of study IP. The participant was feeling well and had a follow up scheduled with their obstetrician/gynecologist.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, exposure during pregnancy, was not reported.

The investigator's assessment of the relationship between the event of exposure during pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-011735	Exposure during pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2003 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Progesterone	2020 - Dec 2020	Birth Control
Vitamins nos	Sep 2020 - Ongoing	Vitamin Supplement
Ibuprofen	07 Jan 2021 (Study Day 144) - 09 Jan 2021 (Study Day 146)	Left Arm Injection Site Pain
Vitamins nos	18 Jan 2021 (Study Day 155) - Ongoing	Pregnancy Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	22 Feb 2021 (Study Day 190) - Ongoing	Seasonal Allergies

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 1/mild	Related	07 Jan 2021 (Study Day 144) - 09 Jan 2021 (Study Day 146)
Pregnancy	Grade 1/mild	Not related	18 Jan 2021 (Study Day 155) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US365-2038 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 25 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: Not Administered
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	14 Apr 2021 (Study Day 202) – Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US365-2038, a 34-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 25 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 05 Dec 2020. The participant was unblinded on 05 Dec 2020 and consented to receive the second dose of mRNA-1273. No doses were administered in Part B.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriongonadotropin Beta	25 Sep 2020 (Study Day 1)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 22 Apr 2021 (Study Day 210), the participant had a positive pregnancy test and was 7 weeks pregnant on 29 Apr 2021 (Study Day 217). The first day of the participant's last menstrual period was 31 Mar 2021 (Study Day 188), the estimated date of conception was 14 Apr 2021 (Study Day 202), and the estimated due date was 05 Jan 2022 (Study Day 468). The participant discontinued apixaban PO due to pregnancy and was started on enoxaparin SC instead.

Action taken with study IP in response to the pregnancy was not applicable.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-163265	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	Jan 2019 - Ongoing	Supplement
Ibuprofen	26 Sep 2020 (Study Day 2) - 26 Sep 2020 (Study Day 2)	Pain At Injection Site Left Arm (Ediary Symptoms)
Metoclopramide	30 Nov 2020 (Study Day 67) - 30 Nov 2020 (Study Day 67)	Pica Territory Infarct Mass Effect
Ondansetron	30 Nov 2020 (Study Day 67) - 04 Dec 2020 (Study Day 71)	Nausea And Vomiting (Related To Cryptogenic Stroke)
Ondansetron	30 Nov 2020 (Study Day 67) - 30 Nov 2020 (Study Day 67)	Pica Territory Infarct Mass Effect
Meclozine	01 Dec 2020 (Study Day 68) - Ongoing	Pica Territory Infarct Mass Effect
Bloodwork*	02 Dec 2020 (Study Day 69) - 02 Dec 2020 (Study Day 69)	Adverse Event
Ascorbic acid	04 Dec 2020 (Study Day 71) - Ongoing	Supplementation
Ferrous sulfate	04 Dec 2020 (Study Day 71) - Ongoing	Supplementation
Hypercoagulability labs.*	04 Dec 2020 (Study Day 71) - 04 Dec 2020 (Study Day 71)	Adverse Event
Mr brain without contrast*	04 Dec 2020 (Study Day 71) - 04 Dec 2020 (Study Day 71)	Adverse Event
Mra head without contrast*	04 Dec 2020 (Study Day 71) - 04 Dec 2020 (Study Day 71)	Adverse Event
Mra neck without contrast*	04 Dec 2020 (Study Day 71) - 04 Dec 2020 (Study Day 71)	Adverse Event
Apixaban	05 Dec 2020 (Study Day 72) - Ongoing	Stroke Prevention

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	05 Dec 2020 (Study Day 72) - 07 Dec 2020 (Study Day 74)	Stroke Prevention
Lumbar puncture*	05 Dec 2020 (Study Day 72) - 05 Dec 2020 (Study Day 72)	Adverse Event
Transthoracic echocardiogram*	05 Dec 2020 (Study Day 72) - 05 Dec 2020 (Study Day 72)	Adverse Event
Doppler ultrasound (lower extremity)*	06 Dec 2020 (Study Day 73) - 06 Dec 2020 (Study Day 73)	Adverse Event
Acetylsalicylic acid	07 Dec 2020 (Study Day 74) - Ongoing	Stroke Prevention
Closure of the patent foramen ovale*	07 Dec 2020 (Study Day 74) - 07 Dec 2020 (Study Day 74)	Adverse Event
Fentanyl	07 Dec 2020 (Study Day 74) - 07 Dec 2020 (Study Day 74)	Anesthesia For Procedure Related To Cryptogenic Stroke
Midazolam	07 Dec 2020 (Study Day 74) - 07 Dec 2020 (Study Day 74)	Anesthesia For Procedure Related To Cryptogenic Stroke
Ondansetron	07 Dec 2020 (Study Day 74) - 07 Dec 2020 (Study Day 74)	Anesthesia For Procedure Related To Cryptogenic Stroke
Cefazolin	08 Dec 2020 (Study Day 75) - 08 Dec 2020 (Study Day 75)	Antibiotic Prophylaxis For Procedure Related To Cryptogenic Stroke

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US368-2178 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 01 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 03 Nov 2020 (Study Day 34)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	15 Feb 2021 (Study Day 138) – Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US368-2178, a 33-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 01 Oct 2020 (Study Day 1). The second dose was administered in the right arm on 03 Nov 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 15 Jan 2021. The participant was unblinded on 15 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	01 Oct 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	03 Nov 2020 (Study Day 34)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 04 Mar 2021 (Study Day 155), the participant had 2 positive urine pregnancy tests at home. The participant was using barrier contraception until 01 Feb 2021 (Study Day 124). The first day of the participant's last menstrual period was 03 Feb 2021 (Study Day 126), the estimated date of conception was 15 Feb 2021 (Study Day 138), and the estimated due date was 10 Nov 2021 (Study Day 406). The participant was scheduled to follow-up with their obstetrician in April 2021.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-037927	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Psoriasis	Psoriasis	2002 - Ongoing
Pilonidal sinus repair	Pilonidal cyst removal	2005 - 2005
Tenoplasty	Rt hand tendon repair	2008 - 2008

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; ferrous fumarate; norethisterone acetate	2005 - 01 Jan 2021 (Study Day 93)	Contraception
Ibuprofen	02 Oct 2020 (Study Day 2) - 02 Oct 2020 (Study Day 2)	Injection Site Pain, Muscle Aches
Ibuprofen	03 Nov 2020 (Study Day 34) - 04 Nov 2020 (Study Day 35)	Fever, fatigue, Inj Site Pain
Acetylsalicylic acid; caffeine; paracetamol	05 Nov 2020 (Study Day 36) - 05 Nov 2020 (Study Day 36)	Headache
Acetylsalicylic acid; caffeine; paracetamol	23 Nov 2020 (Study Day 54) - 24 Nov 2020 (Study Day 55)	Headache

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid; betacarotene; calcium carbonate; colecalciferol; docosahexaenoic acid; ferrous fumarate; folic acid; nicotinamide; pyridoxine hydrochloride; riboflavin; thiamine mononitrate; tocopheryl	01 Jan 2021 (Study Day 93) - Ongoing	General Health

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US370-2046 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 25 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 23 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Bipolar I Disorder/Bipolar Disorder With Psychosis	SAE	Grade 3/ severe	Not related	26 Feb 2021 (Study Day 155) – 09 Mar 2021 (Study Day 166)	Recovered/ resolved
Pulmonary Embolism/Pulmonary Embolism	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	01 Mar 2021 (Study Day 158) – 09 Mar 2021 (Study Day 166)	Fatal
Gastrointestinal Haemorrhage/Gastrointestinal Bleed	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	09 Mar 2021 (Study Day 166) – 09 Mar 2021 (Study Day 166)	Fatal
Pulseless Electrical Activity/Pulseless Electrical Activity	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	09 Mar 2021 (Study Day 166) – 09 Mar 2021 (Study Day 166)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US370-2046, a 49-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 25 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 23 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 22 Jan 2021. The participant was unblinded on 22 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 26 Feb 2021 (Study Day 155), 154 days after the first dose in Part A and 126 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of bipolar i disorder. Action taken with the IP was not applicable. The event of bipolar disorder with psychosis lasted for 12 days, after which it was considered to be recovered/resolved on

09 Mar 2021 (Study Day 166). The investigator assessed the event of bipolar i disorder to be not related to the IP.

On 01 Mar 2021 (Study Day 158), 157 days after the first dose in Part A and 129 days after the second dose in Part A of the IP, the participant experienced a Grade 5 serious adverse event of pulmonary embolism. Action taken with the IP was not applicable. The event of pulmonary embolism lasted for 9 days, after which it was considered to be fatal on 09 Mar 2021 (Study Day 166). The investigator assessed the event of pulmonary embolism to be not related to the IP.

On 09 Mar 2021 (Study Day 166), 165 days after the first dose in Part A and 137 days after the second dose in Part A of the IP, the participant experienced a Grade 5 serious adverse event of gastrointestinal haemorrhage. Action taken with the IP was not applicable. The event of gastrointestinal bleed was considered to be fatal on 09 Mar 2021 (Study Day 166). The investigator assessed the event of gastrointestinal haemorrhage to be not related to the IP.

On 09 Mar 2021 (Study Day 166), 165 days after the first dose in Part A and 137 days after the second dose in Part A of the IP, the participant experienced a Grade 5 serious adverse event of pulseless electrical activity. Action taken with the IP was not applicable. The event of pulseless electrical activity was considered to be fatal on 09 Mar 2021 (Study Day 166). The investigator assessed the event of pulseless electrical activity to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 26 Feb 2021 (Study Day 155), the participant experienced a serious adverse event (SAE) of bipolar I disorder (with psychosis) and was admitted to the hospital. Symptoms included bizarre behavior, selective mutism, agitation, and stripping of clothing. Their initial agitation at admission included an event where they ran headfirst into a wall/door and required physical and chemical restraints and a transfer to the emergency department for workup. A head computed tomography (CT) scan and chest x-ray were negative. After medical clearance, they were returned for psychiatric evaluation where their home medications were restarted, and they eventually became cooperative and agreed to be admitted to psychiatric hold, and to restart lithium therapy that they admitted to have stopped 4 to 5 years before. The participant denied alcohol use or use of illicit substances. The initial laboratory test results showed leukocytosis and they were afebrile. A SARS-CoV-2 swab test (ribonucleic acid) was negative. Treatment for the event included lithium, haloperidol, lorazepam, and trazodone.

On 27 Feb 2021 (Study Day 156), laboratory test results included white blood cell (WBC) 12.72×10^6 (reference range 3.90 to 10.60×10^6), blood urea nitrogen (BUN) 12 mmol/L (reference range not reported), carbon dioxide (CO₂) 17.8 mmol/L (reference range 24.0 to 30.0 mmol/L), and creatinine 1.2 mg/dL (reference range 0.5 to 1.5 mg/dL).

On 28 Feb 2021 (Study Day 157), laboratory test results included WBC $12.15 \times 10^6/L$, BUN 12 mmol/L, and creatinine 0.8 mg/dL. From 01 Mar 2021 (Study Day 158) through 04 Mar 2021 (Study Day 161), the participant's behavior improved, and they were cooperative with psychiatric care but continued to show disorganized thought patterns, occasional anxiety/agitation, and selective mutism. While initially quite sedate and withdrawn, their mood and appetite improved, and they began participating in care. They were noted to refuse their continuous positive airway pressure (CPAP) at night.

On 01 Mar 2021 (Study Day 158), the participant experienced an SAE of pulmonary embolism and stayed in the intensive care unit (ICU) for 1 day. Symptoms included new onset shortness of breath, tachycardia, and 1 to 2+ pitting in lower extremity edema. A CT angiogram revealed multiple segmental/subsegmental pulmonary emboli, with left lung worse than right lung. Treatment with enoxaparin was initiated.

On 02 Mar 2021 (Study Day 159), the participant presented the following symptoms for 1 hour: acutely altered and did not answer questions, barely spoke, and followed commands but with a delay. Arterial blood gases results showed pH 7.47 (high) (reference range not reported); partial pressure oxygen 77, partial pressure carbon dioxide 34, total CO₂ 26 (high), glucose 156 (high), bicarbonate 25, and lactate 1.1 (high) (all units and reference ranges not reported). The participant was placed on CPAP; lithium and lorazepam were discontinued; and the participant's mental status improved. The participant experienced urinary retention requiring a foley catheter. The signs of infection and leukocytosis by urinalysis and urine culture were negative, which were noted to be resolved. A transesophageal echocardiogram revealed normal left ventricular ejection fraction and no right ventricular strain; duplex study was negative for deep vein thrombosis; and hypercoagulability workup was negative. Treatment for the event included switching from enoxaparin to apixaban. Over the course of the next few days, the participant continued to have episodes of agitation and was noted to be noncompliant with wearing CPAP at night, pulling at telemetry leads, and occasionally required haloperidol PRN for agitation. They complained only of back pain for which paracetamol was given. The participant's status improved; catheter was discontinued.

On 03 Mar 2021 (Study Day 160), a COVID-19 polymerase chain reaction (PCR) test was negative.

On 04 Mar 2021 (Study Day 161), the participant was transferred back to the psychiatric unit on therapeutic enoxaparin.

On 05 Mar 2021 (Study Day 162), the participant was switched to apixaban PO. They had become more somnolent over the evening, had increased tremors, and showed decreasing interest in food and fluids. A COVID-19 antibody test was nonreactive.

On 06 Mar 2021 (Study Day 163), the participant was found unresponsive in the bathroom, confused, diaphoretic, and tremulous. They were somnolent in a rigid position and softly responded to painful stimuli. Significant examination findings included thick mouth secretion that was aspirated, comfortable breathing, reactive pupils, movement of 4 extremities with rigidity, motor resistance, fine tremor in upper extremity, and soft abdomen. They were transferred to the medical unit where they were noted to be persistently asking for water, but not drinking it when given. They were awake, alert, and oriented to person and place (did not know date) and denied pain. Left conjunctivitis with purulent discharge and lesions were also noted. The psychiatry team considered that the altered mental status (AMS) was suggestive of catatonia since the participant was unresponsive and rigid. The medical team deemed the AMS was less likely related to hypoxemia as their O₂ saturation was 100% on room air. Vital signs included heart rate ≥ 110 beats per minute (bpm), blood pressure 130/70 mm Hg, temperature 97.5 F, and SpO₂ 95% on room air. Chest x-ray and urinalysis were normal/negative. Laboratory test results included WBC $14.57 \times 10^6/L$ at 10:29, $14.01 \times 10^6/L$ at 11:13; CO₂ 20.4 mmol/L (high) at 10:18, 19.0 mmol/L (high) at 11:27, and anion gap 18.0 mmol/L (reference range ≤ 13.9 mmol/L) at 10:18 and 18.6 mmol/L at 11:27. Apixaban treatment was changed back to enoxaparin.

On 07 Mar 2021 (Study Day 164), the participant was responsive to verbal stimuli, but did not remember the events of yesterday. Laboratory test results included WBC $13.79 \times 10^6/L$ and CO₂ 21.7 mmol/L. The participant was on IV fluids, nothing by mouth, and on CPAP at night.

On 08 Mar 2021 (Study Day 165), the participant had a relatively uneventful evening course (did not wear CPAP). They were barely able to stay alert when examined at bedside and was placed on CPAP. A COVID-19 swab PCR test was negative. Laboratory test results included WBC $12.95 \times 10^6/L$, sodium 147 mmol/L (reference range 135 to 145 mmol/L), CO₂ 16.9 mmol/L (high), chloride 112 mmol/L (reference range 98 to 108 mmol/L), and anion gap 18.1 mmol/L.

On 09 Mar 2021 (Study Day 166), the participant experienced SAEs of gastrointestinal hemorrhage and pulseless electrical activity. On the same day, the participant presented with rectal bleeding with clot. At approximately 06:00, they had another episode of hematochezia, larger than the previous episode. They were also noted to be febrile (102.6 F) and tachycardic (125 bpm); normal blood pressure, O₂ saturation 95%, hemoglobin 10.6 g/dL (low) (reference range 13.5 to 17.5 g/dL), hematocrit 35.5% (low) (reference range 41.0% to 53.0%), activated partial thromboplastin time 44.4 (high) (unit and reference range not reported), prothrombin time 17.3 (high) (unit and reference range not reported), sodium 150 mmol/L at 07:51 and 161 mmol/L at 13:35, chloride 115 mmol/L at 07:51 and 116 mmol/L at 13:35, CO₂ 21.0 mmol/L at 07:51 and 13.4 mmol/L at 13:35, creatinine 1.6 mg/dL at 07:51 and 3.5 mg/dL at 13:35, anion gap 14.0 mmol/L at 07:51 and 31.6 mmol/L at 13:35, BUN 30 mmol/L, WBC $15.20 \times 10^6/L$ at 03:47, $17.53 \times 10^9/L$ at 07:53, $15.29 \times 10^9/L$ at 13:35, and international normalized ratio 1.5 (high). The

participant was minimally responsive with answers of 1 or 2 words; remained febrile; diaphoretic; and tachycardic (120 to 130s bpm). The participant was found unresponsive shortly thereafter, with dilated pupils. A stroke code was called, and the participant was found to be pulseless. Cardiopulmonary resuscitation was initiated with return of spontaneous circulation (ROSC); pulseless electrical activity appeared again followed by ROSC approximately 5 times. They were given multiple rounds of epinephrine and sodium bicarbonate. Code event lasted approximately an hour. They were transferred to the ICU but lost pulse immediately upon arrival. Given their hemodynamic instability for 75 minutes the code was called, and time of death declared at 13:59.

Action taken with the study IP in response to the events was not applicable, as the participant had already received both scheduled doses.

The event, bipolar I disorder (with psychosis), was reported as resolved on 09 Mar 2021 (Study Day 166). The events pulmonary embolism, gastrointestinal hemorrhage, and pulseless electrical activity were reported as fatal on 09 Mar 2021 (Study Day 166), and the participant died on the same day. Immediate causes were pulmonary embolism, gastrointestinal hemorrhage, pulseless electrical activity, cardiogenic shock, and morbid obesity.

The investigator assessed the events, bipolar I disorder with psychosis, pulmonary embolism, gastrointestinal hemorrhage, and pulseless electrical activity, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-099844	Bipolar I disorder
MOD-2021-099844	Pulmonary embolism
MOD-2021-099844	Gastrointestinal hemorrhage
MOD-2021-099844	Pulseless electrical activity

Study Completion/Discontinuation

On 09 Mar 2021 (Study Day 166), the participant discontinued from the study due to death. On 09 Mar 2021 (Study Day 166), the participant died due to adverse event. No autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Acne	Acne	Not reported - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Morbid obesity with bmi of 40.0 - 44.9	Not reported - Ongoing
Hypertension	Hypertension	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	Not reported - Ongoing	High Blood Pressure Disorder
Influenza vaccine	Sep 2020 - Sep 2020	Influenza Prophylaxis
Ibuprofen	28 Sep 2020 (Study Day 4) - 28 Sep 2020 (Study Day 4)	Headache
Ibuprofen	24 Oct 2020 (Study Day 30) - 24 Oct 2020 (Study Day 30)	Headache Prevention
Vitamins nos	12 Nov 2020 (Study Day 49) - Ongoing	General Health Supplement
Haloperidol	26 Feb 2021 (Study Day 155) - 26 Feb 2021 (Study Day 155)	Psychosis (Related To Bipolar Disorder)
Head cts and exr*	26 Feb 2021 (Study Day 155) - 26 Feb 2021 (Study Day 155)	Adverse Event
Lorazepam	26 Feb 2021 (Study Day 155) - 28 Feb 2021 (Study Day 157)	Agitation (Related To Bipolar Disorder With Psychosis)
Amlodipine	27 Feb 2021 (Study Day 156) - 09 Mar 2021 (Study Day 166)	Hypertension
Insulin lispro	27 Feb 2021 (Study Day 156) - 08 Mar 2021 (Study Day 165)	Diabetes Mellitus
Lisinopril	27 Feb 2021 (Study Day 156) - 27 Feb 2021 (Study Day 156)	Hypertension
Metformin	27 Feb 2021 (Study Day 156) - 09 Mar 2021 (Study Day 166)	Diabetes Mellitus
Paracetamol	28 Feb 2021 (Study Day 157) - 09 Mar 2021 (Study Day 166)	Lumbar Back Pain
Ct angiogram*	01 Mar 2021 (Study Day 158) - 01 Mar 2021 (Study Day 158)	Adverse Event
Ct scan*	01 Mar 2021 (Study Day 158) - 01 Mar 2021 (Study Day 158)	Adverse Event
Enoxaparin	01 Mar 2021 (Study Day 158) - 04 Mar 2021 (Study Day 161)	Pulmonary Embolism
Haloperidol	01 Mar 2021 (Study Day 158) - 05 Mar 2021 (Study Day 162)	Bipolar Disorder With Psychosis
Iohexol	01 Mar 2021 (Study Day 158) - 01 Mar 2021 (Study Day 158)	Contrast For Ct
Lithium	01 Mar 2021 (Study Day 158) - 09 Mar 2021 (Study Day 166)	Bipolar Disorder With Psychosis
Lorazepam	01 Mar 2021 (Study Day 158) - 02 Mar 2021 (Study Day 159)	Agitation (Related To Bipolar Disorder With Psychosis)
Metoprolol	01 Mar 2021 (Study Day 158) - 09 Mar 2021 (Study Day 166)	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Trazodone	01 Mar 2021 (Study Day 158) - 03 Mar 2021 (Study Day 160)	Bipolar Disorder With Psychosis
Apixaban	05 Mar 2021 (Study Day 162) - 05 Mar 2021 (Study Day 162)	Pulmonary Embolism
Duplex study*	05 Mar 2021 (Study Day 162) - 05 Mar 2021 (Study Day 162)	Adverse Event
Enoxaparin	05 Mar 2021 (Study Day 162) - 09 Mar 2021 (Study Day 166)	Pulmonary Embolism
Transesophageal echocardiogram*	05 Mar 2021 (Study Day 162) - 05 Mar 2021 (Study Day 162)	Adverse Event
Benzatropine	06 Mar 2021 (Study Day 163) - 08 Mar 2021 (Study Day 165)	Upper Extremity Tremor
Calcium chloride; potassium chloride; sodium lactate	06 Mar 2021 (Study Day 163) - 06 Mar 2021 (Study Day 163)	Hydration
Erythromycin	06 Mar 2021 (Study Day 163) - 09 Mar 2021 (Study Day 166)	Conjunctivitis
Haloperidol	06 Mar 2021 (Study Day 163) - 07 Mar 2021 (Study Day 164)	Psychosis (Related To Bipolar Disorder)
Lorazepam	06 Mar 2021 (Study Day 163) - 06 Mar 2021 (Study Day 163)	Agitation (Related To Bipolar Disorder With Psychosis)
Chest x-ray*	08 Mar 2021 (Study Day 165) - 08 Mar 2021 (Study Day 165)	Adverse Event
Lorazepam	08 Mar 2021 (Study Day 165) - 08 Mar 2021 (Study Day 165)	Agitation (Related To Bipolar Disorder With Psychosis)
Solutions affecting the electrolyte balance	08 Mar 2021 (Study Day 165) - 08 Mar 2021 (Study Day 165)	Hydration
Urine culture*	08 Mar 2021 (Study Day 165) - 08 Mar 2021 (Study Day 165)	Adverse Event
Vancomycin	09 Mar 2021 (Study Day 166) - 09 Mar 2021 (Study Day 166)	Fever

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Back Pain	Grade 2/moderate	Not related	27 Feb 2021 (Study Day 156) - 09 Mar 2021 (Study Day 166)
Conjunctivitis	Grade 2/moderate	Not related	06 Mar 2021 (Study Day 163) - 09 Mar 2021 (Study Day 166)
Tremor	Grade 2/moderate	Not related	06 Mar 2021 (Study Day 163) - 09 Mar 2021 (Study Day 166)
Pyrexia	Grade 2/moderate	Not related	09 Mar 2021 (Study Day 166) - 09 Mar 2021 (Study Day 166)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US372-2025 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 02 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Aug 2020 (Study Day 27)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	Not reported – Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US372-2025, a 30-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 02 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Aug 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 08 Jan 2021. The participant was unblinded on 08 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	02 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	28 Aug 2020 (Study Day 27)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On an unreported date, the participant had a positive pregnancy test. Per the participant, they were 6 weeks pregnant before being contacted by the investigator to complete their eDiary. The participant's last menstrual period was not reported. The estimated date of conception and due date were not reported. The participant did not report using contraceptive.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-115415	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nasal septum deviation	Deviated septum	2000 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; ferrous fumarate; norethisterone acetate	2007 - Ongoing	Birth Control
Ibuprofen	03 Aug 2020 (Study Day 2) - Ongoing	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US372-2247 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 13 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Sep 2020 (Study Day 33)
First Dose of Vaccine in Part B: 01 Feb 2021 (Study Day 173)
Second Dose of Vaccine in Part B: 04 Mar 2021 (Study Day 204)
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Exposure during pregnancy/Exposure during pregnancy	Pregnancy	Not applicable	Not applicable	04 Mar 2021 (Study Day 204) – Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US372-2247, a 24-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 01 Feb 2021. The participant was unblinded on 01 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 01 Feb 2021 (Study Day 173). The second dose was administered in the left arm on 04 Mar 2021 (Study Day 204).

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 04 Mar 2021 (Study Day 204).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	13 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	14 Sep 2020 (Study Day 33)	Negative
Choriogonadotropin Beta	01 Feb 2021 (Study Day 173)	Negative
Choriogonadotropin Beta	04 Mar 2021 (Study Day 204)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 04 Mar 2021 (Study Day 204), the participant had a positive urine pregnancy test. The participant was not using contraception. The first day of the participant's last menstrual period, the estimated date of conception, and the estimated due date were all unreported. The participant was called to schedule an appointment and reported that they were pregnant.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, exposure during pregnancy, was not reported.

The investigator's assessment of the relationship between the event of exposure during pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-034023	Exposure during pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Snoring	Snoring	2000 - 2000
Tonsillitis	Tonsillitis	2001 - 2001
Acne	Acne	2015 - Ongoing
Hypothyroidism	Hypothyroidism	Dec 2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	Dec 2018 - Ongoing	Hypothyroidism
Tretinoin	Dec 2018 - Ongoing	Acne

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US374-2148 (Part B)
Vaccination Group: mRNA-1273
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine: 28 Aug 2020 (Study Day 1)
Second Dose of Vaccine: 25 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abortion Spontaneous/Spontaneous Abortion	SAE	Grade 3/ severe	Not related	29 Jan 2021 (Study Day 155) – 29 Jan 2021 (Study Day 155)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2148, a 24-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 25 Jan 2021. The participant was not unblinded on 25 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 29 Jan 2021 (Study Day 155), 154 days after the first dose and 126 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of abortion spontaneous. Action taken with the IP was not applicable. The event of spontaneous abortion was considered to be recovered/resolved on 29 Jan 2021 (Study Day 155). The investigator assessed the event of abortion spontaneous to be not related to the IP.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	28 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	25 Sep 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 16 Jan 2021 (Study Day 142), the participant had positive home urine pregnancy tests on 16 Jan 2021 (Study Day 142) and 17 Jan 2021 (Study Day 143). The first day of the participant's last menstrual period was on 16 Dec 2020 (Study Day 111). The estimated date of conception and estimated due date were not reported.

On 29 Jan 2021 (Study Day 155), at an estimated sixth week of pregnancy, the participant experienced a serious adverse event of spontaneous abortion. The participant reported suffering a miscarriage and consulted their obstetrician/gynecologist, who confirmed the miscarriage on the same date; the cause was not otherwise specified.

Action taken with the study IP in response to the event of spontaneous abortion was not applicable, as the participant had already received both scheduled doses.

The event of spontaneous abortion was reported as resolved on 29 Jan 2021 (Study Day 155).

The investigator assessed the event, spontaneous abortion, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005522	Abortion spontaneous

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	2016 - Ongoing
Depression	Depression	2016 - Ongoing
Post-traumatic stress disorder	Post traumatic stress disorder	Nov 2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	30 Aug 2020 (Study Day 3) - 01 Sep 2020 (Study Day 5)	Headache
Influenza vaccine	20 Nov 2020 (Study Day 85) - 20 Nov 2020 (Study Day 85)	Flu Prophylaxis
Nitrofurantoin	21 Feb 2021 (Study Day 178) - Ongoing	Urinary Tract Infection
Escitalopram	07 Mar 2021 (Study Day 192) - Ongoing	Depression
Prazosin	07 Mar 2021 (Study Day 192) - Ongoing	Post Traumatic Stress Disorder

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	21 Feb 2021 (Study Day 178) - 28 Feb 2021 (Study Day 185)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US374-2463 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 26 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 27 Oct 2020 (Study Day 32)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure during pregnancy	Pregnancy	Not applicable	Not related	25 Mar 2021 (Study Day 181) - Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2463, a 23-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 26 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 27 Oct 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 25 Jan 2021. The participant was unblinded on 25 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 18 Mar 2021 (Study Day 174), the participant had a positive urine pregnancy test. The participant reported using no contraception. The first day of the participant's last menstrual period was on 15 Mar 2021 (Study Day 171). The estimated date of conception was 25 Mar 2021 (Study Day 181) and the estimated due date was 23 Dec 2021 (Study Day 454).

On 22 Apr 2021, the participant contacted the health care provided and reported that they were pregnant with their first child. The participant had an appointment to see their obstetrician doctor on 06 May 2021 (Study Day 223). The participant agreed to be followed through pregnancy outcome.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-087221	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hyperhidrosis	Hyperhidrosis	2009 - Ongoing
Allergy to animal	Cat dander allergy	2013 - Ongoing
Food allergy	Fish allergy	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Botulinum toxin type a	11 Jun 2020 (Study Day -107) - Ongoing	Hyperhidrosis
Etonogestrel	10 Jul 2020 (Study Day -78) - 16 Nov 2020 (Study Day 52)	Contraception
Ibuprofen	27 Oct 2020 (Study Day 32) - 27 Oct 2020 (Study Day 32)	Generalized Pain And Fever
Paracetamol	28 Oct 2020 (Study Day 33) - 28 Oct 2020 (Study Day 33)	Generalized Pain And Fever
Ciprofloxacin	30 Nov 2020 (Study Day 66) - 11 Dec 2020 (Study Day 77)	Urinary Tract Infection
Influenza vaccine	07 Dec 2020 (Study Day 73) - 07 Dec 2020 (Study Day 73)	Influenza Prophylaxis
Metronidazole	11 Dec 2020 (Study Day 77) - 18 Dec 2020 (Study Day 84)	Trichomoniasis Vaginalis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US375-2385 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 02 Oct 2020 (Study Day 30)
First Dose of Vaccine in Part B: 11 Jan 2021 (Study Day 131)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not reported	12 Feb 2021 (Study Day 163) – Ongoing	Not reported

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US375-2385, a 31-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 11 Jan 2021 (Study Day 131). The second dose was not administered.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 12 Feb 2021 (Study Day 163).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	03 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	02 Oct 2020 (Study Day 30)	Negative
Choriogonadotropin Beta	11 Jan 2021 (Study Day 131)	Negative
Choriogonadotropin Beta	12 Feb 2021 (Study Day 163)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 12 Feb 2021 (Study Day 163), the participant had a positive urine pregnancy test. The participant's first day of the last menstrual period was reported as 04 Jan 2021 (Study Day 124), the estimated date of conception and the estimated due date were not reported; the participant had an appointment with their obstetrician on 15 Mar 2021 (Study Day 194). The participant reported that they stopped using drospirenone/ethinylestradiol PO for contraception on 12 Feb 2021 (Study Day 163).

On 20 Feb 2021 (Study Day 171), the participant had a blood test, which confirmed their pregnancy.

Study IP was discontinued as a result of the pregnancy.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014254	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - Ongoing
Nystagmus	Pendular nystagmus	(b) (6) 1988 (Study Day (b) (6) - Ongoing
Eye operation	Eye surgery	2000 - 2000
Migraine	Migraine headaches	2016 - Ongoing
Polycystic ovaries	Polycystic ovarian syndrome	2018 - Ongoing
Seasonal allergy	Seasonal allergies	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amitriptyline	2017 - 01 Dec 2020 (Study Day 90)	Migraine Headaches
Loratadine	2018 - Ongoing	Seasonal Allergies
Metformin	2018 - 01 Dec 2020 (Study Day 90)	Polycystic Ovarian Syndrome
Drospirenone; ethinylestradiol	2019 - 12 Feb 2021 (Study Day 163)	Contraceptive
Vitamins nos	12 Feb 2021 (Study Day 163) - Ongoing	Pregnancy Dietary Supplement
Pap smear*	15 Mar 2021 (Study Day 194) - 15 Mar 2021 (Study Day 194)	Diagnostic
Transvaginal ultrasound*	15 Mar 2021 (Study Day 194) - 15 Mar 2021 (Study Day 194)	Diagnostic
Magnesium	22 Mar 2021 (Study Day 201) - Ongoing	Headaches
Paracetamol	22 Mar 2021 (Study Day 201) - Ongoing	Headaches

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US376-2286 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 17 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 15 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	09 Feb 2021 (Study Day 146) – Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US376-2286, a 37-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 17 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 15 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 31 Dec 2020. The participant was unblinded on 31 Dec 2020 and had already received both doses of mRNA-1273 in Part A.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	17 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	15 Oct 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 16 Mar 2021 (Study Day 181), the participant had a positive pregnancy test. The first day of the participant's last menstrual period was 07 Feb 2021 (Study Day 144), the estimated date of conception was 09 Feb 2021 (Study Day 146), and the estimated due date was 02 Nov 2021 (Study Day 412).

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-052795	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myopia	Nearsighted	1992 - Ongoing
Anxiety	Anxiety	1999 - Ongoing
Acne	Acne	2000 - Ongoing
Asthma	Asthma	2001 - Ongoing
Autoimmune thyroiditis	Hashimoto disease	2002 - Ongoing
Constipation	Frequent constipation	2002 - Ongoing
Epilepsy	Seizure disorder/epilepsy	2005 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine sodium	Aug 2002 - 19 Mar 2021 (Study Day 184)	Hashimotos
Levetiracetam	May 2005 - Ongoing	Epilepsy
Escitalopram oxalate	Jul 2008 - Ongoing	Anxiety
Vitamins nos	Jul 2010 - Ongoing	Wellness
Lacosamide	Aug 2016 - Ongoing	Epilepsy
Ibuprofen	16 Oct 2020 (Study Day 30) - 16 Oct 2020 (Study Day 30)	Pain At Injection Site

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	16 Oct 2020 (Study Day 30) - 16 Oct 2020 (Study Day 30)	Headache
Levothyroxine sodium	19 Mar 2021 (Study Day 184) - Ongoing	Hashimotos

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US377-2017 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 06 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 34)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	03 Apr 2021 (Study Day 241) – Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US377-2017, a 24-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 26 Jan 2021. The participant was unblinded on 26 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	06 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	08 Sep 2020 (Study Day 34)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 03 April 2021 (Study Day 241), the participant had a positive pregnancy test. The first day of the participant's last menstrual period, the estimated date of conception, and the estimated due date were all not reported.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-070618	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Right temporal pain	2018 - Ongoing
Insomnia	Insomnia	2019 - Ongoing
Muscle spasms	Muscle spasms lumbar spine	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cyclobenzaprine hydrochloride	2019 - Ongoing	Muscle Spasms Lumbar Spine
Zolpidem tartrate	2019 - Ongoing	Insomnia
Paracetamol	06 Oct 2020 (Study Day 62) - 06 Oct 2020 (Study Day 62)	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US382-2443 (Part B)
Vaccination Group: mRNA-1273 in Part A, no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 28 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 27 Oct 2020 (Study Day 30)
First Dose of Vaccine in Part B: Not administered
Second Dose of Vaccine in Part B: Not administered
Reason for Narrative: Death

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pulmonary Mass/Right Lower Lobe Pulmonary Nodule Concerning For Primary Lung Malignancy	Death	Grade 5	Not related	11 Jan 2021 (Study Day 106) – 11 Feb 2021 (Study Day 137)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US382-2443, a 75-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 27 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant was unblinded on 13 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 11 Jan 2021 (Study Day 106), 105 days after the first dose in Part A and 76 days after the second dose in Part A of the IP, the participant experienced a Grade 5 serious adverse event of pulmonary mass. Action taken with the IP was not applicable. The event of right lower lobe pulmonary nodule concerning for primary lung malignancy lasted for 32 days, after which it was considered to be fatal on 11 Feb 2021 (Study Day 137). The investigator assessed the event of pulmonary mass to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 11 Jan 2021 (Study Day 106), the participant experienced a fatal serious adverse event of pulmonary mass. The participant had a pulmonary nodule in the right lower lobe, concerning for primary lung malignancy.

On 11 Feb 2021 (Study Day 137), the participant's spouse reported that the participant died, and the cause of death was likely the participant's recent diagnosis of possible right lower lobe pulmonary nodule concerning for primary lung malignancy.

Action taken with the study IP in response to the event of pulmonary mass was not applicable, as the participant had already received both scheduled doses.

The participant died on 11 Feb 2021 (Study Day 137). The cause of death was likely the pulmonary mass.

The investigator assessed the event, pulmonary mass, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014149	Pulmonary mass

Study Completion/Discontinuation

On 11 Feb 2021 (Study Day 137), the participant discontinued from the study due to death. On 11 Feb 2021 (Study Day 137), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Female sterilisation	Tubal ligation	1976 - Ongoing
Myopia	Nearsighted	1990 - Ongoing
Intervertebral disc protrusion	Herniated disc	1997 - 2014
Chronic obstructive pulmonary disease	Copd	2006 - Ongoing
Chronic obstructive pulmonary disease	Shortness of breath related to copd	2006 - Ongoing
Pneumonia	Pneumonia	2008 - 2012
Dysphagia	Trouble swallowing	2010 - Ongoing
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Sinusitis	Sinus infections	2010 - Ongoing
Anxiety	Anxiety	2014 - Ongoing
Atrial fibrillation	Atrial fibrillation	2014 - Ongoing
Intervertebral disc operation	Back surgery for herniated disc	2014 - Ongoing
Dyspepsia	Heartburn	2015 - Ongoing
Dyspepsia	Indigestion	2015 - Ongoing
Gastrointestinal ulcer haemorrhage	Ulcers - gi hemorrhage	2015 - 2015
Gastroesophageal reflux disease	Acid reflux	2015 - Ongoing
Hypertension	Hypertension	2016 - Ongoing
Increased tendency to bruise	Easy bruising	2017 - Ongoing
Osteoporosis	Osteoporosis	2018 - Ongoing
Hypertonic bladder	Overactive bladder	2019 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Urinary incontinence	Urinary incontinence	2019 - Ongoing
Constipation	Frequent constipation	Mar 2020 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	Mar 2020 - Ongoing
Chest discomfort	Chest discomfort	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2010 - Ongoing	Copd, Shortness Of Breath
Digoxin	2014 - Ongoing	Atrial Fibrillation
Duloxetine	2014 - Ongoing	Anxiety
Diphtheria vaccine toxoid; pertussis vaccine acellular; tetanus vaccine toxoid	28 May 2014 (Study Day -2315) - 28 May 2014 (Study Day -2315)	Vaccine
Levosaltamol	2015 - Ongoing	Copd
Pantoprazole	2015 - Ongoing	Acid Reflux
Vitamins nos	2015 - Ongoing	Supplement
Budesonide	2016 - Ongoing	Copd
Diltiazem	2016 - Ongoing	Hypertension
Pneumococcal vaccine	14 Apr 2016 (Study Day -1628) - 14 Apr 2016 (Study Day -1628)	Vaccine
Acetylsalicylic acid	2017 - Ongoing	Supplement
Dextromethorphan hydrobromide; guaifenesin	2017 - Ongoing	Seasonal Allergies
Montelukast	2017 - Ongoing	Shortness Of Breath, Copd
Denosumab	2018 - Ongoing	Osteoporosis
Ipratropium bromide	2018 - Ongoing	Seasonal Allergies
Calcium carbonate	2019 - Ongoing	Supplement
Cod-liver oil	2019 - Ongoing	Supplement
Colecalciferol	2019 - Ongoing	Supplement
Formoterol fumarate	2019 - Ongoing	Copd
Prednisone	2019 - Ongoing	Copd
Vitamin e nos	2019 - Ongoing	Supplement
Influenza vaccine	15 Oct 2019 (Study Day -349) - 15 Oct 2019 (Study Day -349)	Vaccine
Linaclotide	2020 - Ongoing	Constipation
Revefenacin	Jan 2020 - Ongoing	Copd
Macrogol 3350	Feb 2020 - Ongoing	Constipation
Furosemide	04 Dec 2020 (Study Day 68) - 05 Dec 2020 (Study Day 69)	Abdominal Pain And Swollen Feet
Oxygen	04 Dec 2020 (Study Day 68) - Ongoing	Copd
Metoprolol	06 Dec 2020 (Study Day 70) - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Furosemide	12 Dec 2020 (Study Day 76) - 12 Dec 2020 (Study Day 76)	Abdominal Pain
Prednisone	14 Dec 2020 (Study Day 78) - 19 Dec 2020 (Study Day 83)	Copd

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pain In Extremity	Grade 2/moderate	Not related	14 Nov 2020 (Study Day 48) - 15 Nov 2020 (Study Day 49)
Peripheral Swelling	Grade 2/moderate	Not related	02 Dec 2020 (Study Day 66) - 08 Dec 2020 (Study Day 72)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US391-2113 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 02 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	18 Apr 2021 (Study Day 227) – Ongoing	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US391-2113, a 32-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 03 Mar 2021. The participant was unblinded on 03 Mar 2021 and had already received both doses of mRNA-1273 in Part A.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	04 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	02 Oct 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 02 May 2021 (Study Day 241), the participant had a positive pregnancy test. The participant's last menstrual period was on 04 Apr 2021 (Study Day 213). The estimated date of conception was 18 Apr 2021 (Study Day 227) and the estimated due date was 09 Jan 2022 (Study Day 493). The participant did not report using contraceptive.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-101909	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma (mild)	2001 - Ongoing
Anxiety	Anxiety	2003 - Ongoing
Nausea	Nausea	Mar 2020 - Ongoing
Weight decreased	Weight loss	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2001 - Ongoing	Asthma
Clonazepam	May 2019 - Ongoing	Anxiety
Paracetamol	03 Oct 2020 (Study Day 30) - Ongoing	Pain At The Injection Site
Upper lower endoscopy*	06 Oct 2020 (Study Day 33) - 06 Oct 2020 (Study Day 33)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US393-2147 (Part B)
Vaccination Group: Placebo in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 16 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: Not Administered
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Ventricular Arrhythmia/Arrhythmia (Ventricular)	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	21 Jan 2021 (Study Day 128) – 21 Jan 2021 (Study Day 128)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US393-2147, an 84-year-old not Hispanic or Latino female, received the first dose of Placebo in the right arm on 16 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and consented to receive 2 doses of mRNA 1273. The first dose was not administered. The second dose was not administered.

Event Details

On 21 Jan 2021 (Study Day 128), the participant experienced a Grade 5 serious adverse event of ventricular arrhythmia. Action taken with the IP was not applicable. The event of arrhythmia (ventricular) was considered to be fatal on 21 Jan 2021 (Study Day 128). The investigator assessed the event of ventricular arrhythmia to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 21 Jan 2021 (Study Day 128), the participant experienced a fatal serious adverse event of ventricular arrhythmia leading to bradycardia/asystole. The participant developed acute abdominal pain. A CT scan of abdomen and pelvis did not show any significant acute abnormality. Laboratory test results included blood glucose 145, serum creatinine 3.03, Hgb 8.8, and hematocrit 28.1 (no units or reference ranges provided). The participant became significantly bradycardic, and a rapid

response was called; the participant's oxygen saturation was 84%, the participant's pulse was eventually lost, and they experienced asystole and died.

Action taken with study IP in response to the events was not applicable.

The participant died on 21 Jan 2021 (Study Day 128), and the cause of death was reported as ventricular arrhythmia. It was unknown if an autopsy was performed.

The investigator assessed the event, ventricular arrhythmia, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001757	Ventricular arrhythmia

Study Completion/Discontinuation

On 21 Jan 2021 (Study Day 128), the participant discontinued from the study due to death. On 21 Jan 2021 (Study Day 128), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug intolerance	Ambien intolerance	Not reported - Ongoing
Drug intolerance	Corticosteroid intolerance	Not reported - Ongoing
Cardiac murmur	Heart murmur - unknown etiology	(b) (6) 1936 - Ongoing
Asthma	Asthma	1939 - Ongoing
Migraine	Migraines	1945 - 2010
Uterine leiomyoma	Fibroid tumors	1950 - Ongoing
Drug hypersensitivity	Allergy to morphine, codeine, and demerol	1956 - Ongoing
Drug hypersensitivity	Penicillin allergy	1956 - Ongoing
Drug hypersensitivity	Statin medication allergy	1956 - Ongoing
Hypertension	Hypertension	1956 - Ongoing
Nephrolithiasis	Kidney stones	1959 - 1959
Pneumonia	Lung infection	1960 - 1960
Blood cholesterol increased	High cholesterol	1984 - Ongoing
Hepatic enzyme increased	Liver enzyme elevation	1984 - 1984
Postmenopause	Post-menopausal	1989 - Ongoing
Chronic kidney disease	Chronic kidney disease	2000 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Upper limb fracture	Left arm fracture	2000 - 2000
Cataract	Bilateral cataracts	2009 - 2009
Renal cyst	Bilateral kidney cysts benign	2010 - Ongoing
Restless legs syndrome	Restless leg syndrome	2010 - Ongoing
Obesity	Obesity	2011 - Ongoing
Cardiac failure congestive	Congestive heart failure	2014 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2014 - Ongoing
Emphysema	Emphysema	2014 - Ongoing
Poor peripheral circulation	Poor circulation in legs	2014 - Ongoing
Upper limb fracture	Left shoulder fracture	2015 - 2015
Deafness bilateral	Bilateral hearing loss	2016 - Ongoing
Fluid retention	Bilateral ankle/ feet fluid retention	2016 - Ongoing
Urinary incontinence	Bladder incontinence	2016 - Ongoing
Intestinal ischaemia	Ischemic bowel disease	2017 - 2017
Myalgia	Muscle aches	2017 - Ongoing
Seasonal allergy	Seasonal allergies	2017 - Ongoing
Transfusion	Blood transfusion	2017 - 2017
Abdominal hernia	Abdominal hernia	2019 - Ongoing
Herpes zoster	Shingles	2019 - 2019
Constipation	Constipation	2020 - Ongoing
Anaemia	Anemia	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2000 - Ongoing	Emphysema/Copd/Asthma
Metoprolol	2010 - Ongoing	Hypertension
Pramipexole	2016 - Ongoing	Restless Leg Syndrome
Fluticasone	2017 - Ongoing	Seasonal Allergies
Umeclidinium bromide; vilanterol trifenate	2017 - Ongoing	Emphysema
Ipratropium; salbutamol	2018 - Ongoing	Emphysema/ Copd/Asthma
Vitamin b12 nos	2018 - Ongoing	Vitamin Supplement
Docusate sodium	Apr 2020 - Ongoing	Constipation
Ferrous sulfate	Apr 2020 - Ongoing	Anemia
Hydralazine	May 2020 - Ongoing	Hypertension
Verapamil	May 2020 - Ongoing	Hypertension
Furosemide	Sep 2020 - Ongoing	Bilateral Ankle/ Feetfluid Retention
Potassium	Sep 2020 - Ongoing	Bilateral Ankle/ Feetfluid Retention

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chest x ray*	05 Oct 2020 (Study Day 20) - 05 Oct 2020 (Study Day 20)	Adverse Event
Ecg*	05 Oct 2020 (Study Day 20) - 05 Oct 2020 (Study Day 20)	Adverse Event
Pramipexole dihydrochloride	05 Oct 2020 (Study Day 20) - Ongoing	Restless Leg Syndrome
Electrocardiogram*	07 Oct 2020 (Study Day 22) - 07 Oct 2020 (Study Day 22)	Adverse Event
Echocardiogram*	08 Oct 2020 (Study Day 23) - 08 Oct 2020 (Study Day 23)	Adverse Event
Glyceryl trinitrate	11 Oct 2020 (Study Day 26) - Ongoing	Worsening Chf
Nifedipine	11 Oct 2020 (Study Day 26) - Ongoing	Worsening Congestive Heart Failure
Doxycycline hyclate	22 Dec 2020 (Study Day 98) - Ongoing	Unknown Indication
Prednisone	22 Dec 2020 (Study Day 98) - Ongoing	Copd
Amiodarone	29 Dec 2020 (Study Day 105) - Ongoing	Worsening Chf
Apixaban	29 Dec 2020 (Study Day 105) - 06 Jan 2021 (Study Day 113)	Worsening Chf
Chest x-ray*	29 Dec 2020 (Study Day 105) - 29 Dec 2020 (Study Day 105)	Adverse Event
Dialysis*	29 Dec 2020 (Study Day 105) - 29 Dec 2020 (Study Day 105)	Adverse Event
Diltiazem	29 Dec 2020 (Study Day 105) - Ongoing	Worsening Chf
Echocardiogram*	29 Dec 2020 (Study Day 105) - 29 Dec 2020 (Study Day 105)	Adverse Event
Electrocardiogram*	29 Dec 2020 (Study Day 105) - 29 Dec 2020 (Study Day 105)	Adverse Event
Epoetin alfa	29 Dec 2020 (Study Day 105) - Ongoing	Chronic Kidney Disease
Glucagon	29 Dec 2020 (Study Day 105) - Ongoing	Diabetes Mellitus
Glucose	29 Dec 2020 (Study Day 105) - Ongoing	Diabetes Mellitus Type 2
Insulin	29 Dec 2020 (Study Day 105) - Ongoing	Diabetes Mellitus Type 2
Methylprednisolone	29 Dec 2020 (Study Day 105) - Ongoing	Worsening Copd
Pantoprazole	29 Dec 2020 (Study Day 105) - 06 Jan 2021 (Study Day 113)	Gerd
Electrocardiogram*	30 Dec 2020 (Study Day 106) - 30 Dec 2020 (Study Day 106)	Adverse Event
Electrocardiogram*	01 Jan 2021 (Study Day 108) - 01 Jan 2021 (Study Day 108)	Adverse Event
Nuclear medicine myocardial perfusion scan*	01 Jan 2021 (Study Day 108) - 01 Jan 2021 (Study Day 108)	Adverse Event
Regadenoson	01 Jan 2021 (Study Day 108) - 01 Jan 2021 (Study Day 108)	Worsening Of Chf
Guaifenesin	03 Jan 2021 (Study Day 110) - Ongoing	Pneumonia Caused By COVID
Oxygen	03 Jan 2021 (Study Day 110) - 21 Jan 2021 (Study Day 128)	Acute Respiratory Failure
Plantago ovata	03 Jan 2021 (Study Day 110) - Ongoing	Pneumonia Caused By COVID
Ct chest without contrast*	04 Jan 2021 (Study Day 111) - 04 Jan 2021 (Study Day 111)	Adverse Event
Ondansetron	04 Jan 2021 (Study Day 111) - Ongoing	COVID-19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Retro-peritoneal ultrasound*	04 Jan 2021 (Study Day 111) - 04 Jan 2021 (Study Day 111)	Adverse Event
Tiotropium	04 Jan 2021 (Study Day 111) - Ongoing	COVID-19
Chest x-ray*	06 Jan 2021 (Study Day 113) - 06 Jan 2021 (Study Day 113)	Adverse Event
Blood transfusion*	07 Jan 2021 (Study Day 114) - 07 Jan 2021 (Study Day 114)	Adverse Event
Electrocardiogram*	07 Jan 2021 (Study Day 114) - 07 Jan 2021 (Study Day 114)	Adverse Event
Blood transfusion*	08 Jan 2021 (Study Day 115) - 08 Jan 2021 (Study Day 115)	Adverse Event
Chest x-ray*	08 Jan 2021 (Study Day 115) - 08 Jan 2021 (Study Day 115)	Adverse Event
Blood transfusion*	11 Jan 2021 (Study Day 118) - 11 Jan 2021 (Study Day 118)	Adverse Event
Blood transfusion*	16 Jan 2021 (Study Day 123) - 16 Jan 2021 (Study Day 123)	Adverse Event
Electrocardiogram*	17 Jan 2021 (Study Day 124) - 17 Jan 2021 (Study Day 124)	Adverse Event
Chest x-ray*	18 Jan 2021 (Study Day 125) - 18 Jan 2021 (Study Day 125)	Adverse Event
Blood transfusion*	19 Jan 2021 (Study Day 126) - 19 Jan 2021 (Study Day 126)	Adverse Event
Ct abd/pelv without contrast*	21 Jan 2021 (Study Day 128) - 21 Jan 2021 (Study Day 128)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gastroesophageal Reflux Disease	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 122) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US300-2149 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 11 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Oesophageal Carcinoma/ Esophageal Cancer	SAE	Grade 3/severe	Not related	09 Apr 2021 (Study Day 242) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US300-2149, a 57-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 23 Feb 2021. The participant was unblinded on 23 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 09 Apr 2021 (Study Day 242), 241 days after the first dose in Part A and 212 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of oesophageal carcinoma. Action taken with the IP was not applicable. The event of oesophageal cancer was considered to be ongoing. The investigator assessed the event of oesophageal carcinoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-082387	Oesophageal carcinoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hereditary motor and sensory neuropathy	Charcot-marie tooth disorder	04 Mar 2016 (Study Day -1621) - 24 Sep 2019 (Study Day -322)
Leg amputation	Right leg amputation	16 Jul 2016 (Study Day -1487) - 16 Jul 2016 (Study Day -1487)
Drug hypersensitivity	Vancomycin allergy	May 2019 - Ongoing
Leg amputation	Left leg amputation	24 Sep 2019 (Study Day -322) - 24 Sep 2019 (Study Day -322)
Peptic ulcer	Peptic ulcer disease	04 Jul 2020 (Study Day -38) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2016 - Ongoing	Bilateral Leg Amputation
Pantoprazole	10 Jul 2020 (Study Day -32) - Ongoing	Peptic Ulcer Disease

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US301-2073 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 06 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 11 Jan 2021 (Study Day 159)
Second Dose of Vaccine in Part B: 08 Feb 2021 (Study Day 187)
Reason for Narrative: SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Amyotrophic Lateral Sclerosis/Worsening Of Amyotrophic Lateral Sclerosis	SAE, AE leading to study discontinuation	Grade 3/ severe	Not related	26 Feb 2021 (Study Day 205) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US301-2073, a 70-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 11 Jan 2021 (Study Day 159). The second dose was administered in the left arm on 08 Feb 2021 (Study Day 187).

Event Details

On 26 Feb 2021 (Study Day 205), 204 days after the first dose in Part A/46 days after the first dose in Part B and 176 days after the second dose in Part A/18 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of amyotrophic lateral sclerosis. Action taken with the IP was not applicable. The event of worsening of amyotrophic lateral sclerosis was considered to be ongoing. The investigator assessed the event of amyotrophic lateral sclerosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-036352	Amyotrophic lateral sclerosis

Study Completion/Discontinuation

On 05 Mar 2021 (Study Day 212), the participant discontinued from the study due to serious adverse event.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies, unspecified	1980 - Ongoing
Blood testosterone decreased	Low testosterone	2014 - Ongoing
Prostate cancer	Prostate cancer	Nov 2015 - Nov 2015
Dysphagia	Difficulty swallowing	28 Jun 2020 (Study Day -39) - Ongoing
Tongue movement disturbance	Loss of control of tongue muscles	28 Jun 2020 (Study Day -39) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Testosterone	01 Jan 2015 (Study Day -2044) - 01 Jan 2021 (Study Day 149)	Hormone Replacement
Influenza vaccine	29 Oct 2020 (Study Day 85) - 29 Oct 2020 (Study Day 85)	Influenza Prevention
Pneumococcal vaccine	29 Oct 2020 (Study Day 85) - 29 Oct 2020 (Study Day 85)	Pneumonia Prevention
Calcium carbonate	26 Feb 2021 (Study Day 205) - 02 Mar 2021 (Study Day 209)	Worsening Of Als (Ae #1)
Dextromethorphan hydrobromide; guaifenesin	26 Feb 2021 (Study Day 205) - 02 Mar 2021 (Study Day 209)	Worsening Of Als (Ae #1)
Docusate sodium	26 Feb 2021 (Study Day 205) - 02 Mar 2021 (Study Day 209)	Worsening Of Als (Ae #1)
Feeding tube*	26 Feb 2021 (Study Day 205) - 26 Feb 2021 (Study Day 205)	Adverse Event
Glucose	26 Feb 2021 (Study Day 205) - 02 Mar 2021 (Study Day 209)	Worsening Of Als (Ae #1)
Magnesium hydroxide	26 Feb 2021 (Study Day 205) - 02 Mar 2021 (Study Day 209)	Worsening Of Als (Ae #1)
Melatonin	26 Feb 2021 (Study Day 205) - 02 Mar 2021 (Study Day 209)	Worsening Of Als (Ae #1)
Ondansetron	26 Feb 2021 (Study Day 205) - 02 Mar 2021 (Study Day 209)	Worsening Of Als (Ae #1)
Paracetamol	26 Feb 2021 (Study Day 205) - 02 Mar 2021 (Study Day 209)	Worsening Of Als (Ae #1)
Sodium chloride	26 Feb 2021 (Study Day 205) - 26 Feb 2021 (Study Day 205)	Worsening Of Als (Ae #1)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glycopyrronium	05 Mar 2021 (Study Day 212) - Ongoing	Excess Saliva, Due To Worsening Of Als
Tramadol	05 Mar 2021 (Study Day 212) - Ongoing	Pain, Due To Worsening Of Als

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US301-2171 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 18 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 15 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Epididymitis/Epididymitis	SAE	Grade 2/ moderate	Not related	12 Mar 2021 (Study Day 207) – 13 Apr 2021 (Study Day 239)	Recovered/ resolved
Leukocytosis/Leukocytosis	SAE	Grade 1/ mild	Not related	12 Mar 2021 (Study Day 207) – 13 Apr 2021 (Study Day 239)	Recovered/ resolved
Urinary Tract Infection/ Urinary Tract Infection	SAE	Grade 1/ mild	Not related	12 Mar 2021 (Study Day 207) – 13 Apr 2021 (Study Day 239)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US301-2171, a 64-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 18 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 15 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Mar 2021. The participant was unblinded on 11 Mar 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 12 Mar 2021 (Study Day 207), 206 days after the first dose in Part A and 178 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of epididymitis. Action taken with the IP was not applicable. The event of epididymitis lasted for 33 days, after which it was considered to be recovered/resolved on 13 Apr 2021 (Study Day 239). The investigator assessed the event of epididymitis to be not related to the IP.

On 12 Mar 2021 (Study Day 207), 206 days after the first dose in Part A and 178 days after the second dose in Part A of the IP, the participant experienced a Grade 1/mild serious adverse event of leukocytosis. Action taken with the IP was not applicable. The event of leukocytosis lasted for 33 days, after which it was considered to be recovered/resolved on 13 Apr 2021 (Study Day 239). The investigator assessed the event of leukocytosis to be not related to the IP.

On 12 Mar 2021 (Study Day 207), 206 days after the first dose in Part A and 178 days after the second dose in Part A of the IP, the participant experienced a Grade 1/mild serious adverse event of urinary tract infection. Action taken with the IP was not applicable. The event of urinary tract infection lasted for 33 days, after which it was considered to be recovered/resolved on 13 Apr 2021 (Study Day 239). The investigator assessed the event of urinary tract infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-045387	Epididymitis
MOD-2021-045387	Leukocytosis
MOD-2021-045387	Urinary tract infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies, unspecified	1960 - Ongoing
Food allergy	Allergy to citrus	1970 - Ongoing
Osteoarthritis	Osteoarthritis, bilateral fingers	1973 - Ongoing
Obesity	Obesity	2016 - Ongoing
Hypertonic bladder	Overactive bladder	2017 - Ongoing
Type 2 diabetes mellitus	Diabetes, type ii	2018 - Ongoing
Back pain	Back pain, lumbar	12 Sep 2018 (Study Day -706) - Nov 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Boron; chromium; copper; germanium; iodine; manganese; molybdenum; selenium; silicon; sitosterol; vanadium; vitamin d nos; zinc	09 Oct 2020 (Study Day 53) - 18 Mar 2021 (Study Day 213)	Nutritional Supplement
Influenza vaccine	27 Oct 2020 (Study Day 71) - 27 Oct 2020 (Study Day 71)	Influenza Prevention

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amoxicillin; clavulanic acid	12 Mar 2021 (Study Day 207) - 13 Apr 2021 (Study Day 239)	Uti (Ae #1)
Docusate sodium	12 Mar 2021 (Study Day 207) - 21 Mar 2021 (Study Day 216)	Epididymitis
Glipizide	12 Mar 2021 (Study Day 207) - Ongoing	T2dm
Hydrocodone; paracetamol	12 Mar 2021 (Study Day 207) - 21 Mar 2021 (Study Day 216)	Pain Due To Uti, Leukocytosis
Insulin aspart	12 Mar 2021 (Study Day 207) - 16 Mar 2021 (Study Day 211)	T2dm
Metformin	12 Mar 2021 (Study Day 207) - Ongoing	T2dm
Tamsulosin hydrochloride	12 Mar 2021 (Study Day 207) - Ongoing	Urinary Tract Infection (Ae #1)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US302-2167 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 17 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dehydration/Dehydration	SAE	Grade 4	Not related	19 Mar 2021 (Study Day 215) – 22 Mar 2021 (Study Day 218)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US302-2167, a 21-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 14 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Jan 2021. The participant was unblinded on 04 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 19 Mar 2021 (Study Day 215), 214 days after the first dose in Part A and 186 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of dehydration. Action taken with the IP was not applicable. The event of dehydration lasted for 4 days, after which it was considered to be recovered/resolved on 22 Mar 2021 (Study Day 218). The investigator assessed the event of dehydration to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-057349	Dehydration

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Amoxicillin allergy	2003 - Ongoing
Sciatica	Left leg sciatic nerve pain	2015 - Ongoing
Helicobacter infection	Presence of h. pylori infection	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2015 - Ongoing	Left Leg Sciatic Nerve Pain
Clarithromycin	2017 - Ongoing	H-Pylori
Etonogestrel	24 Apr 2019 (Study Day -481) - Ongoing	Contraception
Fluconazole	24 Aug 2020 (Study Day 8) - 24 Aug 2020 (Study Day 8)	Dysuria
Paracetamol	14 Sep 2020 (Study Day 29) - 18 Sep 2020 (Study Day 33)	Pain At Injection Site/Headache
Fluconazole	18 Sep 2020 (Study Day 33) - 18 Sep 2020 (Study Day 33)	Dysuria
Fluconazole	05 Oct 2020 (Study Day 50) - 08 Oct 2020 (Study Day 53)	Yeast Infection
Ondansetron	15 Oct 2020 (Study Day 60) - Ongoing	Acute Gastritis
Promethazine	15 Oct 2020 (Study Day 60) - 26 Oct 2020 (Study Day 71)	Vomiting
Sucralfate	15 Oct 2020 (Study Day 60) - Ongoing	Acute Gastritis
Citalopram	16 Feb 2021 (Study Day 184) - Ongoing	Anxiety
Pantoprazole	15 Mar 2021 (Study Day 211) - Ongoing	Acute Gastritis
Lorazepam	22 Mar 2021 (Study Day 218) - Ongoing	Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anxiety	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 169) - Ongoing
Dehydration	Grade 2/moderate	Not related	14 Mar 2021 (Study Day 210) - 16 Mar 2021 (Study Day 212)
Cholecystitis	Grade 3/severe	Not related	19 Mar 2021 (Study Day 215) - 29 Mar 2021 (Study Day 225)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US303-2108 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 05 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 36)
First Dose of Vaccine in Part B: 02 Mar 2021 (Study Day 210)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dental Caries/Tooth Decay On Right Side Of The Mouth.	SAE	Grade 3/ severe	Not related	12 Apr 2021 (Study Day 251) – 25 Apr 2021 (Study Day 264)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US303-2108, a 29-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 02 Mar 2021. The participant was unblinded on 02 Mar 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 02 Mar 2021 (Study Day 210). The second dose was not administered.

Event Details

On 12 Apr 2021 (Study Day 251), 250 days after the first dose in Part A/41 days after the first dose in Part B and 215 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of dental caries. Action taken with the IP was not applicable. The event of tooth decay on right side of the mouth lasted for 14 days, after which it was considered to be recovered/resolved on 25 Apr 2021 (Study Day 264). The investigator assessed the event of dental caries to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-101184	Dental caries

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	2005 - Ongoing
Headache	Chronic headache	2009 - Ongoing
Drug hypersensitivity	Penicillin allergy	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2005 - Ongoing	Asthma
Acetylsalicylic acid; caffeine; paracetamol	08 Aug 2020 (Study Day 4) - 25 Aug 2020 (Study Day 21)	Headache
Acetylsalicylic acid; butalbital; caffeine	24 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 21)	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US303-2249 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 19 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 21 Sep 2020 (Study Day 34)
First Dose of Vaccine in Part B: 28 Jan 2021 (Study Day 163)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 3/ severe	Not related	02 Feb 2021 (Study Day 168) – 01 Mar 2021 (Study Day 195)	Recovered/resolved with sequelae
Pneumonia/Bilateral Pneumonia	SAE	Grade 3/ severe	Not related	01 Mar 2021 (Study Day 195) – 05 Mar 2021 (Study Day 199)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US303-2249, a 72-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 28 Jan 2021. The participant was unblinded on 28 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 28 Jan 2021 (Study Day 163). The second dose was not administered.

Event Details

On 01 Mar 2021 (Study Day 195), 194 days after the first dose in Part A/32 days after the first dose in Part B and 161 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of pneumonia. The IP dose was delayed due to the bilateral pneumonia. The event of bilateral pneumonia lasted for 5 days, after which it was considered to be recovered/resolved on 05 Mar 2021 (Study Day 199). The investigator assessed the event of pneumonia to be not related to the IP.

Severe COVID-19 Details

On 02 Feb 2021 (Study Day 168), 167 days after the first dose in Part A/5 days after the first dose in Part B and 134 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 3/Severe serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 21 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 09 Feb 2021 (Study Day 175), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
08 Feb 2021 (Study Day 174)	Body Aches	Moderate
08 Feb 2021 (Study Day 174)	Chills	Moderate
08 Feb 2021 (Study Day 174)	Cough	Moderate
08 Feb 2021 (Study Day 174)	Difficulty Breathing	Mild
08 Feb 2021 (Study Day 174)	Fatigue	Moderate
08 Feb 2021 (Study Day 174)	Headache	Mild
08 Feb 2021 (Study Day 174)	Muscle Aches (Myalgia)	Moderate
08 Feb 2021 (Study Day 174)	Nasal Congestion	Severe
08 Feb 2021 (Study Day 174)	New Loss of Taste	Moderate
08 Feb 2021 (Study Day 174)	Runny Nose (Rhinorrhea)	Moderate
08 Feb 2021 (Study Day 174)	Shortness of Breath	Moderate
08 Feb 2021 (Study Day 174)	Sore Throat	Moderate

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
02 Feb 2021 (Study Day 168)	Oxygen Saturation	88%
02 Feb 2021 - 02 Feb 2021 (Study Day 168-168)	Oxygen Saturation of SpO2 <= 93% on room air at sea level	Yes
09 Feb 2021 - 09 Feb 2021 (Study Day 175-175)	Clinical Evidence of Pneumonia	Yes

The IP dose was delayed due to the COVID-19. The event of COVID-19 lasted for 28 days, after which it was considered to be recovered/resolved with sequelae on 01 Mar 2021 (Study Day 195). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-013211	COVID-19
MOD-2021-013211	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Menorrhagia	Menorrhagia	1981 - 1983
Hysterectomy	Hysterectomy	1983 - 1983
Arthroscopy	Right knee arthroscopy	2004 - 2004
Arthroscopy	Left knee arthroscopy	2005 - 2005
Osteoarthritis	Osteoarthritis	2006 - Ongoing
Seasonal allergy	Seasonal allergies	2007 - Ongoing
Allergy to surgical sutures	Polyglactin suture hypersensitivity	2014 - Ongoing
Cholecystectomy	Cholecystectomy	2014 - 2014
Cholecystitis	Cholecystitis	2014 - 2014
Asthma	Asthma	2015 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disorder	2015 - Ongoing
Gastroesophageal reflux disease	Acid reflux	2017 - Ongoing
Hypertension	Hypertension	2017 - Ongoing
Oedema peripheral	Edema bilateral lower leg	2017 - Ongoing
Dyslipidaemia	Dyslipidemia	2018 - Ongoing
Hypertonic bladder	Over active bladder	2018 - Ongoing
Oestrogen deficiency	Estrogen deficiency	2018 - Ongoing
Impaired gastric emptying	Gastroparesis	Jun 2020 - Jun 2020
Oesophagogastrroduodenoscopy	Esophagogastrroduodenoscopy	Jun 2020 - Jun 2020
Radioisotope scan	Gastric emptying scintigraphy	Jun 2020 - Jun 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone	2008 - Ongoing	Medical History: Seasonal Allergies

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fexofenadine	2009 - Ongoing	Medical History: Seasonal Allergies
Chondroitin; glucosamine	2015 - Ongoing	Medical History: Osteoarthritis
Montelukast	2015 - Ongoing	Medical History: Seasonal Allergies
Fluticasone furoate; umeclidinium bromide; vilanterol trifenate	2017 - Ongoing	Medical History: Copd & Asthma
Hydrochlorothiazide; olmesartan	2017 - Ongoing	Medical History: Hypertension
Omeprazole	2017 - Ongoing	Medical History: Acid Reflux
Colesevelam	2018 - Ongoing	Dyslipidemia
Estradiol	2018 - Ongoing	Estrogen Deficiency
Furosemide	2018 - Ongoing	Medical History: Bilateral Lower Leg Edema
Oxybutynin	2019 - Ongoing	Medical History: Overactive Bladder
Metoclopramide	Jul 2020 - Ongoing	Medical History: Gastroparesis
Dupilumab	Jan 2021 - Ongoing	Asthma
Basal metabolic panel*	09 Feb 2021 (Study Day 175) - 09 Feb 2021 (Study Day 175)	Adverse Event
Budesonide	09 Feb 2021 (Study Day 175) - 12 Feb 2021 (Study Day 178)	COVID-19
Ceftriaxone	09 Feb 2021 (Study Day 175) - 12 Feb 2021 (Study Day 178)	COVID-19
Chest x-ray*	09 Feb 2021 (Study Day 175) - 09 Feb 2021 (Study Day 175)	Adverse Event
Codeine phosphate; promethazine hydrochloride	09 Feb 2021 (Study Day 175) - 24 Mar 2021 (Study Day 218)	COVID-19
Complete blood count*	09 Feb 2021 (Study Day 175) - 09 Feb 2021 (Study Day 175)	Adverse Event
Enoxaparin	09 Feb 2021 (Study Day 175) - 12 Feb 2021 (Study Day 178)	COVID-19
Formoterol	09 Feb 2021 (Study Day 175) - 12 Feb 2021 (Study Day 178)	COVID-19
Other antivirals	09 Feb 2021 (Study Day 175) - 09 Feb 2021 (Study Day 175)	COVID-19
Oxygen	09 Feb 2021 (Study Day 175) - 12 Feb 2021 (Study Day 178)	COVID-19
Pantoprazole	09 Feb 2021 (Study Day 175) - 12 Feb 2021 (Study Day 178)	COVID-19
Paracetamol	09 Feb 2021 (Study Day 175) - 12 Feb 2021 (Study Day 178)	COVID-19
Prednisone	09 Feb 2021 (Study Day 175) - 12 Feb 2021 (Study Day 178)	COVID-19
Rapid covid-19 test*	09 Feb 2021 (Study Day 175) - 09 Feb 2021 (Study Day 175)	Adverse Event
Salbutamol	09 Feb 2021 (Study Day 175) - 12 Feb 2021 (Study Day 178)	COVID-19
Sodium chloride	09 Feb 2021 (Study Day 175) - 12 Feb 2021 (Study Day 178)	COVID-19
Azithromycin	10 Feb 2021 (Study Day 176) - 12 Feb 2021 (Study Day 178)	COVID-19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Basal metabolic panel*	01 Mar 2021 (Study Day 195) - 01 Mar 2021 (Study Day 195)	Adverse Event
Benzonatate	01 Mar 2021 (Study Day 195) - 05 Mar 2021 (Study Day 199)	Bilateral Pneumonia
Blood cultures*	01 Mar 2021 (Study Day 195) - 01 Mar 2021 (Study Day 195)	Adverse Event
Chest x-ray*	01 Mar 2021 (Study Day 195) - 01 Mar 2021 (Study Day 195)	Adverse Event
Complete blood count*	01 Mar 2021 (Study Day 195) - 01 Mar 2021 (Study Day 195)	Adverse Event
Ct angiogram chest with contrast*	01 Mar 2021 (Study Day 195) - 01 Mar 2021 (Study Day 195)	Adverse Event
Elevated d-dimer*	01 Mar 2021 (Study Day 195) - 01 Mar 2021 (Study Day 195)	Adverse Event
Enoxaparin	01 Mar 2021 (Study Day 195) - 05 Mar 2021 (Study Day 199)	Bilateral Pneumonia
Flutter/pcp therapy*	01 Mar 2021 (Study Day 195) - 01 Mar 2021 (Study Day 195)	Adverse Event
Ipratropium bromide; salbutamol sulfate	01 Mar 2021 (Study Day 195) - 05 Mar 2021 (Study Day 199)	Bilateral Pneumonia
Levofloxacin	01 Mar 2021 (Study Day 195) - 05 Mar 2021 (Study Day 199)	Bilateral Pneumonia
Pantoprazole	01 Mar 2021 (Study Day 195) - 05 Mar 2021 (Study Day 199)	Bilateral Pneumonia
Paracetamol	01 Mar 2021 (Study Day 195) - 05 Mar 2021 (Study Day 199)	Bilateral Pneumonia
Piperacillin sodium; tazobactam sodium	01 Mar 2021 (Study Day 195) - 05 Mar 2021 (Study Day 199)	Bilateral Pneumonia
Pro-calcitonin*	01 Mar 2021 (Study Day 195) - 01 Mar 2021 (Study Day 195)	Adverse Event
Salbutamol	01 Mar 2021 (Study Day 195) - 05 Mar 2021 (Study Day 199)	Bilateral Pneumonia
Chest x-ray*	03 Mar 2021 (Study Day 197) - 03 Mar 2021 (Study Day 197)	Adverse Event
Salbutamol	05 Mar 2021 (Study Day 199) - Ongoing	Bilateral Pneumonia
Fluconazole	19 Mar 2021 (Study Day 213) - 19 Mar 2021 (Study Day 213)	Perineal Irritation In Female
Nystatin	19 Mar 2021 (Study Day 213) - 22 Mar 2021 (Study Day 216)	Perineal Irritation In Female

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dyspnoea	Grade 3/severe	Not related	01 Mar 2021 (Study Day 195) - 05 Mar 2021 (Study Day 199)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Haematochezia	Grade 2/moderate	Not related	17 Mar 2021 (Study Day 211) - 19 Mar 2021 (Study Day 213)
Haemorrhoids	Grade 1/mild	Not related	19 Mar 2021 (Study Day 213) - Ongoing
Perineal Disorder	Grade 1/mild	Not related	19 Mar 2021 (Study Day 213) - 22 Mar 2021 (Study Day 216)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US303-2343 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 29 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Oropharyngeal Pain/Sore Throat	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	24 Mar 2021 (Study Day 205) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US303-2343, a 29-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 23 Feb 2021. The participant was unblinded on 23 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 24 Mar 2021 (Study Day 205), 204 days after the first dose in Part A and 176 days after the second dose in Part A of the IP, the participant experienced a Grade 1/mild non-serious adverse event of oropharyngeal pain. The IP dose was withdrawn due to the sore throat. The event of sore throat was considered to be ongoing. The investigator assessed the event of oropharyngeal pain to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	02 Sep 2020 (Study Day 2) - 02 Sep 2020 (Study Day 2)	Pain At Injection Site
Amoxicillin	24 Mar 2021 (Study Day 205) - Ongoing	Sore Throat

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Oropharyngeal Pain	Grade 1/mild	Not related	24 Mar 2021 (Study Day 205) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US304-2262 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 20 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 17 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intentional Self-Injury/Act Of Self-Harm	SAE	Grade 2/ moderate	Not related	24 Feb 2021 (Study Day 189) – 24 Feb 2021 (Study Day 189)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US304-2262, a 22-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 16 Jan 2021. The participant was unblinded on 16 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 24 Feb 2021 (Study Day 189), 188 days after the first dose in Part A and 160 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of intentional self-injury. Action taken with the IP was not applicable. The event of act of self-harm lasted for 1 day, after which it was considered to be recovered/resolved on 24 Feb 2021 (Study Day 189). The investigator assessed the event of intentional self-injury to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-038806	Intentional self-injury

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Asthma	Ashtma	2005 - Ongoing
Obesity	Severe obesity	2010 - Ongoing
Anxiety	Anxiety	2016 - Ongoing
Depression	Depression	2016 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit hyperactive disorder	2019 - Ongoing
Insomnia	Insomnia	Feb 2020 - Ongoing
Facial paralysis	Bells palsy	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol sulfate	2010 - Ongoing	Asthma
Fluticasone propionate	2014 - Ongoing	Seasonal Allergies
Bupropion	2019 - Ongoing	Depression
Buspirone	2019 - Ongoing	Anxiety
Clonidine	Oct 2019 - Ongoing	Anxiety
Matricaria recutita flower; melatonin; melissa officinalis herb; passiflora incarnata herb; theanine	Feb 2020 - Ongoing	Insomnia
Methylphenidate	Feb 2020 - Ongoing	Attention Deficit Hyperactive Disorder
Trazodone	Feb 2020 - Ongoing	Insomnia
Fexofenadine hydrochloride; pseudoephedrine hydrochloride	Mar 2020 - Ongoing	Seasonal Allergies
Montelukast	Apr 2020 - Ongoing	Seasonal Allergies
Baclofen	08 Jul 2020 (Study Day -43) - 13 Jul 2020 (Study Day -38)	Bells Palsy
Prednisone	08 Jul 2020 (Study Day -43) - 18 Jul 2020 (Study Day -33)	Bells Palsy
Valaciclovir	08 Jul 2020 (Study Day -43) - 15 Jul 2020 (Study Day -36)	Bells Palsy
Ibuprofen	18 Sep 2020 (Study Day 30) - 18 Sep 2020 (Study Day 30)	Solicited Symptom- Headaches
Dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	01 Oct 2020 (Study Day 43) - 15 Oct 2020 (Study Day 57)	Viral Syndrome Of Unknown Etiology
Desvenlafaxine	09 Nov 2020 (Study Day 82) - Ongoing	Worsening Depression

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Alprazolam	11 Dec 2020 (Study Day 114) - Ongoing	Anxiety
Prednisone	04 Jan 2021 (Study Day 138) - 15 Jan 2021 (Study Day 149)	L5 Slipped Disc
Cannabis sativa	08 Mar 2021 (Study Day 201) - Ongoing	Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US304-2309 (Part B)
Vaccination Group: Placebo in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 22 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 24 Sep 2020 (Study Day 34)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Stab Wound/Abdominal Stab Wound	SAE	Grade 4	Not related	13 Feb 2021 (Study Day 176) – 04 Mar 2021 (Study Day 195)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US304-2309, a 39-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 22 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 13 Jan 2021. The participant was unblinded on 13 Jan 2021 and consented to receive 2 doses of mRNA-1273. The first dose was not administered. The second dose was not administered.

Event Details

On 13 Feb 2021 (Study Day 176), 175 days after the first dose in Part A and 142 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of stab wound. Action taken with the IP was not applicable. The event of abdominal stab wound lasted for 20 days, after which it was considered to be recovered/resolved on 04 Mar 2021 (Study Day 195). The investigator assessed the event of stab wound to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-015266	Stab wound

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	2008 - Ongoing
Migraine	Migraines	2008 - Ongoing
Blood testosterone decreased	Low testosterone	2016 - Ongoing
Drug abuse	Narcotic abuse	2016 - Ongoing
Insomnia	Insomnia	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram	2008 - Ongoing	Depression
Ibuprofen	2008 - Ongoing	Migraines
Paracetamol	2008 - Ongoing	Migraines
Sumatriptan	2008 - Ongoing	Migraines
Topiramate	2008 - Ongoing	Migraines
Testosterone	2016 - Ongoing	Low Testosterone
Nicotine	Jan 2020 - Ongoing	Smoking Prophylaxis
Ibuprofen	15 Sep 2020 (Study Day 25) - Ongoing	Fatigue, Generalized Muscle And Body Aches, Headache Due To Strep Throat
Amoxicillin	19 Sep 2020 (Study Day 29) - 29 Sep 2020 (Study Day 39)	Strep Throat
Clonidine	Oct 2020 - Ongoing	Hypertension
Lisinopril	Oct 2020 - Ongoing	Hypertension
Melatonin	Oct 2020 - Ongoing	Insomnia
Amitriptyline	01 Jan 2021 (Study Day 133) - Ongoing	Insomnia
Abdominal wall reconstruction*	13 Feb 2021 (Study Day 176) - 13 Feb 2021 (Study Day 176)	Adverse Event
Exploratory laparotomy*	13 Feb 2021 (Study Day 176) - 13 Feb 2021 (Study Day 176)	Adverse Event
Tap block*	13 Feb 2021 (Study Day 176) - 13 Feb 2021 (Study Day 176)	Adverse Event
Topiramate	16 Feb 2021 (Study Day 179) - Ongoing	Abdominal Stabbing
Zaleplon	16 Feb 2021 (Study Day 179) - Ongoing	Insomnia
Buprenorphine hydrochloride; naloxone hydrochloride	18 Feb 2021 (Study Day 181) - Ongoing	Narcotic Abuse

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US305-2005 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 30 Jul 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 26 Aug 2020 (Study Day 28)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Right Hip Joint Replacement (Worsening Of Osteoarthritis)	SAE	Grade 3/severe	Not related	24 Feb 2021 (Study Day 210) – 25 Feb 2021 (Study Day 211)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US305-2005, a 72-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 30 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 26 Aug 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 24 Feb 2021 (Study Day 210), 209 days after the first dose in Part A and 182 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of right hip joint replacement (worsening of osteoarthritis) lasted for 2 days, after which it was considered to be recovered/resolved on 25 Feb 2021 (Study Day 211). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-070963	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Basal cell carcinoma	Basal cell carcinoma- face	Not reported - 2018
Inguinal hernia	Inguinal hernia	Not reported - 2018
Inguinal hernia repair	Inguinal hernia repair	Not reported - 2018
Blood cholesterol increased	High cholesterol	2005 - Ongoing
Osteoarthritis	Osteoarthritis-left knee-right hip	2010 - Ongoing
Atrial fibrillation	A fib	2018 - Ongoing
Erectile dysfunction	Erectile dysfunction	2018 - Ongoing
Hypertension	Htn	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fish oil	2005 - Ongoing	High Cholesterol
Glucosamine	2005 - Ongoing	Supplement
Ascorbic acid	2010 - Ongoing	Health Maintenance
Vitamins nos	2010 - Ongoing	Health Maintenance
Sildenafil	2018 - Ongoing	Erectile Dysfunction
Evolocumab	Nov 2018 - Ongoing	High Cholesterol
Apixaban	Dec 2018 - Ongoing	A-Fib
Losartan	Dec 2018 - Ongoing	A-Fib/Htn
Metoprolol	Dec 2018 - Ongoing	A-Fib/Htn
Influenza vaccine	25 Sep 2020 (Study Day 58) - 25 Sep 2020 (Study Day 58)	Vaccination
Right hip resurfacing surgery*	24 Feb 2021 (Study Day 210) - 24 Feb 2021 (Study Day 210)	Medical History
Meloxicam	25 Feb 2021 (Study Day 211) - 11 Apr 2021 (Study Day 256)	Right Hip Resurfacing Surgery
Oxycodone	25 Feb 2021 (Study Day 211) - 26 Feb 2021 (Study Day 212)	Right Hip Resurfacing Surgery
Paracetamol	25 Feb 2021 (Study Day 211) - 11 Apr 2021 (Study Day 256)	Right Hip Resurfacing Surgery

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US305-2028 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 30 Jul 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 25 Aug 2020 (Study Day 27)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Musculoskeletal Chest Pain/ Musculoskeletal Chest Pain	SAE	Grade 3/ severe	Not related	03 Apr 2021 (Study Day 248) – 04 Apr 2021 (Study Day 249)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US305-2028, a 60-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 30 Jul 2020 (Study Day 1). The second dose was administered in the right arm on 25 Aug 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 03 Apr 2021 (Study Day 248), 247 days after the first dose in Part A and 221 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of musculoskeletal chest pain. Action taken with the IP was not applicable. The event of musculoskeletal chest pain lasted for 2 days, after which it was considered to be recovered/resolved on 04 Apr 2021 (Study Day 249). The investigator assessed the event of musculoskeletal chest pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-066935	Musculoskeletal chest pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	Not reported - Ongoing
Cataract	Cataracts	Not reported - Ongoing
Depression	Anxiety/depression	Not reported - Ongoing
Diabetes mellitus	Diabetes	Not reported - Ongoing
Drug hypersensitivity	Allergy to anti reflux medications	Not reported - Ongoing
Drug hypersensitivity	Allergy to erythromycin	Not reported - Ongoing
Dyspepsia	Heartburn	Not reported
Fistula	Sinus fistula	Not reported - Ongoing
Herpes virus infection	Herpes	Not reported - Ongoing
Hiatus hernia	Hiatal hernia	Not reported
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Hypothyroidism	Hypothyroidism	Not reported - Ongoing
Incontinence	Mild incontinence	Not reported - Ongoing
Large intestine benign neoplasm	Benign colon mass	Not reported - Ongoing
Muscle spasms	Muscle spasms in back	Not reported - Ongoing
Post-traumatic stress disorder	Ptsd	Not reported - Ongoing
Postmenopause	Post menopausal	Not reported - Ongoing
Uterine dilation and curettage	Dilatation and curettage	1984 - Not reported
Caesarean section	C-section	1989 - 1989
Hysteropexy	Uterine suspension surgery	1991 - 1991
Laparoscopy	Abdominal laparoscopy	1991 - 1991
Caesarean section	C-section	1992 - 1992
Sinus operation	Nose & sinus surgery	1992 - 1993
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Transient ischaemic attack	Transient ischemic attack	2013 - 2013
Transient ischaemic attack	Transient ischemic attack	2017 - 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glimepiride	Not reported - Ongoing	Diabetes
Lysine	Not reported - Ongoing	Herpes
Methocarbamol	Not reported - Ongoing	Muscle Spasms
Glipizide	2008 - Ongoing	Diabetes Militus
Pioglitazone	2008 - Ongoing	Diabetes

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pioglitazone	2008 - Ongoing	Diabetes Mellitus
Levothyroxine	2013 - Ongoing	Hypothyroidism
Fluticasone propionate	05 Aug 2020 (Study Day 7) - Ongoing	Seasonal Allergies
Glyceryl trinitrate	05 Aug 2020 (Study Day 7) - 05 Aug 2020 (Study Day 7)	Chest Pain Nos
Cholecystectomy*	10 Mar 2021 (Study Day 224) - 10 Mar 2021 (Study Day 224)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Procedural Pain	Grade 1/mild	Not related	11 Mar 2021 (Study Day 225) - 12 Mar 2021 (Study Day 226)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US305-2312 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 28 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 25 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 16 Jan 2021 (Study Day 142)
Second Dose of Vaccine in Part B: 12 Feb 2021 (Study Day 169)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arthritis Bacterial/Septic Right Knee	SAE	Grade 3/ severe	Not related	27 Jan 2021 (Study Day 153) – 31 Jan 2021 (Study Day 157)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US305-2312, a 51-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 16 Jan 2021. The participant was unblinded on 16 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 16 Jan 2021 (Study Day 142). The second dose was administered in the right arm on 12 Feb 2021 (Study Day 169).

Event Details

On 27 Jan 2021 (Study Day 153), 152 days after the first dose in Part A/11 days after the first dose in Part B and 124 days after the second dose in Part A/16 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of arthritis bacterial. The IP dose was not changed due to the septic right knee. The event of septic right knee lasted for 5 days, after which it was considered to be recovered/resolved on 31 Jan 2021 (Study Day 157). The investigator assessed the event of arthritis bacterial to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-079786	Arthritis bacterial

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Pollen allergy	1974 - Ongoing
Testis cancer	Testicular cancer	1999 - 2000
Hip arthroplasty	Right hip replacement	2004 - 2004
Osteonecrosis	Avascular necrosis	2004 - 2004
Blood cholesterol increased	High cholesterol	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fenofibrate	28 Aug 2020 (Study Day 1) - Ongoing	High Cholesterol
Endoscopic procedure for vocal cords*	16 Feb 2021 (Study Day 173) - 16 Feb 2021 (Study Day 173)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US306-2079 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 04 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 32)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nephrolithiasis/Worsening Of Recurrent Nephrolithiasis	SAE	Grade 4	Not related	19 Apr 2021 (Study Day 259) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US306-2079, a 40-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 26 Jan 2021. The participant was unblinded on 26 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 19 Apr 2021 (Study Day 259), 258 days after the first dose in Part A and 227 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of nephrolithiasis. Action taken with the IP was not applicable. The event of worsening of recurrent nephrolithiasis was considered to be ongoing. The investigator assessed the event of nephrolithiasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-089739	Nephrolithiasis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1985 - Ongoing
Small intestinal obstruction	Small bowel obstruction	1995 - 1995
Muscle spasms	Muscle spasms	1998 - Ongoing
Nephrolithiasis	Nephrolithiasis, recurrent	1998 - Ongoing
Migraine	Migraines	2000 - Ongoing
Anxiety	Anxiety	2013 - Ongoing
Bipolar disorder	Bipolar depression	2013 - Ongoing
Insomnia	Insomnia	2013 - Ongoing
Neuropathy peripheral	Neuropathy, unspecified bilateral hands	2017 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome- constipation	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Buspirone	2013 - Ongoing	Anxiety
Lamotrigine	2013 - Ongoing	Anxiety
Propranolol hydrochloride	2013 - Ongoing	Migraines
Trazodone	2013 - Ongoing	Insomnia
Vilazodone hydrochloride	2013 - Ongoing	Bipolar Depression
Ethinylestradiol; ferrous fumarate; norethisterone acetate	2018 - Ongoing	Contraception
Cefixime	2019 - Ongoing	Muscle Spasms Legs
Docusate sodium	2019 - Ongoing	Irritable Bowel Syndrome-Constipation
Macrogol 3350	2019 - Ongoing	Ibs- Constipation
Gabapentin	Jan 2020 - Ongoing	Neuropathy-Bilateral Hands, Unspecified
Vitamins nos	Mar 2020 - Ongoing	Nutritional Supplement
Aripiprazole	13 May 2020 (Study Day -83) - 29 Sep 2020 (Study Day 57)	Bipolar Depression
Paracetamol	05 Sep 2020 (Study Day 33) - 11 Sep 2020 (Study Day 39)	Headache
Ct abdomen/pelvis with contrast*	07 Sep 2020 (Study Day 35) - 07 Sep 2020 (Study Day 35)	Adverse Event
Docusate sodium; sennoside a+b	07 Sep 2020 (Study Day 35) - 10 Sep 2020 (Study Day 38)	Ibs- Constipation
Hydrocodone bitartrate; paracetamol	07 Sep 2020 (Study Day 35) - 09 Sep 2020 (Study Day 37)	Bilateral Nephrolithiasis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Morphine	07 Sep 2020 (Study Day 35) - 10 Sep 2020 (Study Day 38)	Bilateral Nephrolithiasis
Ondansetron	07 Sep 2020 (Study Day 35) - 07 Sep 2020 (Study Day 35)	Bilateral Nephrolithiasis
Prochlorperazine	07 Sep 2020 (Study Day 35) - 07 Sep 2020 (Study Day 35)	Bilateral Nephrolithiasis
Sodium chloride	07 Sep 2020 (Study Day 35) - 07 Sep 2020 (Study Day 35)	Bilateral Nephrolithiasis
Sodium chloride	07 Sep 2020 (Study Day 35) - 10 Sep 2020 (Study Day 38)	Bilateral Nephrolithiasis
Tamsulosin hydrochloride	07 Sep 2020 (Study Day 35) - 10 Sep 2020 (Study Day 38)	Bilateral Nephrolithiasis
Guaifenesin	08 Sep 2020 (Study Day 36) - Ongoing	Seasonal Allergies
Levofloxacin	08 Sep 2020 (Study Day 36) - 10 Sep 2020 (Study Day 38)	Bilateral Nephrolithiasis
Calcium chloride; potassium chloride; sodium lactate	09 Sep 2020 (Study Day 37) - 09 Sep 2020 (Study Day 37)	Bilateral Nephrolithiasis
Cefazolin sodium	09 Sep 2020 (Study Day 37) - 09 Sep 2020 (Study Day 37)	Bilateral Nephrolithiasis
Hydrocodone bitartrate; paracetamol	09 Sep 2020 (Study Day 37) - 16 Sep 2020 (Study Day 44)	Post Op Pain
Hydromorphone hydrochloride	09 Sep 2020 (Study Day 37) - 09 Sep 2020 (Study Day 37)	Bilateral Nephrolithiasis
Iohexol	09 Sep 2020 (Study Day 37) - 09 Sep 2020 (Study Day 37)	Bilateral Nephrolithiasis
Placement of rental stent*	09 Sep 2020 (Study Day 37) - 09 Sep 2020 (Study Day 37)	Adverse Event
Right ureteroscopy with laser lithotripsy*	09 Sep 2020 (Study Day 37) - 09 Sep 2020 (Study Day 37)	Adverse Event
Aripiprazole	30 Sep 2020 (Study Day 58) - Ongoing	Bipolar Depression
Atropa belladonna extract; papaver somniferum powder	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Pain Generalized
Calcium chloride; potassium chloride; sodium lactate	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Cartilage; hyaluronic acid	03 Nov 2020 (Study Day 92) - 06 Nov 2020 (Study Day 95)	Nausea, Generalized
Cefazolin	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Urinary Tract Infection
Dexamethasone	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Fentanyl	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Pain- Generalized
Heparin	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Iv Patency
Hydrocodone bitartrate; paracetamol	03 Nov 2020 (Study Day 92) - 11 Dec 2020 (Study Day 130)	Worsening Of Recurrent Nephrolithiasis
Hydromorphone hydrochloride	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Pain- Generalized
Lidocaine	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lithotripsy*	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Adverse Event
Midazolam hydrochloride	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Morphine	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Pain Generalized
Ondansetron	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Nausea- Generalized
Oxybutynin hydrochloride	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Oxycodone hydrochloride; paracetamol	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Pain Generalized
Pethidine hydrochloride	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Pain- Generalized
Phenylephrine	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Propofol	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Sodium chloride	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Suxamethonium chloride	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Ureteral stent*	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Adverse Event
Percutaneous nephrolithotomy*	10 Dec 2020 (Study Day 129) - 10 Dec 2020 (Study Day 129)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US306-2102 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 05 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 02 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 14 Jan 2021 (Study Day 163)
Second Dose of Vaccine in Part B: 15 Feb 2021 (Study Day 195)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Suicidal Ideation/Suicidal Ideation	SAE	Grade 4	Not related	26 Jan 2021 (Study Day 175) – 03 Feb 2021 (Study Day 183)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US306-2102, a 20-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 02 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 14 Jan 2021 (Study Day 163). The second dose was administered in the left arm on 15 Feb 2021 (Study Day 195).

Event Details

On 26 Jan 2021 (Study Day 175), 174 days after the first dose in Part A/12 days after the first dose in Part B and 146 days after the second dose in Part A/20 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of suicidal ideation. The IP dose was not changed due to the suicidal ideation. The event of suicidal ideation lasted for 9 days, after which it was considered to be recovered/resolved on 03 Feb 2021 (Study Day 183). The investigator assessed the event of suicidal ideation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014554	Suicidal ideation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypothyroidism	Hypothyroidism	2008 - Ongoing
Obesity	Obesity	2008 - Ongoing
Asthma	Asthma (moderate)	2012 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes mellitus	2012 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2014 - Ongoing
Depression	Depression	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	2008 - Ongoing	Hypothyroidism
Beclometasone	2012 - Ongoing	Asthma
Metformin	2012 - Ongoing	Type 2 Diabetes Mellitus
Salbutamol	2012 - Ongoing	Asthma
Venlafaxine hydrochloride	2017 - 14 Dec 2020 (Study Day 132)	Depression
Amphetamine aspartate; amphetamine sulfate; dexamphetamine saccharate; dexamphetamine sulfate	Jul 2019 - 14 Nov 2020 (Study Day 102)	Attention Deficit Hyperactivity Disorder
Dexamethylphenidate hydrochloride	15 Nov 2020 (Study Day 103) - Ongoing	Attention Deficit Hyperactivity Disorder
Venlafaxine hydrochloride	15 Dec 2020 (Study Day 133) - Ongoing	Depression
Diphenhydramine hydrochloride	26 Jan 2021 (Study Day 175) - 26 Jan 2021 (Study Day 175)	Allergic Reaction To Peanut Butter
Famotidine	26 Jan 2021 (Study Day 175) - 26 Jan 2021 (Study Day 175)	Allergic Reaction To Peanut Butter
Methylprednisolone	26 Jan 2021 (Study Day 175) - 26 Jan 2021 (Study Day 175)	Allergic Reaction To Peanut Butter
Ondansetron	26 Jan 2021 (Study Day 175) - 26 Jan 2021 (Study Day 175)	Nausea
Prednisone	26 Jan 2021 (Study Day 175) - 26 Jan 2021 (Study Day 175)	Allergic Reaction To Peanut Butter
Salbutamol	26 Jan 2021 (Study Day 175) - 26 Jan 2021 (Study Day 175)	Asthma
Sodium chloride	26 Jan 2021 (Study Day 175) - 26 Jan 2021 (Study Day 175)	Allergic Reaction To Peanut Butter

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Trazodone	26 Jan 2021 (Study Day 175) - 27 Jan 2021 (Study Day 176)	Depression
Venlafaxine hydrochloride	26 Jan 2021 (Study Day 175) - 27 Jan 2021 (Study Day 176)	Depression
Asenapine maleate	27 Jan 2021 (Study Day 176) - 27 Jan 2021 (Study Day 176)	Schizophrenia
Prednisone	27 Jan 2021 (Study Day 176) - 27 Jan 2021 (Study Day 176)	Allergic Reaction To Peanut Butter
Influenza vaccine	28 Jan 2021 (Study Day 177) - 28 Jan 2021 (Study Day 177)	Influenza Prophylaxis
Olanzapine	28 Jan 2021 (Study Day 177) - Ongoing	Schizophrenia
Prednisone	28 Jan 2021 (Study Day 177) - 28 Jan 2021 (Study Day 177)	Allergic Reaction To Peanut Butter
Prednisone	29 Jan 2021 (Study Day 178) - 29 Jan 2021 (Study Day 178)	Allergic Reaction To Peanut Butter
Prednisone	30 Jan 2021 (Study Day 179) - 30 Jan 2021 (Study Day 179)	Allergic Reaction To Peanut Butter
Prednisone	31 Jan 2021 (Study Day 180) - 31 Jan 2021 (Study Day 180)	Allergic Reaction To Peanut Butter
Lisinopril	08 Feb 2021 (Study Day 188) - Ongoing	Hypertension
Buspirone	26 Mar 2021 (Study Day 234) - Ongoing	Depression
Trazodone	26 Mar 2021 (Study Day 234) - Ongoing	Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Food Allergy	Grade 1/mild	Not related	26 Jan 2021 (Study Day 175) - 26 Jan 2021 (Study Day 175)
Nausea	Grade 1/mild	Not related	26 Jan 2021 (Study Day 175) - 26 Jan 2021 (Study Day 175)
Tachycardia	Grade 1/mild	Not related	26 Jan 2021 (Study Day 175) - 26 Jan 2021 (Study Day 175)
Paranoia	Grade 1/mild	Not related	27 Jan 2021 (Study Day 176) - 03 Feb 2021 (Study Day 183)
Schizophrenia	Grade 1/mild	Not related	27 Jan 2021 (Study Day 176) - Ongoing
Hypertension	Grade 1/mild	Not related	08 Feb 2021 (Study Day 188) - Ongoing
Cough	Grade 1/mild	Not related	21 Feb 2021 (Study Day 201) - 27 Feb 2021 (Study Day 207)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US306-2118 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 06 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 30 Jan 2021 (Study Day 178)
Second Dose of Vaccine in Part B: 03 Mar 2021 (Study Day 210)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arthritis/Worsening Arthritis Right Knee	SAE	Grade 4	Not related	20 Apr 2021 (Study Day 258) – 20 Apr 2021 (Study Day 258)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US306-2118, a 70-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 30 Jan 2021. The participant was unblinded on 30 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 30 Jan 2021 (Study Day 178). The second dose was administered in the left arm on 03 Mar 2021 (Study Day 210).

Event Details

On 20 Apr 2021 (Study Day 258), 257 days after the first dose in Part A/80 days after the first dose in Part B and 229 days after the second dose in Part A/48 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of arthritis. Action taken with the IP was not applicable. The event of worsening arthritis right knee lasted for 1 day, after which it was considered to be recovered/resolved on 20 Apr 2021 (Study Day 258). The investigator assessed the event of arthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-097337	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Postmenopausal	01 Jan 2000 (Study Day -7523) - Ongoing
Seasonal allergy	Seasonal allergies	01 Apr 2018 (Study Day -858) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	01 Jan 2018 (Study Day -948) - Ongoing	Nutritional Supplement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US306-2157 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 07 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 19 Jan 2021 (Study Day 166)
Second Dose of Vaccine in Part B: 25 Feb 2021 (Study Day 203)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening Osteoarthritis Bilateral Knees	SAE	Grade 4	Not related	27 Jan 2021 (Study Day 174) – 27 Mar 2021 (Study Day 233)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US306-2157, a 65-year-old Hispanic or Latino male, received the first dose of Placebo in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 19 Jan 2021. The participant was unblinded on 19 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 19 Jan 2021 (Study Day 166). The second dose was administered in the left arm on 25 Feb 2021 (Study Day 203).

Event Details

On 27 Jan 2021 (Study Day 174), 173 days after the first dose in Part A/8 days after the first dose in Part B and 145 days after the second dose in Part A/29 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of osteoarthritis. The IP dose was not changed due to the worsening osteoarthritis bilateral knees. The event of worsening osteoarthritis bilateral knees lasted for 60 days, after which it was considered to be recovered/resolved on 27 Mar 2021 (Study Day 233). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-061546	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Eczema	Eczema, generalized	Jan 1956 - Ongoing
Back pain	Chronic back pain	Jan 1988 - Ongoing
Atrial fibrillation	Atrial fibrillation	Jan 2003 - Ongoing
Onychomycosis	Nail fungus, bilateral feet	Jan 2010 - Ongoing
Seasonal allergy	Seasonal allergies	Jan 2010 - Ongoing
Depression	Depression	Jan 2014 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	Jan 2016 - Ongoing
Blood testosterone decreased	Low testosterone level	Jan 2018 - Ongoing
Osteoarthritis	Osteoarthritis, bilateral knees	Jan 2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	Jan 2010 - Ongoing	Seasonal Allergies
Hydrocodone; paracetamol	Jan 2012 - Ongoing	Chronic Back Pain
Citalopram	Jan 2014 - Ongoing	Depression
Clobetasol	Jan 2015 - Ongoing	Eczema, Generalized
Sotalol	Jan 2015 - Ongoing	Atrial Fibrillation
Fenofibrate	Jan 2016 - Ongoing	Hypercholesterolemia
Cyclobenzaprine	Jan 2019 - Ongoing	Chronic Back Pain
Celecoxib	Jun 2019 - Ongoing	Osteoarthritis, Bilateral Knees
Testosterone cipionate	Feb 2020 - Ongoing	Low Testosterone Level
Apixaban	Mar 2020 - Ongoing	Atrial Fibrillation
Fluconazole	06 Aug 2020 (Study Day -1) - Ongoing	Nail Fungus, Bilateral Feet
Hydrocortisone	28 Aug 2020 (Study Day 22) - 28 Aug 2020 (Study Day 22)	Osteoarthritis, Bilateral Knees
Influenza vaccine	14 Oct 2020 (Study Day 69) - 14 Oct 2020 (Study Day 69)	Influenza Prophylaxis
Ct left knee without contrast*	27 Jan 2021 (Study Day 174) - 27 Jan 2021 (Study Day 174)	Adverse Event
Ct right knee without contrast*	27 Jan 2021 (Study Day 174) - 27 Jan 2021 (Study Day 174)	Adverse Event
Bupivacaine	11 Feb 2021 (Study Day 189) - 11 Feb 2021 (Study Day 189)	Worsening Osteoarthritis Bilateral Knees

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium chloride; potassium chloride; sodium lactate	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)	Worsening Osteoarthritis Bilateral Knees
Cefazolin	11 Feb 2021 (Study Day 189) - 12 Feb 2021 (Study Day 190)	Infection Prophylaxis
Cyclobenzaprine	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)	Muscle Spasms, Generalized
Dexamethasone	11 Feb 2021 (Study Day 189) - 11 Feb 2021 (Study Day 189)	Worsening Osteoarthritis Bilateral Knees
Diphenhydramine	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)	Post Operative Itching
Docusate sodium	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)	Post Operative Constipation
Famotidine	11 Feb 2021 (Study Day 189) - 11 Feb 2021 (Study Day 189)	Worsening Osteoarthritis Bilateral Knees
Fentanyl	11 Feb 2021 (Study Day 189) - 11 Feb 2021 (Study Day 189)	Post Operative Pain
Hydromorphone	11 Feb 2021 (Study Day 189) - 11 Feb 2021 (Study Day 189)	Post Operative Pain
Ketorolac	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)	Post Operative Pain
Magnesium hydroxide	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)	Post Operative Constipation
Meloxicam	11 Feb 2021 (Study Day 189) - 11 Feb 2021 (Study Day 189)	Worsening Osteoarthritis Bilateral Knees
Metoclopramide	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)	Gerd
Midazolam	11 Feb 2021 (Study Day 189) - 11 Feb 2021 (Study Day 189)	Worsening Osteoarthritis Bilateral Knees
Omeprazole	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)	Gerd
Ondansetron	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)	Post Operative Nausea
Oxycodone	11 Feb 2021 (Study Day 189) - 11 Feb 2021 (Study Day 189)	Post Operative Pain
Oxycodone hydrochloride; paracetamol	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)	Post Operative Pain
Paracetamol	11 Feb 2021 (Study Day 189) - 11 Feb 2021 (Study Day 189)	Post Operative Pain
Right knee replacement*	11 Feb 2021 (Study Day 189) - 11 Feb 2021 (Study Day 189)	Medical History
Sodium chloride	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)	Worsening Osteoarthritis Bilateral Knees
Tramadol	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)	Post Operative Pain
Apixaban	12 Feb 2021 (Study Day 190) - 13 Feb 2021 (Study Day 191)	Atrial Fibrillation
Bisacodyl	12 Feb 2021 (Study Day 190) - 12 Feb 2021 (Study Day 190)	Post Operative Constipation
Bupivacaine	25 Mar 2021 (Study Day 231) - 25 Mar 2021 (Study Day 231)	Worsening Osteoarthritis Bilateral Knees

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium chloride; potassium chloride; sodium lactate	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)	Worsening Osteoarthritis Bilateral Knees
Cefazolin	25 Mar 2021 (Study Day 231) - 26 Mar 2021 (Study Day 232)	Infection Prophylaxis
Cyclobenzaprine	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)	Muscle Spasms, Generalized
Dexamethasone	25 Mar 2021 (Study Day 231) - 25 Mar 2021 (Study Day 231)	Worsening Osteoarthritis Bilateral Knees
Diphenhydramine	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)	Post Operative Constipation
Diphenhydramine	25 Mar 2021 (Study Day 231) - 25 Mar 2021 (Study Day 231)	Post Operative Itching
Docusate sodium	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)	Post Operative Constipation
Hydromorphone	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)	Post Operative Pain
Left knee replacement*	25 Mar 2021 (Study Day 231) - 25 Mar 2021 (Study Day 231)	Adverse Event
Magnesium hydroxide	25 Mar 2021 (Study Day 231) - 25 Mar 2021 (Study Day 231)	Post Operative Constipation
Meloxicam	25 Mar 2021 (Study Day 231) - 25 Mar 2021 (Study Day 231)	Worsening Osteoarthritis Bilateral Knees
Metoclopramide	25 Mar 2021 (Study Day 231) - 25 Mar 2021 (Study Day 231)	Gerd
Midazolam	25 Mar 2021 (Study Day 231) - 25 Mar 2021 (Study Day 231)	Worsening Osteoarthritis Bilateral Knees
Omeprazole	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)	Gerd
Ondansetron	25 Mar 2021 (Study Day 231) - 25 Mar 2021 (Study Day 231)	Post Operative Nausea
Ondansetron	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)	Post Operative Nausea
Oxycodone hydrochloride	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)	Post Operative Pain
Oxycodone hydrochloride; paracetamol	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)	Post Operative Pain
Paracetamol	25 Mar 2021 (Study Day 231) - 25 Mar 2021 (Study Day 231)	Post Operative Pain
Paracetamol	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)	Post Operative Pain
Sodium chloride	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)	Worsening Osteoarthritis Bilateral Knees
Tramadol	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)	Post Operative Pain
Apixaban	26 Mar 2021 (Study Day 232) - 27 Mar 2021 (Study Day 233)	Atrial Fibrillation
Sodium chloride	26 Mar 2021 (Study Day 232) - 27 Mar 2021 (Study Day 233)	Worsening Osteoarthritis Bilateral Knees

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anxiety	Grade 2/moderate	Not related	11 Feb 2021 (Study Day 189) - Ongoing
Gastroesophageal Reflux Disease	Grade 2/moderate	Not related	11 Feb 2021 (Study Day 189) - Ongoing
Muscle Spasms	Grade 2/moderate	Not related	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)
Obesity	Grade 1/mild	Not related	11 Feb 2021 (Study Day 189) - Ongoing
Post Procedural Constipation	Grade 2/moderate	Not related	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)
Post Procedural Pruritus	Grade 2/moderate	Not related	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)
Procedural Nausea	Grade 2/moderate	Not related	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)
Procedural Pain	Grade 2/moderate	Not related	11 Feb 2021 (Study Day 189) - 13 Feb 2021 (Study Day 191)
Sleep Apnoea Syndrome	Grade 1/mild	Not related	11 Feb 2021 (Study Day 189) - Ongoing
Muscle Spasms	Grade 2/moderate	Not related	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)
Post Procedural Constipation	Grade 2/moderate	Not related	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)
Post Procedural Pruritus	Grade 2/moderate	Not related	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)
Procedural Nausea	Grade 2/moderate	Not related	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)
Procedural Pain	Grade 2/moderate	Not related	25 Mar 2021 (Study Day 231) - 27 Mar 2021 (Study Day 233)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US308-2122 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 27 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 29 Sep 2020 (Study Day 34)
First Dose of Vaccine in Part B: 22 Jan 2021 (Study Day 149)
Second Dose of Vaccine in Part B: 19 Feb 2021 (Study Day 177)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nephrolithiasis/Kidney Stones	SAE	Grade 2/ moderate	Not related	17 Feb 2021 (Study Day 175) – 26 Feb 2021 (Study Day 184)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US308-2122, a 68-year-old not Hispanic or Latino female, received the first dose of Placebo in the right arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 29 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 22 Jan 2021. The participant was unblinded on 22 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 06 Jan 2021 (Study Day 149). The second dose was administered in the right arm on 19 Feb 2021 (Study Day 177).

Event Details

On 17 Feb 2021 (Study Day 175), 174 days after the first dose in Part A/26 days after the first dose in Part B and 141 days after the second dose in Part A/2 days before the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of nephrolithiasis. The IP dose was not changed due to the kidney stones. The event of kidney stones lasted for 10 days, after which it was considered to be recovered/resolved on 26 Feb 2021 (Study Day 184). The investigator assessed the event of nephrolithiasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-060134	Nephrolithiasis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Food allergy	Banana allergy	2000 - Ongoing
Food allergy	Shell fish allergy	2000 - Ongoing
Postmenopause	Post menopause	2002 - 2002
Migraine	Migraines	2007 - Ongoing
Seasonal allergy	Seasonal allergies	2007 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Epinephrine	2000 - Ongoing	Banana Allergy And Shell Fish Allergy (Never Been Used To Date)
Ketotifen fumarate	2007 - Ongoing	Seasonal Allergy Eye Drops
Sumatriptan	2007 - Ongoing	Migraines
Magnesium	2010 - Ongoing	Nutritional Supplement
Vitamin d nos	2010 - Ongoing	Nutritional Supplement
Acetylsalicylic acid	2016 - Ongoing	Cardiac Preventative
Influenza vaccine	16 Oct 2020 (Study Day 51) - 16 Oct 2020 (Study Day 51)	Prophylaxis
Morphine	26 Feb 2021 (Study Day 184) - 26 Feb 2021 (Study Day 184)	Kidney Stone
Ondansetron	26 Feb 2021 (Study Day 184) - 03 Mar 2021 (Study Day 189)	Kidney Stone
Ketorolac	27 Feb 2021 (Study Day 185) - 03 Mar 2021 (Study Day 189)	Kidney Stone
Tamsulosin	27 Feb 2021 (Study Day 185) - 03 Mar 2021 (Study Day 189)	Kidney Stone

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US308-2221 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 13 Oct 2020 (Study Day 34)
First Dose of Vaccine in Part B: 08 Jan 2021 (Study Day 121)
Second Dose of Vaccine in Part B: 11 Feb 2021 (Study Day 155)
Reason for Narrative: Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 2/ moderate	Not related	01 Jan 2021 (Study Day 114) – 22 Jan 2021 (Study Day 135)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US308-2221, a 36-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 13 Oct 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 08 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 08 Jan 2021 (Study Day 121). The second dose was administered in the left arm on 11 Feb 2021 (Study Day 155).

Severe COVID-19 Details

On 01 Jan 2021 (Study Day 114), 113 days after the first dose in Part A/7 days before the first dose in Part B and 80 days after the second dose in Part A/41 days before the second dose in Part B of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 13 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 08 Jan 2021 (Study Day 121), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
14 Jan 2021 (Study Day 127)	Fatigue	Mild
14 Jan 2021 (Study Day 127)	Nausea	Moderate
14 Jan 2021 (Study Day 127)	New Loss of Smell	Mild
14 Jan 2021 (Study Day 127)	Vomiting	Moderate
15 Jan 2021 (Study Day 128)	Headache	Mild
15 Jan 2021 (Study Day 128)	Nausea	Mild
15 Jan 2021 (Study Day 128)	New Loss of Smell	Mild
15 Jan 2021 (Study Day 128)	O2 Saturation (%)	93
16 Jan 2021 (Study Day 129)	Nausea	Mild
16 Jan 2021 (Study Day 129)	New Loss of Smell	Mild
17 Jan 2021 (Study Day 130)	Nausea	Mild
17 Jan 2021 (Study Day 130)	New Loss of Smell	Mild
18 Jan 2021 (Study Day 131)	New Loss of Smell	Mild
18 Jan 2021 (Study Day 131)	New Loss of Taste	Mild
21 Jan 2021 (Study Day 134)	Nausea	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
15 Jan 2021 (Study Day 128)	Oxygen Saturation	93%
15 Jan 2021 - 15 Jan 2021 (Study Day 128-128)	Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 22 days, after which it was considered to be recovered/resolved on 22 Jan 2021 (Study Day 135). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004656	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rhinitis allergic	Allergic rhinitis	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	2018 - Ongoing	Allergic Rhinitis
Magnesium	2019 - Ongoing	Supplement
Influenza vaccine	30 Oct 2020 (Study Day 51) - 30 Oct 2020 (Study Day 51)	Influenza Prophylaxis
Ibuprofen	15 Jan 2021 (Study Day 128) - 15 Jan 2021 (Study Day 128)	Headache R/T COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US309-2176 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 20 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 18 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: 14 Jan 2021 (Study Day 148)
Second Dose of Vaccine in Part B: 26 Feb 2021 (Study Day 191)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pancreatitis/Pancreatitis	SAE	Grade 2/ moderate	Not related	30 Mar 2021 (Study Day 223) – 10 Apr 2021 (Study Day 234)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US309-2176, a 47-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 14 Jan 2021 (Study Day 148). The second dose was administered in the left arm on 26 Feb 2021 (Study Day 191).

Event Details

On 30 Mar 2021 (Study Day 223), 222 days after the first dose in Part A/75 days after the first dose in Part B and 193 days after the second dose in Part A/32 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of pancreatitis. Action taken with the IP was not applicable. The event of pancreatitis lasted for 12 days, after which it was considered to be recovered/resolved on 10 Apr 2021 (Study Day 234). The investigator assessed the event of pancreatitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-074402	Pancreatitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergic rhinitis	(b) (6) 1973 - Ongoing
Adenoidectomy	Adenoid removal	1978 - 1978
Asthma	Asthma mild	1978 - Ongoing
Foot fracture	Right foot fracture	2001 - 2001
Meniscus injury	Left knee torn meniscus	2005 - 2005
Meniscus operation	Left knee torn meniscus repair	2005 - 2005
Attention deficit hyperactivity disorder	Adhd	2010 - Ongoing
Tendon rupture	Tendon tear right hand	2012 - 2012
Arthroscopy	Arthroscopy on left knee	2015 - 2015
Spinal stenosis	Spinal stenosis	2016 - Ongoing
Spinal fusion surgery	C4-6 fuse surgery	2017 - 2017
Hypertension	Hypertension	2019 - Ongoing
Type 2 diabetes mellitus	Dmt2	Feb 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1990 - Ongoing	Asthma
Cetirizine hydrochloride	2000 - Ongoing	Seasonal Allergies
Amphetamine aspartate; amphetamine sulfate; dexamphetamine saccharate; dexamphetamine sulfate	2015 - Ongoing	Attention Deficit Hyperactivity Disorder
Cyclobenzaprine	2017 - Ongoing	Spinal Stenosis
Lisinopril	2019 - Ongoing	Hypertension
Calcium; magnesium; zinc gluconate	Feb 2020 - Ongoing	General Health
Metformin	Feb 2020 - Ongoing	Type II Diabetes
Ibuprofen	24 Aug 2020 (Study Day 5) - 24 Aug 2020 (Study Day 5)	Fever(Solicited Ae)
Influenza vaccine	06 Nov 2020 (Study Day 79) - 06 Nov 2020 (Study Day 79)	Prophylaxis Influenza

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US309-2238 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 27 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 01 Oct 2020 (Study Day 36)
First Dose of Vaccine in Part B: 26 Feb 2021 (Study Day 184)
Second Dose of Vaccine in Part B: 26 Mar 2021 (Study Day 212)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abdominal Pain/ Abdominal Pain	SAE	Grade 2/ moderate	Not related	17 Apr 2021 (Study Day 234) – 21 Apr 2021 (Study Day 238)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The MedDRA Preferred Term/ Verbatim Term of Abdominal Pain/Abdominal Pain was updated to Ovarian Cyst/Left Ovary Cyst after the database lock.

Participant US309-2238, a 32-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 29 Jan 2021. The participant was unblinded on 29 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 26 Feb 2021 (Study Day 184). The second dose was administered in the left arm on 26 Mar 2021 (Study Day 212).

Event Details

On 17 Apr 2021 (Study Day 234), 233 days after the first dose in Part A/50 days after the first dose in Part B and 198 days after the second dose in Part A/22 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of abdominal pain. The IP dose was not changed due to the abdominal pain. The event of abdominal pain lasted for 5 days, after which it was considered to be recovered/resolved on 21 Apr 2021 (Study Day 238). The investigator assessed the event of abdominal pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-097160	Ovarian cyst

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastroesophageal reflux disease	Acid reflux gastroesophageal reflux disease	Not reported - Ongoing
Obesity	Obesity	Not reported - Ongoing
Back pain	Low back pain	2015 - Ongoing
Intrauterine contraception	Iud (will replace in 2021)	2016 - Ongoing
Pain in extremity	Right leg pain (due to fall)	Sep 2019 - Ongoing
Gastrectomy	Gastric sleeve	28 Apr 2020 (Study Day -121) - 28 Apr 2020 (Study Day -121)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levonorgestrel	2016 - Ongoing	Contraceptive
Prochlorperazine	07 Sep 2020 (Study Day 12) - 26 Sep 2020 (Study Day 31)	Headache
Guaifenesin	11 Jan 2021 (Study Day 138) - 29 Jan 2021 (Study Day 156)	Allergies/Sinusitis
Diphenhydramine hydrochloride	12 Jan 2021 (Study Day 139) - 26 Feb 2021 (Study Day 184)	Allergies/Sinusitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US309-2259 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 28 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 01 Oct 2020 (Study Day 35)
First Dose of Vaccine in Part B: 05 Jan 2021 (Study Day 131)
Second Dose of Vaccine in Part B: 05 Feb 2021 (Study Day 162)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Sepsis/Sepsis	SAE	Grade 3/severe	Not related	25 Jan 2021 (Study Day 151) – 02 Feb 2021 (Study Day 159)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US309-2259, a 58-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 05 Jan 2021. The participant was unblinded on 05 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 05 Jan 2021 (Study Day 131). The second dose was administered in the left arm on 05 Feb 2021 (Study Day 162).

Event Details

On 25 Jan 2021 (Study Day 151), 150 days after the first dose in Part A/20 days after the first dose in Part B and 116 days after the second dose in Part A/11 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of sepsis. The IP dose was not changed due to the sepsis. The event of sepsis lasted for 9 days, after which it was considered to be recovered/resolved on 02 Feb 2021 (Study Day 159). The investigator assessed the event of sepsis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010040	Sepsis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Renal cancer	Renal cell carcinoma	2002 - 2002
Hypercholesterolaemia	Hypercholesterolemia	2005 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Blood testosterone decreased	Low testosterone	2012 - Ongoing
Glucose tolerance impaired	Pre - diabetic	2018 - 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2005 - Ongoing	Hypertension
Colesevelam hydrochloride	2005 - Ongoing	Hypercholesterolemia
Telmisartan	2005 - Ongoing	Hypertension
Vitamins nos	2008 - Ongoing	Dietary Supplement
Testosterone cypionate	2012 - Ongoing	Low Testosterone
Kidney stone removal*	22 Jan 2021 (Study Day 148) - 22 Jan 2021 (Study Day 148)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Blood Pressure Increased	Grade 2/moderate	Not related	25 Jan 2021 (Study Day 151) - 02 Feb 2021 (Study Day 159)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US311-2043 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 31 Jul 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 26 Aug 2020 (Study Day 27)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diverticulitis/Diverticulitis With Spontaneous Resolution	SAE	Grade 3/ severe	Not related	09 Mar 2021 (Study Day 222) – 13 Mar 2021 (Study Day 226)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2043, a 75-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 31 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 26 Aug 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 09 Mar 2021 (Study Day 222), 221 days after the first dose in Part A and 195 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of diverticulitis. Action taken with the IP was not applicable. The event of diverticulitis with spontaneous resolution lasted for 5 days, after which it was considered to be recovered/resolved on 13 Mar 2021 (Study Day 226). The investigator assessed the event of diverticulitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-045207	Diverticulitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cataract	Bilateral cataracts	Not reported - Jan 2020
Seasonal allergy	Seasonal allergies	1975 - Ongoing
Gout	Gout (primarily right big toe)	1995 - Ongoing
Hypertension	Hypertension	1995 - Ongoing
Oedema peripheral	Bilateral lower extremity pedal edema	2015 - Ongoing
Body tinea	Tinea corporis	2018 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2019 - Ongoing
Cataract operation	Bilateral cataract surgery	Jan 2020 - Jan 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Allopurinol	1995 - Ongoing	Gout
Atenolol	1995 - 01 Feb 2021 (Study Day 186)	Htn
Furosemide	1995 - Ongoing	Bilateral Lower Extremity Pedal Edema
Lisinopril	1995 - Ongoing	Htn
Minoxidil	1995 - 01 Feb 2021 (Study Day 186)	Htn
Loratadine	2019 - Ongoing	Seasonal Allergies
Tamsulosin	2019 - Ongoing	Bph
Corticosteroid nos	Dec 2020 - Dec 2020	Right Knee Pain
Atenolol	02 Feb 2021 (Study Day 187) - Ongoing	Hypertension
Minoxidil	02 Feb 2021 (Study Day 187) - Ongoing	Hypertension
Blood transfusion, auxiliary products	09 Mar 2021 (Study Day 222) - 09 Mar 2021 (Study Day 222)	Diverticulitis
Pantoprazole	13 Mar 2021 (Study Day 226) - Ongoing	Barrett's Esophagus

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Barrett's Oesophagus	Grade 2/moderate	Not related	10 Mar 2021 (Study Day 223) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US311-2113 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 05 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 02 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Haematuria/Intermittent Hematuria	SAE	Grade 2/moderate	Not related	02 Mar 2021 (Study Day 210) – Ongoing	Not recovered/not resolved
Tendon Rupture/Full Thickness Tear Of Supraspinatus Tendon	SAE	Grade 3/severe	Not related	23 Mar 2021 (Study Day 231) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2113, a 61-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 02 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 22 Jan 2021. The participant was unblinded on 22 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 02 Mar 2021 (Study Day 210), 209 days after the first dose in Part A and 181 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of haematuria. Action taken with the IP was not applicable. The event of intermittent hematuria was considered to be ongoing. The investigator assessed the event of haematuria to be not related to the IP.

On 23 Mar 2021 (Study Day 231), 230 days after the first dose in Part A and 202 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of tendon rupture. Action taken with the IP was not applicable. The event of full thickness tear of supraspinatus tendon was considered to be ongoing. The investigator assessed the event of tendon rupture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-060173	Haematuria
MOD-2021-060173	Tendon rupture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1978 - Ongoing
Seasonal allergy	Seasonal allergies	1978 - Ongoing
Cholecystectomy	Cholecystectomy	1990 - 1990
Cholelithiasis	Cholelithiasis	1990 - 1990
Arthralgia	Left chronic knee pain	2010 - Ongoing
Osteoarthritis	Left knee osteoarthritis	2010 - Ongoing
Osteoarthritis	Right knee osteoarthritis	2010 - 2016
Constipation	Constipation	2015 - Ongoing
Neuralgia	Neuralgia	2015 - Ongoing
Knee arthroplasty	Total right knee replacement	2016 - 2016
Hypertonic bladder	Overactive bladder	2017 - Ongoing
Muscle spasms	Bilateral leg cramping	Jan 2020 - Ongoing
Sleep apnoea syndrome	Sleep apnea	Jun 2020 - Ongoing
Oedema peripheral	Bilateral lower extremity edema	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1978 - Ongoing	Asthma
Celecoxib	2015 - Ongoing	Chronic Pain
Docusate sodium	2015 - Ongoing	Constipation
Flunisolide	2015 - Ongoing	Allergies
Gabapentin	2015 - Ongoing	Chronic Pain
Desmopressin	2017 - Ongoing	Overactive Bladder
Linaclotide	2019 - Ongoing	Constipation

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pregabalin	Jun 2020 - Ongoing	Neuralgia/Chronic Pain
Hydrochlorothiazide	18 Aug 2020 (Study Day 14) - Ongoing	Left Knee Edema
Diclofenac	25 Aug 2020 (Study Day 21) - 01 Sep 2020 (Study Day 28)	Right Shoulder Pain
Tramadol	25 Aug 2020 (Study Day 21) - 01 Sep 2020 (Study Day 28)	Right Shoulder Pain
Bismuth subsalicylate	16 Sep 2020 (Study Day 43) - 17 Sep 2020 (Study Day 44)	Diarrhea
Hydrocortisone	10 Nov 2020 (Study Day 98) - 10 Nov 2020 (Study Day 98)	Osteoarthritis/Knee Joint Aspiration
Knee joint aspiration*	10 Nov 2020 (Study Day 98) - 10 Nov 2020 (Study Day 98)	Adverse Event
Mupirocin	27 Dec 2020 (Study Day 145) - Ongoing	Left Breast Sore
Nitrofurantoin	29 Jan 2021 (Study Day 178) - Ongoing	Uti
Nitrofurantoin	17 Feb 2021 (Study Day 197) - 21 Feb 2021 (Study Day 201)	Uti
Tramadol	25 Feb 2021 (Study Day 205) - Ongoing	R Hamstring Injury

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 1/mild	Not related	26 Jan 2021 (Study Day 175) - Ongoing
Muscle Injury	Grade 2/moderate	Not related	25 Feb 2021 (Study Day 205) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US311-2119 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 05 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: 07 Jan 2021 (Study Day 156)
Second Dose of Vaccine in Part B: 04 Feb 2021 (Study Day 184)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cholecystitis/Cholecystitis Secondary To Cholelithiasis	SAE	Grade 3/ severe	Not related	01 Apr 2021 (Study Day 240) – 01 Apr 2021 (Study Day 240)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2119, a 49-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 07 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 07 Jan 2021 (Study Day 156). The second dose was administered in the left arm on 04 Feb 2021 (Study Day 184).

Event Details

On 01 Apr 2021 (Study Day 240), 239 days after the first dose in Part A/84 days after the first dose in Part B and 210 days after the second dose in Part A/56 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of cholecystitis. Action taken with the IP was not applicable. The event of cholecystitis secondary to cholelithiasis lasted for 1 day, after which it was considered to be recovered/resolved on 01 Apr 2021 (Study Day 240). The investigator assessed the event of cholecystitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-067020	Cholecystitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1999 - Ongoing
Type 2 diabetes mellitus	Type II diabetes	1999 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	1999 - Ongoing	Diabetes Type 2
Valsartan	1999 - Ongoing	Hypertension
Ascorbic acid	2015 - Ongoing	Health Supplement
Vitamin d nos	2015 - Ongoing	Health Supplement
Vitamin b12 nos	2018 - Ongoing	Health Supplement
Dulaglutide	2019 - Ongoing	Diabetes Type 2
Empagliflozin	May 2020 - Ongoing	Diabetes Type 2
Amlodipine	25 Aug 2020 (Study Day 21) - Ongoing	Hypertension
Pravastatin	25 Aug 2020 (Study Day 21) - Ongoing	Diabetes
Aluminium hydroxide; magnesium hydroxide; simeticone	31 Aug 2020 (Study Day 27) - 31 Aug 2020 (Study Day 27)	Abdomina Pain Secondary To Cholelithiasis
Ibuprofen	31 Aug 2020 (Study Day 27) - 31 Aug 2020 (Study Day 27)	Abdominal Pain Secondary To Cholelithiasis
Influenza vaccine	21 Sep 2020 (Study Day 48) - 21 Sep 2020 (Study Day 48)	Flu Vaccine
Semaglutide	Jan 2021 - Ongoing	Diabetes
Paracetamol	05 Feb 2021 (Study Day 185) - 05 Feb 2021 (Study Day 185)	Muscle/Body Ache And Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US311-2173 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 10 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 32)
First Dose of Vaccine in Part B: 05 Jan 2021 (Study Day 149)
Second Dose of Vaccine in Part B: 02 Feb 2021 (Study Day 177)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hip Arthroplasty/Revision Of Left Hip Replacement	SAE	Grade 1/ mild	Not related	19 Apr 2021 (Study Day 253) – 19 Apr 2021 (Study Day 253)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The MedDRA Preferred Term/ Verbatim Term of Hip Arthroplasty/Revision Of Left Hip Replacement was updated to Device Loosening/Left Hip Prosthetic Instability after the database lock.

Participant US311-2173, a 77-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 05 Jan 2021. The participant was unblinded on 05 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 05 Jan 2021 (Study Day 149). The second dose was administered in the left arm on 02 Feb 2021 (Study Day 177).

Event Details

On 19 Apr 2021 (Study Day 253), 252 days after the first dose in Part A/104 days after the first dose in Part B and 221 days after the second dose in Part A/76 days after the second dose in Part B of the IP, the participant experienced a Grade 1/mild serious adverse event of hip arthroplasty. Action taken with the IP was not applicable. The event of revision of left hip replacement lasted for 1 day, after which it was considered to be recovered/resolved on 19 Apr 2021 (Study Day 253). The investigator assessed the event of hip arthroplasty to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-089929	Device loosening

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Sciatica	Lower back/sciatic pain	1987 - Mar 1987
Spinal laminectomy	Laminectomy (l4-l5)	Mar 1987 - Mar 1987
Hysterectomy	Hysterectomy	1992 - 1992
Ovarian mass	Right ovarian mass	1992 - 1992
Drug eruption	Allergy to doxycycline (rash)	1999 - Ongoing
Forearm fracture	Left forearm fracture s/p mva	2001 - 2001
Drug hypersensitivity	Allergy to levaquin (tendinitis)	2005 - Ongoing
Basal cell carcinoma	Basal cell carcinoma	2010 - Ongoing
Depression	Depression	2010 - Ongoing
Insomnia	Insomnia	2010 - Ongoing
Cataract	Right eye/od cataract	2015 - Ongoing
Ventricular extrasystoles	Arrhythmia-pvc	2015 - Ongoing
Coronary arterial stent insertion	Open heart surgery - coronary stent	2016 - 2016
Coronary artery disease	Coronary artery disease	2016 - 2016
Cataract	Left eye/od cataract	2017 - Ongoing
Herpes ophthalmic	Right eye/od herpetic ophthalmic	2017 - Ongoing
Increased tendency to bruise	Easy bruisability	2017 - Ongoing
Neuralgia	Nerve pain and neuralgia-lower back and bilateral legs	2017 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2018 - Ongoing
Osteoarthritis	Osteoarthritis-generalized	2018 - Ongoing
Hypertension	Hypertension	2019 - Ongoing
Intervertebral disc degeneration	Degenerative disc disease of lumbar spine	2019 - Ongoing
Osteoporosis	Osteoporosis/djd	2019 - Ongoing
Hip arthroplasty	Left hip replacement	Feb 2019 - Feb 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin d nos	2000 - Ongoing	Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid; calcium pantothenate; cyanocobalamin; nicotinamide; pyridoxine hydrochloride; riboflavin; thiamine mononitrate	2010 - Ongoing	Supplement
Lorazepam	2010 - Ongoing	Insomnia
Calcium	2015 - Ongoing	Bone Health
Flecainide	May 2016 - Ongoing	Arrhythmia-Pvc
Famciclovir	2017 - Ongoing	Ophthalmic Herpes Right Eye
Prednisolone acetate	2017 - Ongoing	Ophthalmic Herpes-Right Eye
Gabapentin	Apr 2017 - Ongoing	Nerve Pain, Neuralgia
Fish oil	2018 - Ongoing	Heart Supplement
Ibuprofen	2018 - Ongoing	Back And Leg Pain
Ubidecarenone	2018 - Ongoing	Heart Supplement
Rosuvastatin calcium	Feb 2018 - Ongoing	Hypercholesterolemia
Hydrocodone bitartrate; paracetamol	Aug 2018 - Ongoing	Back And Leg Pain
Alendronate sodium	2019 - Ongoing	Osteoporosis
Sertraline	2019 - Ongoing	Depression
Losartan	Mar 2020 - Ongoing	Hypertension
Cannabidiol	May 2020 - Ongoing	Supplement
Vitamins nos	May 2020 - Ongoing	Supplement
Diclofenac	Jun 2020 - Ongoing	Back And Muscle Pain
Methocarbamol	24 Aug 2020 (Study Day 15) - 21 Sep 2020 (Study Day 43)	Pain Secondary To Spinal Fusion
Spinal fusion*	24 Aug 2020 (Study Day 15) - 24 Aug 2020 (Study Day 15)	Medical History
Cefalexin	17 Sep 2020 (Study Day 39) - 01 Oct 2020 (Study Day 53)	Poor Wound Healing
Sulfamethoxazole; trimethoprim	17 Sep 2020 (Study Day 39) - 27 Sep 2020 (Study Day 49)	Poor Wound Healing
Cyclobenzaprine hydrochloride	19 Oct 2020 (Study Day 71) - Dec 2020	Back And Muscle Pain
Left hip relocation*	18 Feb 2021 (Study Day 193) - 18 Feb 2021 (Study Day 193)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Joint Dislocation	Grade 3/severe	Not related	18 Feb 2021 (Study Day 193) - 18 Feb 2021 (Study Day 193)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US311-2221 (Part B)
Vaccination Group: Placebo in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 12 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 28)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Colorectal Cancer Metastatic/ Metastatic Stage 4 Colorectal Carcinoma	SAE	Grade 4	Not related	19 Jan 2021 (Study Day 161) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2221, a 48-year-old Hispanic or Latino male, received the first dose of Placebo in the left arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 09 Feb 2021 and consented to receive 2 doses of mRNA-1273. The first dose was not administered. The second dose was not administered.

Event Details

On 19 Jan 2021 (Study Day 161), 160 days after the first dose in Part A and 133 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of colorectal cancer metastatic. Action taken with the IP was not applicable. The event of metastatic stage 4 colorectal carcinoma was considered to be ongoing. The investigator assessed the event of colorectal cancer metastatic to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-011144	Colorectal cancer metastatic

Study Completion/Discontinuation

On 09 Feb 2021 (Study Day 182), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Eczema	Bilateral hands eczema	2008 - Ongoing
Nephrolithiasis	Kidney stones	2010 - 2010
Colon cancer	Colon cancer	2018 - Apr 2018
Cancer surgery	Colon cancer resection	Apr 2018 - Apr 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	03 Dec 2020 (Study Day 114) - 08 Dec 2020 (Study Day 119)	Viral Syndrome
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	04 Dec 2020 (Study Day 115) - 07 Dec 2020 (Study Day 118)	Viral Syndrome

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US311-2262 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 14 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 06 Jan 2021 (Study Day 146)
Second Dose of Vaccine in Part B: 03 Feb 2021 (Study Day 174)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Sepsis/Septicemia	SAE	Grade 3/ severe	Not related	26 Mar 2021 (Study Day 225) – 04 Apr 2021 (Study Day 234)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The MedDRA Preferred Term/ Verbatim Term of Sepsis/Septicemia was updated to Cholangitis Infective/Acute Cholangitis with Gram Negative Bacteremia and Sepsis after the database lock.

Participant US311-2262, a 70-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 06 Jan 2021 (Study Day 146). The second dose was administered in the left arm on 03 Feb 2021 (Study Day 174).

Event Details

On 26 Mar 2021 (Study Day 225), 224 days after the first dose in Part A/79 days after the first dose in Part B and 196 days after the second dose in Part A/51 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of sepsis. Action taken with the IP was not applicable. The event of septicemia lasted for 10 days, after which it was considered to be recovered/resolved on 04 Apr 2021 (Study Day 234). The investigator assessed the event of sepsis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-070514	Cholangitis infective

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Coronary arterial stent insertion	Coronary artery disease/status post stent	2002 - 30 Sep 2003 (Study Day -6163)
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2015 - Ongoing	Hypercholesterolemia
Fish oil	2015 - Ongoing	Supplement
Vitamin d nos	2015 - Ongoing	Supplement
Vitamins nos	2015 - Ongoing	Supplement
Paracetamol	12 Sep 2020 (Study Day 30) - 12 Sep 2020 (Study Day 30)	Muscle Aches
Influenza vaccine	30 Sep 2020 (Study Day 48) - 30 Sep 2020 (Study Day 48)	Influenza Virus Prophylaxis
Varicella zoster vaccine rge (cho)	26 Feb 2021 (Study Day 197) - 26 Feb 2021 (Study Day 197)	Shingles Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US312-2083 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 28 Jul 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 26 Aug 2020 (Study Day 30)
First Dose of Vaccine in Part B: 12 Jan 2021 (Study Day 169)
Second Dose of Vaccine in Part B: 10 Feb 2021 (Study Day 198)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Anaphylactic Reaction/ Anaphylactic Reaction To Steroid Shot	SAE	Grade 3/ severe	Not related	22 Apr 2021 (Study Day 269) – 22 Apr 2021 (Study Day 269)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US312-2083, a 57-year-old not Hispanic or Latino female, received the first dose of Placebo in the right arm on 28 Jul 2020 (Study Day 1). The second dose was administered in the right arm on 26 Aug 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 12 Jan 2021 (Study Day 169). The second dose was administered in the right arm on 10 Feb 2021 (Study Day 198).

Event Details

On 22 Apr 2021 (Study Day 269), 268 days after the first dose in Part A/100 days after the first dose in Part B and 239 days after the second dose in Part A/71 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of anaphylactic reaction. Action taken with the IP was not applicable. The event of anaphylactic reaction to steroid shot lasted for 1 day, after which it was considered to be recovered/resolved on 22 Apr 2021 (Study Day 269). The investigator assessed the event of anaphylactic reaction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-089909	Anaphylactic reaction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Allergy to animal	Feline allergy	1968 - Ongoing
Asthma	Asthma (asymptomatic)	1968 - Ongoing
Seasonal allergy	Seasonal allergies	1968 - Ongoing
Tonsillectomy	Tonsillectomy	1970 - 1970
Anxiety	Anxiety	1980 - Ongoing
Depression	Depression	1980 - Ongoing
Keratomileusis	Bilateral lasik surgery - vision correction	2002 - 2002
Cheilectomy	Cheilectomy - right big toe	2003 - 2003
Cheilectomy	Cheilectomy - left big toe	2005 - 2005
Genital herpes simplex	Herpes simplex virus - vaginal	2010 - Ongoing
Hysterectomy	Partial hysterectomy - birth control	2011 - 2011
Cartilage injury	Labral tear - left hip	Oct 2015 - Feb 2016
Chondroplasty	Labral tear repair surgery - left	Feb 2016 - Feb 2016
Hiatus hernia	Hiatal hernia	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone propionate; salmeterol xinafoate	2002 - Ongoing	Asthma
Valaciclovir hydrochloride	2010 - Ongoing	Herpes Type 2
Fexofenadine hydrochloride	2015 - Ongoing	Seasonal Allergies
Levosulbutamol hydrochloride	2016 - Ongoing	Asthma
Citalopram	Jun 2019 - Ongoing	Depression
Vitamin d nos	Mar 2020 - Ongoing	Supplement
Subject used neti pot for treatment of sinus infection*	18 Aug 2020 (Study Day 22) - 18 Aug 2020 (Study Day 22)	Adverse Event
Vitamins nos	19 Aug 2020 (Study Day 23) - Ongoing	Supplement
Botulinum toxin type a	17 Feb 2021 (Study Day 205) - 17 Feb 2021 (Study Day 205)	Cosmetic Injections

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US312-2090 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 29 Jul 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 26 Aug 2020 (Study Day 29)
First Dose of Vaccine in Part B: 12 Jan 2021 (Study Day 168)
Second Dose of Vaccine in Part B: 10 Feb 2021 (Study Day 197)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Bursitis/Subacromial Bursitis	SAE	Grade 3/ severe	Not related	10 Feb 2021 (Study Day 197) – 20 Apr 2021 (Study Day 266)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US312-2090, a 62-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 29 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 26 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 12 Jan 2021 (Study Day 168). The second dose was administered in the left arm on 10 Feb 2021 (Study Day 197).

Event Details

On 10 Feb 2021 (Study Day 197), 196 days after the first dose in Part A/29 days after the first dose in Part B and 168 days after the second dose in Part A/on the day of the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of bursitis. Action taken with the IP was not applicable. The event of subacromial bursitis lasted for 70 days, after which it was considered to be recovered/resolved on 20 Apr 2021 (Study Day 266). The investigator assessed the event of bursitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-068896	Bursitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rosacea	Rosacea	(b) (6) 1958 (Study Day (b) (6) - Ongoing
Migraine	Migraines	1968 - Ongoing
Finger repair operation	Finger repair surgery - right index, due to partial severage	2000 - 2000
Tendon rupture	Right index finger partially severed	2000 - 2000

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Magnesium	2010 - Ongoing	General Health
Ibuprofen	Jan 2020 - Jun 2020	Migraine
Paracetamol	Jun 2020 - Ongoing	Migraine
Paracetamol	12 Jan 2021 (Study Day 168) - 12 Jan 2021 (Study Day 168)	Injection Site Pain
Paracetamol	10 Feb 2021 (Study Day 197) - Ongoing	Arm Pain
Ibuprofen	11 Feb 2021 (Study Day 198) - Ongoing	Arm Pain (Sirva)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US313-2004 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 06 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 31 Aug 2020 (Study Day 26)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Sciatica/Worsening Sciatica	SAE	Grade 3/ severe	Not related	26 Apr 2021 (Study Day 264) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The MedDRA Preferred Term/ Verbatim Term of Sciatica/Worsening Sciatica was updated to Lumbar Radiculopathy/Lumbar Radiculopathy and Lumbar Spinal Stenosis/Lumbar Spinal Stenosis after the database lock.

Participant US313-2004, a 52-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 31 Aug 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 08 Jan 2021. The participant was unblinded on 08 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 26 Apr 2021 (Study Day 264), 263 days after the first dose in Part A and 238 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of sciatica. Action taken with the IP was not applicable. The event of worsening sciatica was considered to be ongoing. The investigator assessed the event of sciatica to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-093989	Lumbar radiculopathy
MOD-2021-093989	Lumbar spinal stenosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Sciatica	Right sciatica pain	1990 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2010 - Ongoing
Diabetic neuropathy	Diabetic neuropathy bilateral feet	2019 - Ongoing
Hypercholesterolaemia	Borderline hyperlipidemia	01 Jul 2020 (Study Day -36) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glimepiride	2010 - Ongoing	Type II Diabetes
Metformin	2010 - Ongoing	Diabetes Type II
Insulin glargine	2019 - Ongoing	Type II Diabetes
Losartan	Jan 2020 - Ongoing	Hypertension
Gabapentin	May 2020 - Ongoing	Diabetic Neuropathy
Atorvastatin	01 Jul 2020 (Study Day -36) - Ongoing	Borderline Hypertension
Camphor; menthol; methyl salicylate	25 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 20)	Diabetic Neuropathy
Methocarbamol	24 Feb 2021 (Study Day 203) - Ongoing	Right Sciatica Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US313-2046 (Part B)
Vaccination Group: Placebo in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 14 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 12 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Agitation/Acute Agitation	SAE	Grade 2/ moderate	Not related	20 Jan 2021 (Study Day 129) – 22 Jan 2021 (Study Day 131)	Recovered/resolved
Delirium/Delirium	SAE	Grade 3/ severe	Not related	20 Jan 2021 (Study Day 129) – 22 Jan 2021 (Study Day 131)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US313-2046, a 67-year-old not Hispanic or Latino female, received the first dose of Placebo in the right arm on 14 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 12 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 28 Jan 2021 and consented to receive 2 doses of mRNA-1273. The first dose was not administered. The second dose was not administered.

Event Details

On 20 Jan 2021 (Study Day 129), 128 days after the first dose in Part A and 100 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of agitation. Action taken with the IP was not applicable. The event of acute agitation lasted for 3 days, after which it was considered to be recovered/resolved on 22 Jan 2021 (Study Day 131). The investigator assessed the event of agitation to be not related to the IP.

On 20 Jan 2021 (Study Day 129), 128 days after the first dose in Part A and 100 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of delirium. Action taken with the IP was not applicable. The event of delirium lasted for 3 days, after which it was considered to be recovered/resolved on 22 Jan 2021 (Study Day 131). The investigator assessed the event of delirium to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-008108	Agitation
MOD-2021-008108	Delirium

Study Completion/Discontinuation

On 28 Jan 2021 (Study Day 137), the participant discontinued from the study due to physician decision (PI not comfortable with continuing the participant in study due to mental instability).

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Attention deficit hyperactivity disorder	Adhd	1980 - Ongoing
Gastroesophageal reflux disease	Gerd	1980 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	1980 - Ongoing
Malignant melanoma	Melanoma right thigh	2005 - 2005
Postmenopause	Postmenopausal	2005 - Ongoing
Menopausal symptoms	Post menopausal syndrome	2007 - Ongoing
Anxiety	Anxiety	2010 - Ongoing
Depression	Depression	2010 - Ongoing
Hypothyroidism	Hypothyroidism	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole sodium sesquihydrate	2000 - Ongoing	Ibs
Estradiol	2007 - Ongoing	Menopausal Syndrome
Progesterone	2007 - Ongoing	Menopausal Syndrome
Testosterone	2007 - Ongoing	Menopausal Syndrome
Amphetamine aspartate; amphetamine sulfate; dexamphetamine saccharate; dexamphetamine sulfate	2010 - Ongoing	Adhd
Bupropion	2010 - Ongoing	Anxiety
Levothyroxine	2010 - Ongoing	Hypothyroid
Berberine	2015 - Ongoing	Dietary Supplement
Alprazolam	2020 - Ongoing	Anxiety

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ekg*	20 Jan 2021 (Study Day 129) - 20 Jan 2021 (Study Day 129)	Adverse Event
Haloperidol	20 Jan 2021 (Study Day 129) - 20 Jan 2021 (Study Day 129)	Delirium
Lorazepam	20 Jan 2021 (Study Day 129) - 20 Jan 2021 (Study Day 129)	Agitation
Chest xray*	21 Jan 2021 (Study Day 130) - 21 Jan 2021 (Study Day 130)	Adverse Event
Ct scan head*	21 Jan 2021 (Study Day 130) - 21 Jan 2021 (Study Day 130)	Adverse Event
Mri head*	21 Jan 2021 (Study Day 130) - 21 Jan 2021 (Study Day 130)	Adverse Event
Sodium chloride	21 Jan 2021 (Study Day 130) - 21 Jan 2021 (Study Day 130)	Dehydration Prophylaxis
Urine drug test*	21 Jan 2021 (Study Day 130) - 21 Jan 2021 (Study Day 130)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US313-2138 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 19 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Nov 2020 (Study Day 29)
First Dose of Vaccine in Part B: 21 Jan 2021 (Study Day 95)
Second Dose of Vaccine in Part B: 19 Feb 2021 (Study Day 124)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Coronary Artery Disease/Coronary Artery Disease	SAE	Grade 3/ severe	Not related	26 Feb 2021 (Study Day 131) – Ongoing	Not recovered/ not resolved
Femur Fracture/Broken Left Femur	SAE	Grade 3/ severe	Not related	26 Feb 2021 (Study Day 131) – 04 Mar 2021 (Study Day 137)	Recovered/ resolved with sequelae
Gastrointestinal Haemorrhage/Acute Gastrointestinal Bleed	SAE	Grade 3/ severe	Not related	15 Mar 2021 (Study Day 148) – 28 Mar 2021 (Study Day 161)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US313-2138, a 85-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 19 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 16 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Jan 2021. The participant was unblinded on 21 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 21 Jan 2021 (Study Day 95). The second dose was administered in the left arm on 19 Feb 2021 (Study Day 124).

Event Details

On 26 Feb 2021 (Study Day 131), 130 days after the first dose in Part A/36 days after the first dose in Part B and 102 days after the second dose in Part A/7 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of coronary artery disease. Action taken with the IP was not applicable. The event of coronary artery disease was considered to be ongoing. The investigator assessed the event of coronary artery disease to be not related to the IP.

On 26 Feb 2021 (Study Day 131), 130 days after the first dose in Part A/36 days after the first dose in Part B and 102 days after the second dose in Part A/7 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of femur fracture. Action taken with the IP was not applicable. The event of broken left femur lasted for 7 days, after which it was considered to be recovered/resolved with sequelae on 04 Mar 2021 (Study Day 137). The investigator assessed the event of femur fracture to be not related to the IP.

On 15 Mar 2021 (Study Day 148), 147 days after the first dose in Part A/53 days after the first dose in Part B and 119 days after the second dose in Part A/24 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of gastrointestinal haemorrhage. Action taken with the IP was not applicable. The event of acute gastrointestinal bleed lasted for 14 days, after which it was considered to be recovered/resolved on 28 Mar 2021 (Study Day 161). The investigator assessed the event of gastrointestinal haemorrhage to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-027978	Coronary artery disease
MOD-2021-027978	Femur fracture
MOD-2021-027978	Gastrointestinal haemorrhage

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Labile hypertension	Labile hypertension	1985 - Ongoing
Osteoarthritis	Right knee osteoarthritis	2012 - 2013
Knee arthroplasty	Right knee replacement	2013 - 2013

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	1985 - 07 Mar 2021 (Study Day 140)	Labile Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colecalciferol	2017 - Ongoing	Dietary Supplement
Zinc sulfate	2017 - Ongoing	Dietary Supplement
Influenza vaccine	21 Dec 2020 (Study Day 64) - 21 Dec 2020 (Study Day 64)	Influenza Prophylaxis
Varicella zoster vaccine rge (cho)	21 Dec 2020 (Study Day 64) - 21 Dec 2020 (Study Day 64)	Prevent Shingles
12 lead ecg*	26 Feb 2021 (Study Day 131) - 26 Feb 2021 (Study Day 131)	Adverse Event
Chest x-ray*	26 Feb 2021 (Study Day 131) - 26 Feb 2021 (Study Day 131)	Adverse Event
Fentanyl	26 Feb 2021 (Study Day 131) - 26 Feb 2021 (Study Day 131)	Broken Left Femur
Morphine	26 Feb 2021 (Study Day 131) - 26 Feb 2021 (Study Day 131)	Broken Left Femur
X-ray left femur*	26 Feb 2021 (Study Day 131) - 26 Feb 2021 (Study Day 131)	Adverse Event
X-ray left hip*	26 Feb 2021 (Study Day 131) - 26 Feb 2021 (Study Day 131)	Adverse Event
12 lead ecg*	27 Feb 2021 (Study Day 132) - 27 Feb 2021 (Study Day 132)	Adverse Event
Ct angiography chest*	27 Feb 2021 (Study Day 132) - 27 Feb 2021 (Study Day 132)	Adverse Event
Echocardiogram*	27 Feb 2021 (Study Day 132) - 27 Feb 2021 (Study Day 132)	Adverse Event
X-ray femur*	27 Feb 2021 (Study Day 132) - 27 Feb 2021 (Study Day 132)	Adverse Event
Bilateral lower extremity doppler ultrasound*	28 Feb 2021 (Study Day 133) - 28 Feb 2021 (Study Day 133)	Diagnostic
Cardiac stress test*	28 Feb 2021 (Study Day 133) - 28 Feb 2021 (Study Day 133)	Adverse Event
Coronary angiography*	02 Mar 2021 (Study Day 135) - 02 Mar 2021 (Study Day 135)	Adverse Event
Cardiac catheterization*	03 Mar 2021 (Study Day 136) - 03 Mar 2021 (Study Day 136)	Adverse Event
Acetylsalicylic acid	04 Mar 2021 (Study Day 137) - 28 Mar 2021 (Study Day 161)	Dvt Prophylaxis
Clopidogrel bisulfate	04 Mar 2021 (Study Day 137) - 19 Mar 2021 (Study Day 152)	Dvt Prophylaxis
Fluroscopy lowe extremety*	04 Mar 2021 (Study Day 137) - 04 Mar 2021 (Study Day 137)	Adverse Event
Left hip arthroplasty*	04 Mar 2021 (Study Day 137) - 04 Mar 2021 (Study Day 137)	Adverse Event
Vancomycin	04 Mar 2021 (Study Day 137) - 04 Mar 2021 (Study Day 137)	Infection Prophylaxis
X-ray ap pelvis*	04 Mar 2021 (Study Day 137) - 04 Mar 2021 (Study Day 137)	Adverse Event
Atorvastatin	07 Mar 2021 (Study Day 140) - 28 Mar 2021 (Study Day 161)	Coronary Artery Disease
Docusate; senna alexandrina	07 Mar 2021 (Study Day 140) - 09 Mar 2021 (Study Day 142)	Constipation Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxycodone	07 Mar 2021 (Study Day 140) - 19 Mar 2021 (Study Day 152)	Broken Left Femur
Paracetamol	07 Mar 2021 (Study Day 140) - 09 Mar 2021 (Study Day 142)	Broken Left Femur
Metoprolol	08 Mar 2021 (Study Day 141) - Ongoing	Hypertension
Minerals nos; vitamins nos	08 Mar 2021 (Study Day 141) - 08 Mar 2021 (Study Day 141)	Dietary Supplement
Enoxaparin	09 Mar 2021 (Study Day 142) - 15 Mar 2021 (Study Day 148)	Dvt Prophylaxis
Melatonin	09 Mar 2021 (Study Day 142) - Ongoing	Sleep Aid
Ondansetron	09 Mar 2021 (Study Day 142) - 10 Mar 2021 (Study Day 143)	Nausea Prophylaxis
Hydrocodone; paracetamol	10 Mar 2021 (Study Day 143) - 13 Mar 2021 (Study Day 146)	Broken Left Femur
Paracetamol	11 Mar 2021 (Study Day 144) - 11 Mar 2021 (Study Day 144)	Broken Left Femur
Hydrocodone bitartrate; paracetamol	12 Mar 2021 (Study Day 145) - 12 Mar 2021 (Study Day 145)	Broken Left Femur
Lidocaine	12 Mar 2021 (Study Day 145) - 19 Mar 2021 (Study Day 152)	Broken Left Femur
X-ray femur*	12 Mar 2021 (Study Day 145) - 12 Mar 2021 (Study Day 145)	Adverse Event
Hydrocodone; paracetamol	14 Mar 2021 (Study Day 147) - 14 Mar 2021 (Study Day 147)	Broken Left Femur
Paracetamol	14 Mar 2021 (Study Day 147) - 14 Mar 2021 (Study Day 147)	Broken Left Femur
Blood transfusion*	15 Mar 2021 (Study Day 148) - 15 Mar 2021 (Study Day 148)	Adverse Event
Pantoprazole sodium sesquihydrate	15 Mar 2021 (Study Day 148) - 15 Mar 2021 (Study Day 148)	Acute Gastrointestinal Bleed
Sodium chloride	15 Mar 2021 (Study Day 148) - 15 Mar 2021 (Study Day 148)	Hydration Prophylaxis
Upper gi endoscopy*	16 Mar 2021 (Study Day 149) - 16 Mar 2021 (Study Day 149)	Adverse Event
Pantoprazole	19 Mar 2021 (Study Day 152) - 28 Mar 2021 (Study Day 161)	Gi Prophylaxis
Paracetamol	23 Mar 2021 (Study Day 156) - 23 Mar 2021 (Study Day 156)	Broken Left Femur

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Bundle Branch Block Left	Grade 2/moderate	Not related	26 Feb 2021 (Study Day 131) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US313-2149 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 21 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 18 Nov 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Poisoning/Intoxication	SAE	Grade 2/ moderate	Not related	09 Apr 2021 (Study Day 171) – 13 Apr 2021 (Study Day 175)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US313-2149, a 72-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 21 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 18 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 10 Feb 2021. The participant was unblinded on 10 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 09 Apr 2021 (Study Day 171), 170 days after the first dose in Part A and 142 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of poisoning. Action taken with the IP was not applicable. The event of intoxication lasted for 5 days, after which it was considered to be recovered/resolved on 13 Apr 2021 (Study Day 175). The investigator assessed the event of poisoning to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-089862	Poisoning

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Menopausal symptoms	Postmenopausal syndrome	1976 - Ongoing
Spinal osteoarthritis	Osteoarthritis neck	2002 - Ongoing
Osteoarthritis	Osteoarthritis bilateral knees	2005 - Ongoing
Back pain	Chronic back pain	2017 - Ongoing
Fluid retention	Water retention due to ankle swelling	2017 - Ongoing
Gastric ulcer	Stomach ulcers	2017 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2017 - Ongoing
Hypertension	Hypertension	2017 - Ongoing
Osteoporosis	Osteoporosis	2017 - Ongoing
Osteoarthritis	Osteoarthritis bilateral hands	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxycodone	Not reported - Ongoing	Not reported
Alendronate sodium	2017 - Ongoing	Osteoporosis
Pantoprazole	2017 - Ongoing	Stomach Ulcers
Rosuvastatin	2017 - Ongoing	Hypercholesterolemia
Sucralfate	2017 - Ongoing	Stomach Ulcers
Torsemide	2017 - Ongoing	Water Retention
Codeine; paracetamol	2018 - Ongoing	Osteoarthritis Bilateral Hands
Diclofenac	Sep 2020 - Ongoing	Osteoarthritis Neck
Calcium carbonate	27 Dec 2020 (Study Day 68) - 30 Dec 2020 (Study Day 71)	Stomach Prophylaxis
Chest x-ray*	27 Dec 2020 (Study Day 68) - 27 Dec 2020 (Study Day 68)	Adverse Event
Ct scan of cervical spine*	27 Dec 2020 (Study Day 68) - 27 Dec 2020 (Study Day 68)	Adverse Event
Ct scan of head/brain*	27 Dec 2020 (Study Day 68) - 27 Dec 2020 (Study Day 68)	Adverse Event
Fentanyl	27 Dec 2020 (Study Day 68) - 30 Dec 2020 (Study Day 71)	Right Hip Fracture
Magnesium sulfate	27 Dec 2020 (Study Day 68) - 27 Dec 2020 (Study Day 68)	Right Hip Fracture

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxycodone hydrochloride; paracetamol	27 Dec 2020 (Study Day 68) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Potassium chloride	27 Dec 2020 (Study Day 68) - 27 Dec 2020 (Study Day 68)	Hypokalemia
Right hip ct*	27 Dec 2020 (Study Day 68) - 27 Dec 2020 (Study Day 68)	Adverse Event
Thiamine	27 Dec 2020 (Study Day 68) - 27 Dec 2020 (Study Day 68)	Right Hip Fracture
Bupivacaine	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Calcium chloride; potassium chloride; sodium lactate	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Cefazolin	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Infection Prophylaxis
Dexamethasone	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Dexmedetomidine	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Ekg*	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Adverse Event
Famotidine	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Stomach Prophylaxis
Famotidine	28 Dec 2020 (Study Day 69) - 29 Dec 2020 (Study Day 70)	Stomach Prophylaxis
Ferrous sulfate	28 Dec 2020 (Study Day 69) - 15 Jan 2021 (Study Day 87)	Dietary Supplement
Ketorolac	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Lidocaine	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Morphine	28 Dec 2020 (Study Day 69) - 29 Dec 2020 (Study Day 70)	Right Hip Pain
Ondansetron	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Nausea Prophylaxis
Oxycodone	28 Dec 2020 (Study Day 69) - 15 Jan 2021 (Study Day 87)	Right Hip Pain
Paracetamol	28 Dec 2020 (Study Day 69) - 30 Dec 2020 (Study Day 71)	Right Hip Pain
Peng block*	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Adverse Event
Phenylephrine	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Potassium chloride	28 Dec 2020 (Study Day 69) - 09 Jan 2021 (Study Day 81)	Hypokalemia
Propofol	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Right hip xray*	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Adverse Event
Right total hip arthroplasty*	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Rocuronium	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Suxamethonium	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Tobramycin	28 Dec 2020 (Study Day 69) - 30 Dec 2020 (Study Day 71)	Infection Prophylaxis
Tranexamic acid	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Vancomycin	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Infection Prophylaxis
Vitamins nos	28 Dec 2020 (Study Day 69) - 30 Dec 2020 (Study Day 71)	Dietary Supplement
Acetylsalicylic acid	29 Dec 2020 (Study Day 70) - 15 Jan 2021 (Study Day 87)	Cardiac Prophylaxis
Docusate sodium	29 Dec 2020 (Study Day 70) - 15 Jan 2021 (Study Day 87)	Constipation Prophylaxis
Enoxaparin	29 Dec 2020 (Study Day 70) - 29 Dec 2020 (Study Day 70)	Dvt Prophylaxis
Influenza vaccine	29 Dec 2020 (Study Day 70) - 29 Dec 2020 (Study Day 70)	Influenza Prophylaxis
Diclofenac sodium	30 Dec 2020 (Study Day 71) - 06 Jan 2021 (Study Day 78)	Right Hip Pain
Lidocaine	30 Dec 2020 (Study Day 71) - 02 Jan 2021 (Study Day 74)	Right Hip Pain
Vitamin d nos	30 Dec 2020 (Study Day 71) - 15 Jan 2021 (Study Day 87)	Dietary Supplement
Other viral vaccines	05 Jan 2021 (Study Day 77) - 05 Jan 2021 (Study Day 77)	COVID19 Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US314-2137 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 06 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: 18 Jan 2021 (Study Day 166)
Second Dose of Vaccine in Part B: 16 Feb 2021 (Study Day 195)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Renal Cancer/Left Kidney Carcinoma	SAE	Grade 3/severe	Not related	09 Feb 2021 (Study Day 188) – 04 Mar 2021 (Study Day 211)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US314-2137, a 60-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 18 Jan 2021. The participant was unblinded on 18 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 18 Jan 2021 (Study Day 166). The second dose was administered in the left arm on 16 Feb 2021 (Study Day 195).

Event Details

On 09 Feb 2021 (Study Day 188), 187 days after the first dose in Part A/22 days after the first dose in Part B and 158 days after the second dose in Part A/7 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of renal cancer. The IP dose was not changed due to the left kidney carcinoma. The event of left kidney carcinoma lasted for 24 days, after which it was considered to be recovered/resolved on 04 Mar 2021 (Study Day 211). The investigator assessed the event of renal cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-065726	Renal cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dermatitis allergic	Rashes related to food allergies, unspecified location	1960 - Ongoing
Eczema	Eczema - not specified location	1960 - Ongoing
Neuropathy peripheral	Neuropathy in hands and feet	1960 - Ongoing
Tonsillitis	Tonsillitis	1960 - 2005
Urticaria	Hives, unspecified location	1960 - Ongoing
Seasonal allergy	Seasonal allergies	1965 - Ongoing
Upper-airway cough syndrome	Postnasal drip	1965 - Ongoing
Osteoarthritis	Oa in both knees	1972 - Ongoing
Asthma	Asthma	1990 - Ongoing
Hypothyroidism	Hypothyroidism	1992 - Ongoing
Arthralgia	Joint pain - not specified	2000 - Ongoing
Myopia	Nearsighted, bilateral	2000 - Ongoing
Hypertension	Hypertension	2007 - Ongoing
Depression	Depression	2009 - 2010
Postmenopause	Post menopausal	2009 - Ongoing
Uterine cancer	Uterine cancer	2009 - 2009
Herpes zoster	Shingles	2013 - 2017
Dyspepsia	Heartburn	2015 - Ongoing
Cataract	Cataracts, bilateral	2019 - Ongoing
Muscle atrophy	Muscular degeneration	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	1985 - Ongoing	Seasonal Allergies
Thyroid	1992 - Ongoing	Hypothyroidism
Fluticasone propionate	2010 - Ongoing	Seasonal Allergies
Losartan	2017 - Ongoing	Hypertension
Hydrochlorothiazide	2018 - 05 Nov 2020 (Study Day 92)	Hypertension
Influenza vaccine	25 Sep 2020 (Study Day 51) - 25 Sep 2020 (Study Day 51)	Flu Prevention

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Left radical kidney nephrectomy*	04 Mar 2021 (Study Day 211) - 04 Mar 2021 (Study Day 211)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US314-2139 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 06 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 28 Jan 2021 (Study Day 176)
Second Dose of Vaccine in Part B: 04 Mar 2021 (Study Day 211)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nephrolithiasis/ Hospitalization Due To A Kidney Stone	SAE	Grade 3/ severe	Not related	02 Apr 2021 (Study Day 240) – 04 Apr 2021 (Study Day 242)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US314-2139, a 69-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 28 Jan 2021. The participant was unblinded on 28 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 28 Jan 2021 (Study Day 176). The second dose was administered in the left arm on 04 Mar 2021 (Study Day 211).

Event Details

On 02 Apr 2021 (Study Day 240), 239 days after the first dose in Part A/64 days after the first dose in Part B and 211 days after the second dose in Part A/29 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of nephrolithiasis. Action taken with the IP was not applicable. The event of hospitalization due to a kidney stone lasted for 3 days, after which it was considered to be recovered/resolved on 04 Apr 2021 (Study Day 242). The investigator assessed the event of nephrolithiasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-069516	Nephrolithiasis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillitis	Tonsillitis	1960 - 1960
Depression	Depression	1965 - Ongoing
Hypoacusis	Partial hearing loss, bilateral	1965 - Ongoing
Hypothyroidism	Hypothyroidism	1980 - Ongoing
Postmenopause	Post menopausal	2002 - Ongoing
Hypermetropia	Farsighted	2010 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2012 - Ongoing
Insomnia	Insomnia	2014 - Ongoing
Cataract	Cataracts, bilateral	Jan 2020 - Jan 2020
Cataract operation	Cataract surgery, bilateral	Jan 2020 - Jan 2020
Nephrolithiasis	Kidney stones, unspecified location	Mar 2020 - Mar 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bupropion	2008 - Ongoing	Depression
Desvenlafaxine succinate	2012 - Ongoing	Depression
Lithium	2012 - Ongoing	Depression
Simvastatin	2012 - Ongoing	Hyper-Cholesterol
Zolpidem tartrate	2014 - Ongoing	Insomnia
Hydrocodone	11 Aug 2020 (Study Day 6) - Ongoing	Pain After Dental Surgery
Hydrocodone bitartrate; paracetamol	11 Aug 2020 (Study Day 6) - 11 Aug 2020 (Study Day 6)	Dental Pain After Dental Surgery
Paracetamol	11 Aug 2020 (Study Day 6) - 11 Aug 2020 (Study Day 6)	Pain After Dental Surgery
Fractured right wrist surgical repair*	01 Sep 2020 (Study Day 27) - 01 Sep 2020 (Study Day 27)	Adverse Event
Chondroitin sulfate sodium; glucosamine hydrochloride	08 Oct 2020 (Study Day 64) - Ongoing	Bone Health
Oxycodone hydrochloride	08 Oct 2020 (Study Day 64) - Ongoing	Pain
Vitamin d nos	08 Oct 2020 (Study Day 64) - Ongoing	General Health
Hydrocodone; paracetamol	08 Mar 2021 (Study Day 215) - 09 Mar 2021 (Study Day 216)	Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	09 Mar 2021 (Study Day 216) - 10 Mar 2021 (Study Day 217)	Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US315-2037 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 29 Jul 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 26 Aug 2020 (Study Day 29)
First Dose of Vaccine in Part B: 08 Jan 2021 (Study Day 164)
Second Dose of Vaccine in Part B: 19 Feb 2021 (Study Day 206)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Kidney Injury/Acute Kidney Injury	SAE	Grade 3/ severe	Not related	14 Jan 2021 (Study Day 170) – 17 Jan 2021 (Study Day 173)	Recovered/ resolved
Respiratory Failure/Respiratory Insufficiency With Hypoxia	SAE	Grade 4	Not related	14 Jan 2021 (Study Day 170) – 17 Jan 2021 (Study Day 173)	Recovered/ resolved
Leukocytosis/Leucocytosis	SAE	Grade 3/ severe	Not related	15 Jan 2021 (Study Day 171) – 17 Jan 2021 (Study Day 173)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US315-2037, a 69-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 29 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 26 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 08 Jan 2021. The participant was unblinded on 08 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 08 Jan 2021 (Study Day 164). The second dose was administered in the left arm on 19 Feb 2021 (Study Day 206).

Event Details

On 14 Jan 2021 (Study Day 170), 169 days after the first dose in Part A/6 days after the first dose in Part B and 141 days after the second dose in Part A/36 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of acute kidney injury. The IP dose was not changed due to the acute kidney injury. The event of acute kidney injury lasted for 4 days, after which it was considered to be recovered/resolved on 17 Jan 2021 (Study Day 173). The investigator assessed the event of acute kidney injury to be not related to the IP.

On 14 Jan 2021 (Study Day 170), 169 days after the first dose in Part A/6 days after the first dose in Part B and 141 days after the second dose in Part A/36 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of respiratory failure. The IP dose was not changed due to the respiratory insufficiency with hypoxia. The event of respiratory insufficiency with hypoxia lasted for 4 days, after which it was considered to be recovered/resolved on 17 Jan 2021 (Study Day 173). The investigator assessed the event of respiratory failure to be not related to the IP.

On 15 Jan 2021 (Study Day 171), 170 days after the first dose in Part A/7 days after the first dose in Part B and 142 days after the second dose in Part A/35 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of leukocytosis. The IP dose was not changed due to the leukocytosis. The event of leukocytosis lasted for 3 days, after which it was considered to be recovered/resolved on 17 Jan 2021 (Study Day 173). The investigator assessed the event of leukocytosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-078620	Acute kidney injury
MOD-2021-078620	Respiratory failure
MOD-2021-078620	Leukocytosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Type ii diabetes mellitus	1999 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Coronary artery disease	Coronary artery disease	20 Feb 2000 (Study Day -7465) - 24 Feb 2000 (Study Day -7461)
Coronary arterial stent insertion	Coronary artery stent placement	24 Feb 2000 (Study Day -7461) - 24 Feb 2000 (Study Day -7461)
Erectile dysfunction	Erectile dysfunction	2010 - Ongoing
Diabetic neuropathy	Peripheral neuropathy, diabetic	2013 - Ongoing
Coronary artery disease	Coronary artery disease	06 Jun 2013 (Study Day -2610) - 20 Jun 2013 (Study Day -2596)

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Coronary arterial stent insertion	Coronary artery stent placement	20 Jun 2013 (Study Day -2596) - 20 Jun 2013 (Study Day -2596)
Spinal stenosis	Spinal stenosis	2016 - 10 Feb 2020 (Study Day -170)
Procedural pain	Post operative lower back pain	Feb 2020 - Ongoing
Spinal fusion surgery	Spinal decompression and fusion	10 Feb 2020 (Study Day -170) - 10 Feb 2020 (Study Day -170)
Cardiac murmur	Heart murmur	29 Jul 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2000 - Ongoing	Cardiac Prophylaxis
Atorvastatin	2000 - Ongoing	Hyperlipidemia
Metoprolol	2000 - Ongoing	Hypertension
Tadalafil	2010 - Ongoing	Erectile Dysfunction
Glipizide	Jan 2010 - Ongoing	Diabetes Type II
Bupropion	2013 - Ongoing	Peripheral Sensory Neuropathy Bilateral Hands And Legs
Caffeine	2013 - Ongoing	Nutritional Supplement
Gabapentin	2013 - Ongoing	Peripheral Sensory Neuropathy Bilateral Hands And Legs
Lisinopril	2013 - 20 Nov 2020 (Study Day 115)	Kidney Prophylactic For Diabetes Type II
Vitamin d nos	2015 - Ongoing	Nutritional Supplement
Ascorbic acid	2017 - Ongoing	Nutritional Supplement
Glyceryl trinitrate	2018 - Ongoing	History Of Coronary Artery Disease
Metformin	Dec 2019 - Ongoing	Diabetes Type II
Paracetamol	Feb 2020 - Ongoing	Post Operative Lower Back Pain
Tramadol	Feb 2020 - Ongoing	Post Operative Lower Back Pain
Influenza vaccine	10 Sep 2020 (Study Day 44) - 10 Sep 2020 (Study Day 44)	Flu Prophylaxis
Lisinopril	20 Nov 2020 (Study Day 115) - Ongoing	Kidney Prophylactic For Diabetes Type II
Amlodipine	17 Dec 2020 (Study Day 142) - 27 Dec 2020 (Study Day 152)	Coronary Artery Disease
Amlodipine	28 Dec 2020 (Study Day 153) - 14 Jan 2021 (Study Day 170)	Coronary Artery Disease
Coronary artery bypass*	14 Jan 2021 (Study Day 170) - 14 Jan 2021 (Study Day 170)	Adverse Event
Hydromorphone hydrochloride	14 Jan 2021 (Study Day 170) - 16 Jan 2021 (Study Day 172)	Post Coronary Artery Bypass Graft Procedure Pain
Oxygen	14 Jan 2021 (Study Day 170) - 17 Jan 2021 (Study Day 173)	Respiratory Insufficiency With Hypoxia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gluconate sodium; magnesium chloride hexahydrate; potassium chloride; sodium acetate trihydrate; sodium chloride	15 Jan 2021 (Study Day 171) - 15 Jan 2021 (Study Day 171)	Acute Kidney Injury
Macrogol 3350	15 Jan 2021 (Study Day 171) - 15 Jan 2021 (Study Day 171)	Paralytic Ileus
Methylnaltrexone	15 Jan 2021 (Study Day 171) - 15 Jan 2021 (Study Day 171)	Paralytic Ileus
Furosemide	16 Jan 2021 (Study Day 172) - 16 Jan 2021 (Study Day 172)	Fluid Overload
Lidocaine	16 Jan 2021 (Study Day 172) - 19 Jan 2021 (Study Day 175)	Post Coronary Artery Bypass Graft Procedure Pain
Magnesium sulfate	16 Jan 2021 (Study Day 172) - 19 Jan 2021 (Study Day 175)	Electrolyte Imbalance
Potassium phosphate monobasic; sodium phosphate dibasic; sodium phosphate monobasic (anhydrous)	16 Jan 2021 (Study Day 172) - 19 Jan 2021 (Study Day 175)	Electrolyte Imbalance
Furosemide	17 Jan 2021 (Study Day 173) - 19 Jan 2021 (Study Day 175)	Overload
Paracetamol	19 Jan 2021 (Study Day 175) - 10 Feb 2021 (Study Day 197)	Post Procedure (Coronary Artery Bypass) Pain
Furosemide	20 Jan 2021 (Study Day 176) - 23 Jan 2021 (Study Day 179)	Fluid Overload

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Procedural Pain	Grade 2/moderate	Not related	14 Jan 2021 (Study Day 170) - 10 Feb 2021 (Study Day 197)
Fluid Overload	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 171) - 23 Jan 2021 (Study Day 179)
Ileus Paralytic	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 171) - 17 Jan 2021 (Study Day 173)
Electrolyte Imbalance	Grade 2/moderate	Not related	16 Jan 2021 (Study Day 172) - 19 Jan 2021 (Study Day 175)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US315-2118 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 07 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 34)
First Dose of Vaccine in Part B: 12 Jan 2021 (Study Day 159)
Second Dose of Vaccine in Part B: 11 Feb 2021 (Study Day 189)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atelectasis/Atelectasis	SAE	Grade 3/ severe	Not related	24 Mar 2021 (Study Day 230) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US315-2118, a 24-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 12 Jan 2021 (Study Day 159). The second dose was administered in the left arm on 11 Feb 2021 (Study Day 189).

Event Details

On 24 Mar 2021 (Study Day 230), 229 days after the first dose in Part A/71 days after the first dose in Part B and 196 days after the second dose in Part A/41 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of atelectasis. Action taken with the IP was not applicable. The event of atelectasis was considered to be ongoing. The investigator assessed the event of atelectasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-078694	Atelectasis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1997 - Ongoing
Acute myeloid leukaemia	Acute myeloid leukemia	2006 - 2006
Attention deficit hyperactivity disorder	Attention deficit disorder	2006 - 2006
Bone marrow transplant	Bone marrow transplant	2006 - 2006
Dermatitis contact	Adhesive allergy	2006 - Ongoing
Drug hypersensitivity	Albuterol allergy	2006 - Ongoing
Drug hypersensitivity	Amphotericin allergy	2006 - Ongoing
Drug hypersensitivity	Compazine allergy	2006 - Ongoing
Drug hypersensitivity	Labetalol allergy	2006 - Ongoing
Drug hypersensitivity	Oxycontin allergy	2006 - Ongoing
Drug hypersensitivity	Phenergan allergy	2006 - Ongoing
Drug hypersensitivity	Trexall triacetate allergy	2006 - Ongoing
Drug hypersensitivity	Vibramycin allergy	2006 - Ongoing
Drug hypersensitivity	Zofran allergy	2006 - Ongoing
Haemolytic transfusion reaction	Hemolytic transfusion reaction	2006 - 2006
Neuralgia	General nerve pain	2006 - Ongoing
Ovarian failure	Complete ovarian failure	2006 - Ongoing
Food allergy	Mushroom allergy	2008 - Ongoing
Migraine	Migraines	2010 - Ongoing
Cold urticaria	Cold-induced urticaria	2015 - Ongoing
Hypothyroidism	Hypothyroidism	2015 - Ongoing
Back pain	Back pain	2016 - Ongoing
Drug hypersensitivity	Mobic allergy	2018 - Ongoing
Thoracic outlet syndrome	Post traumatic right thoracic outlet syndrome	17 Oct 2019 (Study Day -295) - Ongoing
Muscle spasms	Right shoulder post-operative muscle spasms	Dec 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cyclobenzaprine hydrochloride	Dec 2019 - 23 Mar 2021 (Study Day 229)	Right Shoulder Post Operative Muscle Spasms

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	Dec 2019 - 25 Nov 2020 (Study Day 111)	General Nerve Pain
Tramadol	Dec 2019 - 23 Mar 2021 (Study Day 229)	Back Pain
Arthroscopy right shoulder*	11 Sep 2020 (Study Day 36) - 11 Sep 2020 (Study Day 36)	Medical History
Hydrocodone bitartrate; paracetamol	11 Sep 2020 (Study Day 36) - 13 Sep 2020 (Study Day 38)	Right Shoulder Postoperative Pain
Ibuprofen	11 Sep 2020 (Study Day 36) - Ongoing	Right Shoulder Post Operative Pain
Right distal clavicle resection*	11 Sep 2020 (Study Day 36) - 11 Sep 2020 (Study Day 36)	Medical History
Diazepam	14 Sep 2020 (Study Day 39) - 20 Dec 2020 (Study Day 136)	Right Shoulder Post Operative Muscle Spasms
Ibuprofen	21 Nov 2020 (Study Day 107) - 05 Dec 2020 (Study Day 121)	Viral Syndrome
Echocardiogram*	07 Jan 2021 (Study Day 154) - 07 Jan 2021 (Study Day 154)	Adverse Event
Electrocardiogram*	07 Jan 2021 (Study Day 154) - 07 Jan 2021 (Study Day 154)	Adverse Event
Holtermonitor*	07 Jan 2021 (Study Day 154) - 07 Jan 2021 (Study Day 154)	Adverse Event
Losartan	09 Jan 2021 (Study Day 156) - Feb 2021	Intermittent Elevated Blood Pressure
Anteri scalene resection (right)or*	23 Mar 2021 (Study Day 229) - 23 Mar 2021 (Study Day 229)	Medical History
Diazepam	23 Mar 2021 (Study Day 229) - 06 Apr 2021 (Study Day 243)	Post Procedure Pain
Granisetron	23 Mar 2021 (Study Day 229) - Ongoing	Nausea
Middle scalene resection (right)*	23 Mar 2021 (Study Day 229) - 23 Mar 2021 (Study Day 229)	Medical History
Paracetamol	23 Mar 2021 (Study Day 229) - 06 Apr 2021 (Study Day 243)	Post Procedure Pain
Resection first right rib*	23 Mar 2021 (Study Day 229) - 23 Mar 2021 (Study Day 229)	Medical History
Right brachial plexus neurolysis*	23 Mar 2021 (Study Day 229) - 23 Mar 2021 (Study Day 229)	Medical History
Lidocaine	26 Mar 2021 (Study Day 232) - Ongoing	Post Procedure Pain
Morphine	26 Mar 2021 (Study Day 232) - 06 Apr 2021 (Study Day 243)	Post Procedure Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nausea	Grade 2/moderate	Not related	23 Mar 2021 (Study Day 229) - Ongoing
Procedural Pain	Grade 2/moderate	Not related	23 Mar 2021 (Study Day 229) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US315-2162 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 13 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cerebrovascular Accident/ Acute Cerebrovascular Accident	SAE	Grade 4	Not related	01 Apr 2021 (Study Day 232) – 01 Apr 2021 (Study Day 232)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US315-2162, a 46-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 01 Feb 2021. The participant was unblinded on 01 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 01 Apr 2021 (Study Day 232), 231 days after the first dose in Part A and 203 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of cerebrovascular accident. Action taken with the IP was not applicable. The event of acute cerebrovascular accident lasted for 1 day, after which it was considered to be recovered/resolved on 01 Apr 2021 (Study Day 232). The investigator assessed the event of cerebrovascular accident to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-067852	Cerebrovascular accident

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Mild asthma	1984 - Ongoing
Oral herpes	Herpes labialis	1984 - Ongoing
Bipolar disorder	Bipolar disorder	2001 - Ongoing
Insomnia	Insomnia	2001 - Ongoing
Depression	Depression	2018 - Ongoing
Hysterectomy	Hysterectomy	2018 - 2018
Postmenopause	Postmenopausal	2018 - Ongoing
Uterine leiomyoma	Uterine leiomyoma	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1984 - Ongoing	Mild Asthma
Valaciclovir	1984 - Ongoing	Herpes Labialis
Lamotrigine	2001 - Ongoing	Bipolar Disorder
Zolpidem	2001 - Ongoing	Insomnia
Bupropion hydrochloride	Feb 2020 - Ongoing	Depression
Nitrofurantoin	29 Sep 2020 (Study Day 48) - 03 Oct 2020 (Study Day 52)	Urinary Tract Infection
Influenza vaccine	11 Nov 2020 (Study Day 91) - 11 Nov 2020 (Study Day 91)	Prophylaxis For Influenza Virus

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US315-2175 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 13 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: 30 Dec 2020 (Study Day 140)
Second Dose of Vaccine in Part B: 26 Jan 2021 (Study Day 167)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cholecystitis/ Cholecystitis	SAE	Grade 4	Not related	02 Mar 2021 (Study Day 202) – 03 Mar 2021 (Study Day 203)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US315-2175, a 53-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 30 Dec 2020. The participant was unblinded on 30 Dec 2020 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 30 Dec 2020 (Study Day 140). The second dose was administered in the left arm on 26 Jan 2021 (Study Day 167).

Event Details

On 02 Mar 2021 (Study Day 202), 201 days after the first dose in Part A/62 days after the first dose in Part B and 172 days after the second dose in Part A/35 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of cholecystitis. Action taken with the IP was not applicable. The event of cholecystitis lasted for 2 days, after which it was considered to be recovered/resolved on 03 Mar 2021 (Study Day 203). The investigator assessed the event of cholecystitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-036204	Cholecystitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cardiac murmur	Cardiac murmur	1980 - Ongoing
Endometriosis	Endometriosis	1990 - 2007
Appendectomy	Appendectomy	2007 - 2007
Hysterosalpingo-oophorectomy	Hysterectomy and bilateral salpingo-oophorectomy	2007 - 2007
Anxiety	Anxiety	2015 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2017 - Ongoing
Bundle branch block right	Right bundle branch block	02 May 2018 (Study Day -834) - Ongoing
Hypertension	Hypertension	01 Jul 2020 (Study Day -43) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium carbonate	2010 - Ongoing	Gastroesophageal Reflux Disease
Lansoprazole	2010 - Ongoing	Gastroesophageal Reflux Disease
Ascorbic acid	2019 - Ongoing	Nutritional Supplement
Colecalciferol	2019 - Ongoing	Nutritional Supplement
Valproate semisodium	2019 - Ongoing	Anxiety
Vitamins nos	Mar 2020 - Ongoing	Nutritional Supplement
Atenolol	01 Jul 2020 (Study Day -43) - Ongoing	Hypertension
Influenza vaccine	01 Oct 2020 (Study Day 50) - 01 Oct 2020 (Study Day 50)	Influenza Prophylaxis
Cholecystectomy*	03 Mar 2021 (Study Day 203) - 03 Mar 2021 (Study Day 203)	Adverse Event
Ketorolac tromethamine	03 Mar 2021 (Study Day 203) - 03 Mar 2021 (Study Day 203)	Cholecystitis
Piperacillin sodium; tazobactam sodium	03 Mar 2021 (Study Day 203) - 03 Mar 2021 (Study Day 203)	Cholecystitis
Paracetamol	04 Mar 2021 (Study Day 204) - Ongoing	Post Procedure Pain (Cholecystectomy)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Procedural Pain	Grade 2/moderate	Not related	03 Mar 2021 (Study Day 203) - 09 Mar 2021 (Study Day 209)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US315-2413 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 29 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 27 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cholecystitis/Cholecystitis	SAE	Grade 3/ severe	Not related	06 Apr 2021 (Study Day 190) – 08 Apr 2021 (Study Day 192)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US315-2413, a 48-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 29 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 27 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 06 Apr 2021 (Study Day 190), 189 days after the first dose in Part A and 161 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of cholecystitis. Action taken with the IP was not applicable. The event of cholecystitis lasted for 3 days, after which it was considered to be recovered/resolved on 08 Apr 2021 (Study Day 192). The investigator assessed the event of cholecystitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-070948	Cholecystitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Polycystic ovaries	Bilateral polycystic ovarian syndrome	2010 - Ongoing
Acne	Acne	2018 - Ongoing
Anxiety	Anxiety	2018 - Ongoing
Migraine	Migraines	2018 - Ongoing
Intervertebral disc compression	Cervical disc compression c5-c6	May 2019 - Ongoing
Road traffic accident	Motor vehicle accident	May 2019 - May 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fexofenadine hydrochloride	2000 - Ongoing	Seasonal Allergies
Ethinylestradiol; ferrous fumarate; norethisterone acetate	2010 - Ongoing	Polycystic Ovarian Syndrome
Clindamycin	2018 - Ongoing	Acne
Propranolol	2018 - Ongoing	Medical History - Migraines
Tretinoin	2018 - Ongoing	Acne
Doxycycline	20 Oct 2020 (Study Day 22) - 25 Oct 2020 (Study Day 27)	Sinus Infection
Ibuprofen	28 Oct 2020 (Study Day 30) - 28 Oct 2020 (Study Day 30)	Injection Site Pain
Ibuprofen	04 Nov 2020 (Study Day 37) - 06 Nov 2020 (Study Day 39)	Injection Site Redness
Fluconazole	10 Nov 2020 (Study Day 43) - 10 Nov 2020 (Study Day 43)	Yeast Infection
Lorazepam	10 Nov 2020 (Study Day 43) - Ongoing	Panic Attacks
Hydrocodone; paracetamol	06 Jan 2021 (Study Day 100) - Ongoing	Worsening Of Cervical Disc Compression With Radiculopathy
Botulinum toxin type a	28 Jan 2021 (Study Day 122) - 28 Jan 2021 (Study Day 122)	Migraines

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US316-2068 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 06 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: 20 Jan 2021 (Study Day 168)
Second Dose of Vaccine in Part B: 18 Feb 2021 (Study Day 197)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteomyelitis/Osteomyelitis Right Great Toe	SAE	Grade 4	Not related	29 Mar 2021 (Study Day 236) – 07 Apr 2021 (Study Day 245)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US316-2068, a 66-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 20 Jan 2021. The participant was unblinded on 20 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 20 Jan 2021 (Study Day 168). The second dose was administered in the left arm on 18 Feb 2021 (Study Day 197).

Event Details

On 29 Mar 2021 (Study Day 236), 235 days after the first dose in Part A/68 days after the first dose in Part B and 206 days after the second dose in Part A/39 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of osteomyelitis. Action taken with the IP was not applicable. The event of osteomyelitis right great toe lasted for 10 days, after which it was considered to be recovered/resolved on 07 Apr 2021 (Study Day 245). The investigator assessed the event of osteomyelitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-073114	Osteomyelitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Peripheral sensory neuropathy	Sensory neuropathy bilateral great toes	1988 - Ongoing
Hypersensitivity	Environmental allergies	1990 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Asthma	Mild asthma	2014 - Ongoing
Back pain	Chronic low back pain	2014 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2014 - Ongoing
Glucose tolerance impaired	Glucose intolerance	2014 - Ongoing
Rotator cuff syndrome	Tendinitis left shoulder	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Benazepril	2000 - Ongoing	Hypertension
Hydrochlorothiazide	2000 - Ongoing	Hypertension
Simvastatin	2000 - Ongoing	Hyperlipidemia
Acetylsalicylic acid	2010 - Ongoing	Cardiac Protection
Metoprolol	2010 - Ongoing	Hypertension
Flunisolide	2014 - Ongoing	Environmental Allergies
Fluticasone propionate	2014 - Ongoing	Mild Asthma
Magnesium	2014 - Ongoing	Nutritional Supplement
Omeprazole	2014 - Ongoing	Gastroesophageal Reflux Disease
Salbutamol	2014 - Ongoing	Mild Asthma
Diclofenac	Jun 2020 - Ongoing	Tendinitis Left Shoulder
Influenza vaccine	30 Oct 2020 (Study Day 86) - 30 Oct 2020 (Study Day 86)	Influenza Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Skin Ulcer	Grade 2/moderate	Not related	01 Mar 2021 (Study Day 208) - 07 Apr 2021 (Study Day 245)
Cellulitis	Grade 3/severe	Not related	22 Mar 2021 (Study Day 229) - 22 Apr 2021 (Study Day 260)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US316-2072 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 06 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 02 Feb 2021 (Study Day 181)
Second Dose of Vaccine in Part B: 02 Mar 2021 (Study Day 209)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Angina Unstable/Crescendo Angina	SAE	Grade 4	Not related	15 Feb 2021 (Study Day 194) – 12 Mar 2021 (Study Day 219)	Recovered/resolved
Pneumothorax/Bilateral Pneumothorax	SAE	Grade 4	Not related	16 Mar 2021 (Study Day 223) – 23 Mar 2021 (Study Day 230)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US316-2072, a 71-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 02 Feb 2021. The participant was unblinded on 02 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 02 Feb 2021 (Study Day 181). The second dose was administered in the left arm on 02 Mar 2021 (Study Day 209).

Event Details

On 15 Feb 2021 (Study Day 194), 193 days after the first dose in Part A/13 days after the first dose in Part B and 165 days after the second dose in Part A/15 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of angina unstable. Action taken with the IP was not applicable. The event of crescendo angina lasted for 26 days, after which it was considered to be recovered/resolved on 12 Mar 2021 (Study Day 219). The investigator assessed the event of angina unstable to be not related to the IP.

On 16 Mar 2021 (Study Day 223), 222 days after the first dose in Part A/42 days after the first dose in Part B and 194 days after the second dose in Part A/14 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of pneumothorax. Action

taken with the IP was not applicable. The event of bilateral pneumothorax lasted for 8 days, after which it was considered to be recovered/resolved on 23 Mar 2021 (Study Day 230). The investigator assessed the event of pneumothorax to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-056905	Angina unstable
MOD-2021-056905	Pneumothorax

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1979 - Ongoing
Nasal septum deviation	Deviated septum	1983 - Dec 2019
Hypertension	Hypertension	2004 - Ongoing
Hyperlipidaemia	Hyperlipdemia	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	2000 - Ongoing	Nutritional Supplement
Fish oil	2000 - Ongoing	Nutritional Supplement
Glucosamine	2000 - Ongoing	Nutritional Supplement
Vitamins nos	2000 - Ongoing	Nutritional Supplement
Lisinopril	Jul 2019 - 11 Mar 2021 (Study Day 218)	Hypertension
Influenza vaccine	04 Nov 2020 (Study Day 91) - 04 Nov 2020 (Study Day 91)	Influenza Prevention
Acetylsalicylic acid	08 Nov 2020 (Study Day 95) - 08 Nov 2020 (Study Day 95)	Acute Viral Infection, Unspecified
Glyceryl trinitrate	04 Mar 2021 (Study Day 211) - Ongoing	Crescendo Angina
Acetylsalicylic acid	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Prophylaxis Myocardial Infarction
Chest x-ray*	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chest-x-ray (different hospital)*	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Diagnostic
Coronary angiography*	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Adverse Event
Ecg (different hospital)*	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Adverse Event
Ekg (emergency room)*	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Adverse Event
Ekg (emergency room)*	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Adverse Event
Fentanyl	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Conscious Sedation For Angiography
Glyceryl trinitrate	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Prevent Spasm Of Coronary Arteries
Heparin	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Prevent Clot During Angiography
Lidocaine	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Prevent Pain From Right Radial Arterial Line Placement
Lisinopril	11 Mar 2021 (Study Day 218) - 30 Mar 2021 (Study Day 237)	Hypertension
Midazolam hydrochloride	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Conscious Sedation For Angiography
Placement of arterial line for angiography*	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Diagnostic
Sodium chloride	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Prophylaxis Against Line Clotting Off
Stress echo*	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Adverse Event
Verapamil	11 Mar 2021 (Study Day 218) - 11 Mar 2021 (Study Day 218)	Prevent Spasm Of Coronary Arteries
5 vessel coronary bypass surgery*	12 Mar 2021 (Study Day 219) - 12 Mar 2021 (Study Day 219)	Adverse Event
Chest x-ray*	12 Mar 2021 (Study Day 219) - 12 Mar 2021 (Study Day 219)	Diagnostic
Ecg*	12 Mar 2021 (Study Day 219) - 12 Mar 2021 (Study Day 219)	Adverse Event
Endotracheal intubation*	12 Mar 2021 (Study Day 219) - 12 Mar 2021 (Study Day 219)	Other, Pre-Operative Procedure For Anesthesia
Placement of arterial line*	12 Mar 2021 (Study Day 219) - 12 Mar 2021 (Study Day 219)	Other, Pre-Operative Procedure
Placement of central line*	12 Mar 2021 (Study Day 219) - 12 Mar 2021 (Study Day 219)	Other, Pre-Operative Procedure
Placement of foley catheter*	12 Mar 2021 (Study Day 219) - 12 Mar 2021 (Study Day 219)	Other, Pre-Operative Procedure
Right lower extremity endoscopic vein harvest*	12 Mar 2021 (Study Day 219) - 12 Mar 2021 (Study Day 219)	Adverse Event
Spirometry*	12 Mar 2021 (Study Day 219) - 12 Mar 2021 (Study Day 219)	Other, Pre-Operative Procedure
Trans-esophageal echo*	12 Mar 2021 (Study Day 219) - 12 Mar 2021 (Study Day 219)	Other, Intra-Operative Procedure

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chest x-ray*	13 Mar 2021 (Study Day 220) - 13 Mar 2021 (Study Day 220)	Diagnostic
Ecg*	13 Mar 2021 (Study Day 220) - 13 Mar 2021 (Study Day 220)	Adverse Event
Chest x-ray*	14 Mar 2021 (Study Day 221) - 14 Mar 2021 (Study Day 221)	Diagnostic
Trans-thoracic echo*	14 Mar 2021 (Study Day 221) - 14 Mar 2021 (Study Day 221)	Other, Post-Operative Monitoring
Chest x-ray*	15 Mar 2021 (Study Day 222) - 15 Mar 2021 (Study Day 222)	Diagnostic
Bilateral chest tube insertion*	16 Mar 2021 (Study Day 223) - 16 Mar 2021 (Study Day 223)	Adverse Event
Chest x-ray (3)*	16 Mar 2021 (Study Day 223) - 16 Mar 2021 (Study Day 223)	Adverse Event
Chest x-ray*	17 Mar 2021 (Study Day 224) - 17 Mar 2021 (Study Day 224)	Adverse Event
Chest x-ray*	18 Mar 2021 (Study Day 225) - 18 Mar 2021 (Study Day 225)	Adverse Event
Chest x-ray*	19 Mar 2021 (Study Day 226) - 19 Mar 2021 (Study Day 226)	Adverse Event
Brain mri*	20 Mar 2021 (Study Day 227) - 20 Mar 2021 (Study Day 227)	Adverse Event
Chest x-ray*	20 Mar 2021 (Study Day 227) - 20 Mar 2021 (Study Day 227)	Adverse Event
Chest x-ray*	21 Mar 2021 (Study Day 228) - 21 Mar 2021 (Study Day 228)	Adverse Event
Chest x-ray (2)*	22 Mar 2021 (Study Day 229) - 22 Mar 2021 (Study Day 229)	Adverse Event
Acetylsalicylic acid	23 Mar 2021 (Study Day 230) - Ongoing	Prevent Coronary Thrombosis
Atorvastatin	23 Mar 2021 (Study Day 230) - Ongoing	Coronary Artery Disease
Carvedilol	23 Mar 2021 (Study Day 230) - Ongoing	Coronary Artery Disease
Chest x-ray*	23 Mar 2021 (Study Day 230) - 23 Mar 2021 (Study Day 230)	Adverse Event
Clopidogrel	23 Mar 2021 (Study Day 230) - Ongoing	Coronary Artery Disease
Colchicine	25 Mar 2021 (Study Day 232) - Ongoing	Subcutaneous Emphysema Upper Thorax

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Coronary Artery Disease	Grade 3/severe	Not related	11 Mar 2021 (Study Day 218) - Ongoing
Subcutaneous Emphysema	Grade 2/moderate	Not related	17 Mar 2021 (Study Day 224) - 14 Apr 2021 (Study Day 252)
Lacunar Infarction	Grade 1/mild	Not related	20 Mar 2021 (Study Day 227) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US316-2090 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 10 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: 18 Jan 2021 (Study Day 162)
Second Dose of Vaccine in Part B: 15 Feb 2021 (Study Day 190)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Myocardial Infarction/ Acute Myocardial Infarction	SAE	Grade 4	Not related	27 Apr 2021 (Study Day 261) – 27 Apr 2021 (Study Day 261)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US316-2090, a 66-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 18 Jan 2021. The participant was unblinded on 18 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 18 Jan 2021 (Study Day 162). The second dose was administered in the left arm on 15 Feb 2021 (Study Day 190).

Event Details

On 27 Apr 2021 (Study Day 261), 260 days after the first dose in Part A/99 days after the first dose in Part B and 231 days after the second dose in Part A/71 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of acute myocardial infarction. Action taken with the IP was not applicable. The event of acute myocardial infarction lasted for 1 day, after which it was considered to be recovered/resolved on 27 Apr 2021 (Study Day 261). The investigator assessed the event of acute myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-099028	Acute myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1979 - Ongoing
Sinusitis	Recurrent sinusitis	1979 - 1995
Depression	Depression	1995 - Ongoing
Androgenetic alopecia	Male pattern baldness	1999 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2018 - Ongoing
Panic attack	Panic attacks	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone propionate	2010 - Ongoing	Seasonal Allergies
Lysine	2012 - Ongoing	Nutritional Supplement
Colecalciferol	2015 - Ongoing	Nutritional Supplement
Melatonin	2015 - Ongoing	Nutritional Supplement
Valeriana officinalis	2015 - Ongoing	Nutritional Supplement
Atorvastatin	2018 - 26 Apr 2021 (Study Day 260)	Hyperlipidemia
Finasteride	Jul 2020 - Ongoing	Male Pattern Baldness
Fluoxetine hydrochloride	31 Jul 2020 (Study Day -10) - 12 Aug 2020 (Study Day 3)	Depression
Fluoxetine hydrochloride	12 Aug 2020 (Study Day 3) - Ongoing	Depression
Lorazepam	12 Aug 2020 (Study Day 3) - Ongoing	Panic Attacks
Arginine	29 Sep 2020 (Study Day 51) - Ongoing	Nutritional Supplement
Pneumococcal vaccine polyv	05 Oct 2020 (Study Day 57) - 05 Oct 2020 (Study Day 57)	Prophylaxis For Pneumococcal Bacteria Infection
Paracetamol	11 Nov 2020 (Study Day 94) - 14 Nov 2020 (Study Day 97)	Acute Viral Infection, Unspecified
Diphenhydramine; paracetamol	14 Nov 2020 (Study Day 97) - 14 Nov 2020 (Study Day 97)	Acute Viral Infection, Unspecified

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Haemorrhoidal Haemorrhage	Grade 1/mild	Not related	31 Jan 2021 (Study Day 175) - 01 Feb 2021 (Study Day 176)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US316-2139 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 18 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 15 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 25 Jan 2021 (Study Day 161)
Second Dose of Vaccine in Part B: 22 Feb 2021 (Study Day 189)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chest Pain/Worsening Of Atypical Chest Pain	SAE	Grade 4	Not related	01 Feb 2021 (Study Day 168) – 17 Feb 2021 (Study Day 184)	Recovered/resolved
Hypertension/Worsening Of Hypertension	SAE	Grade 4	Not related	16 Feb 2021 (Study Day 183) – 17 Feb 2021 (Study Day 184)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US316-2139, a 69-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 18 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 15 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 25 Jan 2021. The participant was unblinded on 25 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 25 Jan 2021 (Study Day 161). The second dose was administered in the left arm on 22 Feb 2021 (Study Day 189).

Event Details

On 01 Feb 2021 (Study Day 168), 167 days after the first dose in Part A/7 days after the first dose in Part B and 139 days after the second dose in Part A/21 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of chest pain. The IP dose was not changed due to the worsening of atypical chest pain. The event of worsening of atypical chest pain lasted for 17 days, after which it was considered to be recovered/resolved on 17 Feb 2021 (Study Day 184). The investigator assessed the event of chest pain to be not related to the IP.

On 16 Feb 2021 (Study Day 183), 182 days after the first dose in Part A/22 days after the first dose in Part B and 154 days after the second dose in Part A/6 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of hypertension. The IP dose

was not changed due to the worsening of hypertension. The event of worsening of hypertension lasted for 2 days, after which it was considered to be recovered/resolved on 17 Feb 2021 (Study Day 184). The investigator assessed the event of hypertension to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-018529	Chest pain
MOD-2021-018529	Hypertension

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cardiac murmur	Cardiac murmur	1956 - Ongoing
Breast hyperplasia	Mammary hyperplasia, benign, bilateral	1965 - 2003
Varicose vein	Multiple varicose veins, bilateral	1980 - Ongoing
Aphthous ulcer	Intermittent aphthous stomatitis	2001 - Ongoing
Chest pain	Atypical chest pain	2001 - Ongoing
Hypertension	Hypertension	2003 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2004 - Ongoing
Postmenopause	Postmenopausal	2005 - Ongoing
Stress urinary incontinence	Stress urinary incontinence	2005 - 2008
Atrophic vulvovaginitis	Atrophic vaginitis	2010 - Ongoing
Gastroesophageal reflux disease	Acid reflux	2010 - Ongoing
Anxiety	Anxiety	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hyaluronic acid	1996 - Ongoing	Cosmetic- Upper Lip
Triamcinolone acetonide	2001 - Ongoing	Intermittent Aphthous Stomatitis
Calcium; vitamin d nos	2010 - Ongoing	Nutritional Supplement
Estradiol	2010 - 21 Jan 2021 (Study Day 157)	Atrophic Vaginitis
Famotidine	2010 - Ongoing	Acid Reflux

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide	2010 - 16 Feb 2021 (Study Day 183)	Hypertension
Vitamins nos	2010 - Ongoing	Nutritional Supplement
Alprazolam	2015 - Ongoing	Anxiety
Paracetamol	2015 - Ongoing	Chronic Right Knee Pain
Atorvastatin	2019 - 15 Feb 2021 (Study Day 182)	Hyperlipidemia
Hyaluronic acid	2019 - Ongoing	Nutritional Supplement
Vitamin b12 nos	2019 - Ongoing	Nutritional Supplement
Influenza vaccine	16 Oct 2020 (Study Day 60) - 16 Oct 2020 (Study Day 60)	Influenza Prevention
Varicella zoster vaccine rge (cho)	16 Oct 2020 (Study Day 60) - 16 Oct 2020 (Study Day 60)	Shingles Prevention
Paracetamol	17 Oct 2020 (Study Day 61) - 19 Oct 2020 (Study Day 63)	Reaction To Shingrix Vaccine
Paracetamol	18 Oct 2020 (Study Day 62) - 20 Oct 2020 (Study Day 64)	Reaction To Shingrix Vaccine
Right knee xray*	05 Jan 2021 (Study Day 141) - 05 Jan 2021 (Study Day 141)	Medical History
Varicella zoster vaccine rge (cho)	05 Jan 2021 (Study Day 141) - 05 Jan 2021 (Study Day 141)	Prevent Shingles
Right breast biopsy*	21 Jan 2021 (Study Day 157) - 21 Jan 2021 (Study Day 157)	Diagnostic
Estradiol	08 Feb 2021 (Study Day 175) - Ongoing	Atrophic Vaginitis
Acetylsalicylic acid	16 Feb 2021 (Study Day 183) - 16 Feb 2021 (Study Day 183)	Cardiac Prophylaxis
Atorvastatin	16 Feb 2021 (Study Day 183) - 17 Feb 2021 (Study Day 184)	Hyperlipidemia
Chest xray*	16 Feb 2021 (Study Day 183) - 16 Feb 2021 (Study Day 183)	Diagnostic
Electrocardiogram*	16 Feb 2021 (Study Day 183) - 16 Feb 2021 (Study Day 183)	Diagnostic
Heparin	16 Feb 2021 (Study Day 183) - 17 Feb 2021 (Study Day 184)	Prevent Thrombotic Event
Lisinopril	16 Feb 2021 (Study Day 183) - Ongoing	Worsening Of Hypertension
Metoprolol tartrate	16 Feb 2021 (Study Day 183) - 19 Mar 2021 (Study Day 214)	Worsening Of Hypertension
Paracetamol	16 Feb 2021 (Study Day 183) - 16 Feb 2021 (Study Day 183)	Unknown
Potassium chloride	16 Feb 2021 (Study Day 183) - 16 Feb 2021 (Study Day 183)	Hypokalemia
Acetylsalicylic acid	17 Feb 2021 (Study Day 184) - Ongoing	Cardiac Protection
Cardiac stress test with nuclear imaging*	17 Feb 2021 (Study Day 184) - 17 Feb 2021 (Study Day 184)	Diagnostic
Myocardial perfusion scan*	17 Feb 2021 (Study Day 184) - 17 Feb 2021 (Study Day 184)	Diagnostic
Regadenoson	17 Feb 2021 (Study Day 184) - 17 Feb 2021 (Study Day 184)	Worsening Of Atypical Chest Pain
Technetium (99m tc) sestamibi	17 Feb 2021 (Study Day 184) - 17 Feb 2021 (Study Day 184)	Worsening Of Atypical Chest Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Thallium	17 Feb 2021 (Study Day 184) - 17 Feb 2021 (Study Day 184)	Worsening Of Atypical Chest Pain
Transthoracic echocardiogram*	17 Feb 2021 (Study Day 184) - 17 Feb 2021 (Study Day 184)	Diagnostic
Atorvastatin	18 Feb 2021 (Study Day 185) - Ongoing	Hyperlipidemia
Metoprolol tartrate	20 Mar 2021 (Study Day 215) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypokalaemia	Grade 2/moderate	Not related	16 Feb 2021 (Study Day 183) - 17 Feb 2021 (Study Day 184)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US316-2238 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 15 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 13 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 12 Jan 2021 (Study Day 120)
Second Dose of Vaccine in Part B: 11 Feb 2021 (Study Day 150)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypoxia/Post-Operative Hypoxia	SAE	Grade 4	Not related	25 Feb 2021 (Study Day 164) – 26 Feb 2021 (Study Day 165)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US316-2238, a 47-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 15 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 13 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 12 Jan 2021 (Study Day 120). The second dose was administered in the left arm on 11 Feb 2021 (Study Day 150).

Event Details

On 25 Feb 2021 (Study Day 164), 163 days after the first dose in Part A/44 days after the first dose in Part B and 135 days after the second dose in Part A/14 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of hypoxia. Action taken with the IP was not applicable. The event of post-operative hypoxia lasted for 2 days, after which it was considered to be recovered/resolved on 26 Feb 2021 (Study Day 165). The investigator assessed the event of hypoxia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-041603	Hypoxia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Mild asthma	1974 - Ongoing
Seasonal allergy	Seasonal allergies	1975 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Uterine leiomyoma	Uterine fibroids	2012 - 2013
Hysterectomy	Partial hysterectomy	2013 - 2013
Restless legs syndrome	Restless leg syndrome	2018 - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	2018 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2018 - Ongoing
Obesity	Obesity	Jan 2020 - Ongoing
Tonsillitis	Recurrent tonsillitis	Feb 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2015 - Ongoing	Hypertension
Ramipril	2015 - Ongoing	Hypertension
Fluticasone propionate	2017 - Ongoing	Seasonal Allergies
Ipratropium bromide; salbutamol sulfate	2017 - Ongoing	Mild Asthma
Ropinirole	2018 - Ongoing	Restless Leg Syndrome
Ascorbic acid	Mar 2020 - Ongoing	Nutritional Supplement
Atorvastatin	Mar 2020 - Ongoing	Stroke Prevention
Calcium	Mar 2020 - Ongoing	Nutritional Supplement
Curcuma longa	Mar 2020 - Ongoing	Nutritional Supplement
Insulin aspart	Mar 2020 - 01 Dec 2020 (Study Day 78)	Type 2 Diabetes
Vitamin d nos	Mar 2020 - Ongoing	Nutritional Supplement
Dulaglutide	Jun 2020 - Ongoing	Type 2 Diabetes
Bilateral adenoidectomy*	25 Feb 2021 (Study Day 164) - 25 Feb 2021 (Study Day 164)	Adverse Event
Bilateral tonsillectomy*	25 Feb 2021 (Study Day 164) - 25 Feb 2021 (Study Day 164)	Adverse Event
Hydrocodone bitartrate; paracetamol	27 Feb 2021 (Study Day 166) - 01 Mar 2021 (Study Day 168)	Pain Due To Tonsillectomy And Adenoidectomy

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Procedural Pain	Grade 2/moderate	Not related	25 Feb 2021 (Study Day 164) - 01 Mar 2021 (Study Day 168)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US316-2290 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 19 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Nov 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Orchitis/Acute Left Epididymo-Orchitis	SAE	Grade 4	Not related	06 Mar 2021 (Study Day 139) – 09 Apr 2021 (Study Day 173)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US316-2290, a 42-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 19 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 16 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 24 Feb 2021. The participant was unblinded on 24 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 06 Mar 2021 (Study Day 139), 138 days after the first dose in Part A and 110 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of orchitis. Action taken with the IP was not applicable. The event of acute left epididymo-orchitis lasted for 35 days, after which it was considered to be recovered/resolved on 09 Apr 2021 (Study Day 173). The investigator assessed the event of orchitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-041580	Orchitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing
Hypertension	Hypertension	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	2015 - Ongoing	Seasonal Allergies
Dextromethorphan hydrobromide; guaifenesin	27 Oct 2020 (Study Day 9) - 28 Oct 2020 (Study Day 10)	Viral Infection, Unspecified
Paracetamol	27 Oct 2020 (Study Day 9) - 28 Oct 2020 (Study Day 10)	Viral Infection, Unspecified
Arginine	12 Nov 2020 (Study Day 25) - Ongoing	Hypertension
Paracetamol	07 Feb 2021 (Study Day 112) - 09 Feb 2021 (Study Day 114)	Viral Infection, Unspecified
Ct of abdomen and pelvis without contrast*	10 Mar 2021 (Study Day 143) - 10 Mar 2021 (Study Day 143)	Adverse Event
Ecg*	10 Mar 2021 (Study Day 143) - 10 Mar 2021 (Study Day 143)	Adverse Event
Levofloxacin	10 Mar 2021 (Study Day 143) - 11 Mar 2021 (Study Day 144)	Acute Left Epididymo-Orchitis
Morphine sulfate	10 Mar 2021 (Study Day 143) - 10 Mar 2021 (Study Day 143)	Acute Left Epididymo-Orchitis
Oxycodone; paracetamol	10 Mar 2021 (Study Day 143) - 10 Mar 2021 (Study Day 143)	Acute Left Epididymo-Orchitis
Sodium chloride	10 Mar 2021 (Study Day 143) - 11 Mar 2021 (Study Day 144)	Sinus Tachycardia
Testicular ultrasound*	10 Mar 2021 (Study Day 143) - 10 Mar 2021 (Study Day 143)	Adverse Event
Ibuprofen	11 Mar 2021 (Study Day 144) - 11 Mar 2021 (Study Day 144)	Acute Left Epididymo-Orchitis
Ibuprofen	11 Mar 2021 (Study Day 144) - 07 Apr 2021 (Study Day 171)	Acute Left Epididymo-Orchitis
Paracetamol	11 Mar 2021 (Study Day 144) - 11 Mar 2021 (Study Day 144)	Acute Left Epididymo-Orchitis
Paracetamol	11 Mar 2021 (Study Day 144) - 07 Apr 2021 (Study Day 171)	Acute Left Epididymo-Orchitis
Levofloxacin	12 Mar 2021 (Study Day 145) - 20 Mar 2021 (Study Day 153)	Acute Left Epididymo-Orchitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hydrocele	Grade 1/mild	Not related	10 Mar 2021 (Study Day 143) - Ongoing
Proctitis	Grade 1/mild	Not related	10 Mar 2021 (Study Day 143) - Ongoing
Sinus Tachycardia	Grade 2/moderate	Not related	10 Mar 2021 (Study Day 143) - 11 Mar 2021 (Study Day 144)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US317-2028 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 11 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 12 Mar 2021 (Study Day 214)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arrhythmia/Cardiac Arrhythmia	SAE	Grade 3/ severe	Not related	05 Apr 2021 (Study Day 238) – 06 Apr 2021 (Study Day 239)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The MedDRA Preferred Term/ Verbatim Term of Arrhythmia/Cardiac Arrhythmia was updated to Atrial fibrillation/ Atrial Fibrillation Paroxysmal after the database lock.

Participant US317-2028, a 54-year-old Hispanic or Latino male, received the first dose of Placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 28 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 12 Mar 2021 (Study Day 214). The second dose was not administered.

Event Details

On 05 Apr 2021 (Study Day 238), 237 days after the first dose in Part A/24 days after the first dose in Part B and 209 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of arrhythmia. The IP dose was not changed due to the cardiac arrhythmia. The event of cardiac arrhythmia lasted for 2 days, after which it was considered to be recovered/resolved on 06 Apr 2021 (Study Day 239). The investigator assessed the event of arrhythmia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-074251	Atrial fibrillation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Caffeine consumption	Caffeine consumption	1974 - Ongoing
Alcohol use	Alcohol consumption	1982 - Ongoing
Ex-tobacco user	Past tobacco user	1982 - 2019
Hypertension	Hypertension	2010 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2010 - Ongoing
Presbyopia	Presbyopia	2015 - Ongoing
Drug abuse	Cocaine abuse	2018 - Ongoing
Dyslipidaemia	Dyslipidemia	2018 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2018 - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	2018 - Ongoing
Vitamin B1 deficiency	Thiamine deficiency	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Losartan	2010 - 10 Dec 2020 (Study Day 122)	Hypertension
Metformin	2010 - Ongoing	Diabetes Type 2
Amlodipine	2015 - Ongoing	Hypertension
Radiology chest single view xr*	05 Dec 2020 (Study Day 117) - 05 Dec 2020 (Study Day 117)	Adverse Event
Cardiac cath procedure*	08 Dec 2020 (Study Day 120) - 08 Dec 2020 (Study Day 120)	Adverse Event
Ekg-stress*	08 Dec 2020 (Study Day 120) - 08 Dec 2020 (Study Day 120)	Adverse Event
Magnesium sulfate	08 Dec 2020 (Study Day 120) - 08 Dec 2020 (Study Day 120)	Hypomagnesemia
Glyceryl trinitrate	09 Dec 2020 (Study Day 121) - 09 Dec 2020 (Study Day 121)	Ct Scan Test
Iodine	09 Dec 2020 (Study Day 121) - 09 Dec 2020 (Study Day 121)	Computed Tomography
Radiology: coronary cta w ca score \t\ func*	09 Dec 2020 (Study Day 121) - 09 Dec 2020 (Study Day 121)	Adverse Event
Apixaban	10 Dec 2020 (Study Day 122) - Ongoing	Prophylaxis Atrial Fibrillation
Atorvastatin	10 Dec 2020 (Study Day 122) - Ongoing	Cardiovascular Disease Precaution

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Carvedilol	10 Dec 2020 (Study Day 122) - Ongoing	Cardiac Heart Failure
Clopidogrel	10 Dec 2020 (Study Day 122) - Ongoing	Coronary Artery Disease
Diltiazem	10 Dec 2020 (Study Day 122) - Ongoing	Atrial Fibrillation
Empagliflozin	10 Dec 2020 (Study Day 122) - Ongoing	Worsening Diabetes Type II
Folic acid	10 Dec 2020 (Study Day 122) - 05 Apr 2021 (Study Day 238)	Nutritional Supplement
Glimepiride	10 Dec 2020 (Study Day 122) - Ongoing	Diabetes Type 2
Losartan	10 Dec 2020 (Study Day 122) - Ongoing	Worsening Hypertension
Myocardial spect mult w ef wm*	10 Dec 2020 (Study Day 122) - 10 Dec 2020 (Study Day 122)	Adverse Event
Regadenoson	10 Dec 2020 (Study Day 122) - 10 Dec 2020 (Study Day 122)	Nuclear Myocardia Sect
Simvastatin	10 Dec 2020 (Study Day 122) - Ongoing	Hypercholesterol
Spironolactone	10 Dec 2020 (Study Day 122) - 06 Apr 2021 (Study Day 239)	Worsening Hypertension
Thiamine	10 Dec 2020 (Study Day 122) - Ongoing	Thiamine Deficiency

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US317-2040 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 11 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Gout/Acute Exacerbation Of Gout	SAE	Grade 2/moderate	Not related	21 Feb 2021 (Study Day 195) – 22 Feb 2021 (Study Day 196)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2040, a 77-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 25 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 21 Feb 2021 (Study Day 195), 194 days after the first dose in Part A and 166 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of gout. Action taken with the IP was not applicable. The event of acute exacerbation of gout lasted for 2 days, after which it was considered to be recovered/resolved on 22 Feb 2021 (Study Day 196). The investigator assessed the event of gout to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-043481	Gout

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Coronary artery disease	Coronary artery disease	1988 - Ongoing
Hypertension	Hypertension	1988 - Ongoing
Stent placement	Previous catheterization of a stent placement	1988 - 1988
Anxiety	Anxiety	2003 - Ongoing
Depression	Depression	2003 - Ongoing
Contusion	Bruising right arm	2008 - Ongoing
Gout	Gout big toe right	2009 - Ongoing
Blindness unilateral	Left eye blindness	2010 - Ongoing
Presbyopia	Presbyopia	2010 - Ongoing
Retinal detachment	Left eye retinal detachment	2010 - 2010
Skin laceration	Skin tear left elbow	08 Aug 2020 (Study Day -3) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram	2003 - Ongoing	Anxiety
Lisinopril	2005 - Ongoing	Hypertension
Colchicine	2010 - Ongoing	Gout
Ibuprofen	2010 - Ongoing	Pain From Gout Excess

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US317-2119 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 14 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 22 Jan 2021 (Study Day 162)
Second Dose of Vaccine in Part B: 02 Mar 2021 (Study Day 201)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Rib Fracture/Left Side Rib Cage Multiple Fracture	SAE	Grade 2/ moderate	Not related	09 Feb 2021 (Study Day 180) – Ongoing	Not recovered/not resolved
Pleural Effusion/Left Pleural Effusion Secondary To Left Rib Fracture	SAE	Grade 2/ moderate	Not related	19 Feb 2021 (Study Day 190) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2119, a 66-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 22 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 22 Jan 2021 (Study Day 162). The second dose was administered in the left arm on 02 Mar 2021 (Study Day 201).

Event Details

On 09 Feb 2021 (Study Day 180), 179 days after the first dose in Part A/18 days after the first dose in Part B and 151 days after the second dose in Part A/21 days before the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of rib fracture. The IP dose was not changed due to the left side rib cage multiple fracture. The event of left side rib cage multiple fracture was considered to be ongoing. The investigator assessed the event of rib fracture to be not related to the IP.

On 19 Feb 2021 (Study Day 190), 189 days after the first dose in Part A/28 days after the first dose in Part B and 161 days after the second dose in Part A/11 days before the second dose in Part B of

the IP, the participant experienced a Grade 2/moderate serious adverse event of pleural effusion. The IP dose was not changed due to the left pleural effusion secondary to left rib fracture. The event of left pleural effusion secondary to left rib fracture was considered to be ongoing. The investigator assessed the event of pleural effusion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-029980	Rib fracture
MOD-2021-029980	Pleural effusion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Postmenopausal	2000 - Ongoing
Presbyopia	Presbyopia	2000 - Ongoing
Anxiety	Anxiety	2002 - Ongoing
Bipolar disorder	Bipolar disorder	2002 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease - copd	2002 - Ongoing
Deafness neurosensory	Bilateral sensorial hearing loss	2002 - Ongoing
Depression	Depression	2002 - Ongoing
Excessive cerumen production	Increased cerumen production	2002 - Ongoing
Osteoporosis	Osteoporosis	2002 - Ongoing
Otitis externa	Chronic diffuse otitis externa	2002 - Ongoing
Drug hypersensitivity	Heparin allergy	2007 - Ongoing
Drug hypersensitivity	Lovanox allergy	2007 - Ongoing
Fracture treatment	Left leg fracture pin placed surgery	2007 - 2007
Lower limb fracture	Left leg fracture	2007 - 2007
Constipation	Constipation	2015 - Ongoing
Headache	Headache	2018 - Ongoing
Hepatitis C	Hepatitis c	2018 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease - gerd	12 Jan 2020 (Study Day -215) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Alendronate sodium	2002 - Ongoing	Osteoporosis
Alprazolam	2002 - Ongoing	Anxiety
Brexpiprazole	2002 - Ongoing	Major Depression
Budesonide; formoterol fumarate	2002 - Ongoing	Chronic Obstructive Pulmonary Disease - Copd
Buspirone	2002 - Ongoing	Anxiety
Trazodone	2002 - Ongoing	Depression
Venlafaxine	2002 - Ongoing	Anti-Depressant
Calcium	2015 - Ongoing	Prophylaxis
Fibre, dietary	2015 - Ongoing	Constipation
Vitamins nos	2015 - Ongoing	Prophylaxis
Diclofenac	19 Feb 2019 (Study Day -542) - Ongoing	Left Side Rib Pain
Ketorolac	09 Feb 2021 (Study Day 180) - 11 Feb 2021 (Study Day 182)	Left Rib Pain
Diclofenac	12 Feb 2021 (Study Day 183) - 19 Feb 2021 (Study Day 190)	Left Rib Pain
Oxycodone	12 Feb 2021 (Study Day 183) - Ongoing	Left Rib Pain
Pantoprazole	12 Feb 2021 (Study Day 183) - 14 Feb 2021 (Study Day 185)	Gastroesophageal Reflux Disease - Gerd
Lidocaine	19 Feb 2021 (Study Day 190) - Ongoing	Left Side Rib Pain
Paracetamol	19 Feb 2021 (Study Day 190) - Ongoing	Left Side Rib Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Lymph Node Calcification	Grade 1/mild	Not related	09 Feb 2021 (Study Day 180) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US317-2211 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 19 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 22 Feb 2021 (Study Day 188)
Second Dose of Vaccine in Part B: 22 Mar 2021 (Study Day 216)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abdominal Pain/Acute Exacerbation Of Abdominal Pain	SAE	Grade 2/ moderate	Not related	08 Apr 2021 (Study Day 233) – Ongoing	Not recovered/not resolved
Muscle Spasms/ Worsening Back Muscle Spasm	SAE	Grade 2/ moderate	Not related	10 Apr 2021 (Study Day 235) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2211, a 53-year-old Hispanic or Latino male, received the first dose of Placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 09 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 22 Feb 2021 (Study Day 188). The second dose was administered in the left arm on 22 Mar 2021 (Study Day 216).

Event Details

On 08 Apr 2021 (Study Day 233), 232 days after the first dose in Part A/45 days after the first dose in Part B and 204 days after the second dose in Part A/17 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of abdominal pain. The IP dose was not changed due to the acute exacerbation of abdominal pain. The event of acute exacerbation of abdominal pain was considered to be ongoing. The investigator assessed the event of abdominal pain to be not related to the IP.

On 10 Apr 2021 (Study Day 235), 234 days after the first dose in Part A/47 days after the first dose in Part B and 206 days after the second dose in Part A/19 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of muscle spasms.

The IP dose was not changed due to the worsening back muscle spasm. The event of worsening back muscle spasm was considered to be ongoing. The investigator assessed the event of muscle spasms to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-074452	Abdominal pain
MOD-2021-074452	Back pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dyspepsia	Heartburn	1972 - Ongoing
Tonsillectomy	Tonsillectomy	1972 - 1972
Tonsillitis	Tonsillitis	1972 - 1972
Schizophrenia	Schizophrenia	1975 - Ongoing
Nephrolithiasis	Kidney stones	1983 - Ongoing
Thrombosis	Right leg blood clots	1998 - 2003
Lumbar hernia	Lumbar hernia	2005 - 2008
Overweight	Overweight	2005 - Ongoing
Intervertebral disc operation	Lumbar hernia surgery	2008 - 2008
Insomnia	Insomnia	2010 - Ongoing
Back pain	Chronic back pain	2018 - Ongoing
Diabetic neuropathy	Sensory diabetic neuropathy	2018 - Ongoing
Hypertension	Hypertension	2018 - Ongoing
Muscle spasms	Muscle spasm back	2018 - Ongoing
Muscle spasms	Muscle spasm legs	2018 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Arformoterol	1980 - Ongoing	Chronic Obstructive Pulmonary Disease
Budesonide	1980 - Ongoing	Chronic Obstructive Pulmonary Disease
Budesonide; formoterol fumarate	1980 - Ongoing	Chronic Obstructive Pulmonary Disease
Salbutamol	1980 - Ongoing	Chronic Obstructive Pulmonary Disease
Clonazepam	2000 - 10 Apr 2021 (Study Day 235)	Schizophrenia
Risperidone	2005 - 10 Apr 2021 (Study Day 235)	Schizophrenia
Amphetamine aspartate; amphetamine sulfate; dexamphetamine saccharate; dexamphetamine sulfate	2010 - Ongoing	Attention Deficit Hyperactive Disorder
Temazepam	2010 - Ongoing	Insomnia
Omeprazole	2016 - 2020	Heartburn
Clopidogrel	2018 - Ongoing	Cardiovascular Prophylaxis
Gabapentin	2018 - Ongoing	Diabetes Neuropathy
Glimepiride	2018 - Ongoing	Diabetes Type 2
Metformin hydrochloride; sitagliptin	2018 - Ongoing	Diabetes Mellitus Type 2
Metoprolol	2018 - Ongoing	Hypertension
Donepezil	2019 - Ongoing	Mild Memory Loss
Famotidine	2019 - Mar 2020	Heartburn
Amantadine	2020 - Ongoing	Antiviral Influenza Preventive
Pantoprazole	Apr 2020 - Ongoing	Heartburn
Acetylsalicylic acid; caffeine; paracetamol	25 Sep 2020 (Study Day 38) - 25 Sep 2020 (Study Day 38)	Headache (Secondary To Influenza B Infection)
Paracetamol	25 Sep 2020 (Study Day 38) - 28 Sep 2020 (Study Day 41)	Myalgia, Arthralgia, Headaches - (No Sar Or Maae)
Tramadol	28 Sep 2020 (Study Day 41) - 28 Sep 2020 (Study Day 41)	Arthralgia (Rib Cage)
Ascorbic acid	29 Sep 2020 (Study Day 42) - Ongoing	Fatigue
Methylprednisolone	29 Sep 2020 (Study Day 42) - 03 Oct 2020 (Study Day 46)	Influenza B
Oseltamivir	29 Sep 2020 (Study Day 42) - 03 Oct 2020 (Study Day 46)	Influenza B
Paracetamol	29 Sep 2020 (Study Day 42) - 03 Oct 2020 (Study Day 46)	Influenza B
Vitamin d nos	29 Sep 2020 (Study Day 42) - Ongoing	Fatigue
Ergocalciferol	12 Oct 2020 (Study Day 55) - Ongoing	Vitamin Deficiency

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US317-2250 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 20 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 18 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: 24 Feb 2021 (Study Day 189)
Second Dose of Vaccine in Part B: 24 Mar 2021 (Study Day 217)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Myocardial Infarction/Non St Myocardial Infarction (Nstmi)	SAE	Grade 3/ severe	Not related	26 Feb 2021 (Study Day 191) – 01 Mar 2021 (Study Day 194)	Recovered/resolved
Chest Pain/Chest Pain	SAE	Grade 3/ severe	Not related	26 Feb 2021 (Study Day 191) – 27 Feb 2021 (Study Day 192)	Recovered/resolved
Sciatica/Left Sciatic Exacerbation	SAE	Grade 3/ severe	Not related	26 Feb 2021 (Study Day 191) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2250, a 59-year-old Hispanic or Latino male, received the first dose of Placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 24 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 24 Feb 2021 (Study Day 189). The second dose was administered in the left arm on 24 Mar 2021 (Study Day 217).

Event Details

On 26 Feb 2021 (Study Day 191), 190 days after the first dose in Part A/2 days after the first dose in Part B and 161 days after the second dose in Part A/26 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of acute myocardial infarction. Action taken with the IP was not applicable. The event of non st myocardial infarction (nstmi) lasted for 4 days, after which it was considered to be recovered/resolved on 01 Mar 2021 (Study Day 194). The investigator assessed the event of acute myocardial infarction to be not related to the IP.

On 26 Feb 2021 (Study Day 191), 190 days after the first dose in Part A/2 days after the first dose in Part B and 161 days after the second dose in Part A/26 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of chest pain. Action taken with the IP was not applicable. The event of chest pain lasted for 2 days, after which it was considered to be recovered/resolved on 27 Feb 2021 (Study Day 192). The investigator assessed the event of chest pain to be not related to the IP.

On 26 Feb 2021 (Study Day 191), 190 days after the first dose in Part A/2 days after the first dose in Part B and 161 days after the second dose in Part A/26 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of sciatica. The IP dose was not changed due to the left sciatic exacerbation. The event of left sciatic exacerbation was considered to be ongoing. The investigator assessed the event of sciatica to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-056992	Acute myocardial infarction
MOD-2021-056992	Chest pain
MOD-2021-056992	Sciatica

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Ectrodactyly	Congenital ectrodactylia	(b) (6) 1961 (Study Day (b) (6) - Ongoing
Hypertension	Hypertension mild	1986 - Ongoing
Atrial fibrillation	Paroxysmal atrial fibrillation	2008 - Ongoing
Implantable defibrillator insertion	Post automated implantable cardioverter defibrillator congestive heart failure	2008 - Ongoing
Ischaemic cardiomyopathy	Ischemic cardiomyopathy	2008 - Ongoing
Implantable defibrillator insertion	Defibrillator	04 Dec 2008 (Study Day -4277) - 04 Dec 2016 (Study Day -1355)
Catheterisation cardiac	Cardiac catheter	2012 - 2012
Erectile dysfunction	Erectile dysfunction	2015 - 2015
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2015 - Ongoing
Obesity	Severe obesity	2015 - Ongoing
Sciatica	Left sciatica	2015 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Sciatica	Left side sciatica	2015 - 2015
Type 2 diabetes mellitus	Diabetes type ii	2015 - Ongoing
Catheterisation cardiac	Cardiac catheter	2016 - 2016
Cholecystectomy	Laparoscopic cholecystectomy	2016 - 2016
Cholelithiasis	Gallstones	2016 - 2016
Cardiac resynchronisation therapy	Biventricular dual chamber	04 Dec 2016 (Study Day -1355) - Ongoing
Hyperlipidaemia	Hyperlipidemia	2017 - Ongoing
Myocardial infarction	Heart attack	2017 - 2017
Penile prosthesis insertion	Penile implant	2017 - 2017
Sleep apnoea syndrome	Sleep apnea	2017 - Ongoing
Back pain	Back pain	2018 - Ongoing
Catheterisation cardiac	Cardiac catheter	2018 - 2018
Diabetic neuropathy	Sensorial diabetic peripheral neuropathy	2018 - Ongoing
Ischaemic stroke	Stroke vs. transient ischemic attacks	Apr 2020 - Apr 2020
Device related infection	Penile implant infection and removal of prosthesis	19 May 2020 (Study Day -93) - 30 Jun 2020 (Study Day -51)
Cerebrovascular accident	Cerebrovascular accident	04 Jul 2020 (Study Day -47) - 04 Jul 2020 (Study Day -47)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bumetanide	2008 - 12 Feb 2021 (Study Day 177)	Chronic Heart Failure Diuretic
Amiodarone	2015 - Ongoing	Paroxysmal Atrial Fibrillation
Apixaban	2015 - 12 Feb 2021 (Study Day 177)	Anticoagulant Atrial Fibrillation
Furosemide	2015 - Aug 2020	Hypertension
Lisinopril	2015 - 16 Sep 2020 (Study Day 28)	Hypertension
Metformin	2015 - Ongoing	Diabetes Type Ii
Pantoprazole	2015 - Ongoing	Gastroesophageal Reflux Disease
Atorvastatin	2016 - Ongoing	Hyperlipidemia
Baclofen	2018 - Ongoing	Left Sciatic Pain
Diclofenac	2018 - Ongoing	Left Sciatic Pain
Gabapentin	2018 - Ongoing	Chronic Lower Back Pain
Oxycodone	2018 - Ongoing	Left Sciatic Exacerbation
Paracetamol	2018 - Ongoing	Chronic Lower Back Pain
Carvedilol	Feb 2020 - 12 Feb 2021 (Study Day 177)	Hypertension
Potassium chloride	Feb 2020 - Mar 2021	Chronic Heart Failure
Sacubitril valsartan sodium hydrate	Jun 2020 - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ct angio pulmonary arteries*	12 Sep 2020 (Study Day 24) - 12 Sep 2020 (Study Day 24)	Adverse Event
Ekg*	12 Sep 2020 (Study Day 24) - 12 Sep 2020 (Study Day 24)	Adverse Event
Furosemide	12 Sep 2020 (Study Day 24) - 16 Sep 2020 (Study Day 28)	Diuretic
Sodium chloride	12 Sep 2020 (Study Day 24) - 14 Sep 2020 (Study Day 26)	Flush Iv Catheter
Sodium chloride	12 Sep 2020 (Study Day 24) - 16 Sep 2020 (Study Day 28)	Flush Iv Catheter
Tramadol	12 Sep 2020 (Study Day 24) - 19 Sep 2020 (Study Day 31)	Chronic Lower Back Pain
X-ray - ra ches*	12 Sep 2020 (Study Day 24) - 12 Sep 2020 (Study Day 24)	Adverse Event
Ct lumbar spine*	13 Sep 2020 (Study Day 25) - 13 Sep 2020 (Study Day 25)	Adverse Event
X-ray - ra chest*	13 Sep 2020 (Study Day 25) - 13 Sep 2020 (Study Day 25)	Adverse Event
Us guidance paracentesis*	15 Sep 2020 (Study Day 27) - 15 Sep 2020 (Study Day 27)	Adverse Event
Acetylsalicylic acid	13 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 178)	Cardiac Prophylaxis
Apixaban	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Atrial Fibrillation
Bumetanide	13 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 178)	Chronic Heart Failure Exacerbation
Bumetanide	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Chronic Heart Failure Exacerbation
Carvedilol	13 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 178)	Hypertension
Carvedilol	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Hypertension
Clopidogrel bisulfate	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Acute Coronary Syndrome
Enoxaparin sodium	13 Feb 2021 (Study Day 178) - Ongoing	Heart Attack Prophylaxis
Glucagon	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Diabetes Type Ii
Glucose	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Severe Hypoglycemia Prophylaxis
Glucose; heparin sodium	13 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 178)	Atrial Fibrillation
Glyceryl trinitrate	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Chest Pain
Insulin	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Diabetes Type Ii
Insulin glargine	13 Feb 2021 (Study Day 178) - Ongoing	Diabetes Type Ii
Insulin lispro	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Diabetes Type Ii
Morphine	13 Feb 2021 (Study Day 178) - Ongoing	Left Sciatic Pain
Potassium chloride	13 Feb 2021 (Study Day 178) - Ongoing	Hypopotassemia Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sodium chloride	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Flush Iv Catheter
Spironolactone	13 Feb 2021 (Study Day 178) - Ongoing	Chronic Heart Failure Exacerbation
Tramadol	13 Feb 2021 (Study Day 178) - Ongoing	Left Sciatic Pain
Acetylsalicylic acid	14 Feb 2021 (Study Day 179) - Ongoing	Cardiac Prophylaxis
Carvedilol	14 Feb 2021 (Study Day 179) - Ongoing	Hypertension
Acetylsalicylic acid	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Non St Myocardia Infarction
Atorvastatin	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Coronary Artery Disease
Clonidine	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Hypertension Emergency
Clopidogrel	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Non St Myocardial Infarction
Docusate	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Constipation Prophylaxis
Enoxaparin	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Deep Venous Thrombosis Prophylaxis (Dvt)
Glucagon	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Severe Hypoglycemia Prophylaxes
Glucose	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Severe Hypoglycemia Prophylaxis
Glyceryl trinitrate	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Chest Pain
Hydromorphone	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Chest Pain / Sciatica
Insulin	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Diabetes Mellitus
Ketorolac	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Sciatica
Lorazepam	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Anxiety
Ondansetron	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Emesis Prophylaxis
Paracetamol	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Left Sciatica
Rosuvastatin	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Coronary Artery Disease Dyslipidemia
Spironolactone	26 Feb 2021 (Study Day 191) - 25 Mar 2021 (Study Day 218)	Chronic Heart Failure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Asymptomatic COVID-19	Grade 1/mild	Not related	28 Feb 2021 (Study Day 193) - 11 Mar 2021 (Study Day 204)
Liver Function Test Increased	Grade 1/mild	Not related	01 Mar 2021 (Study Day 194) - Ongoing
Hepatomegaly	Grade 1/mild	Not related	05 Mar 2021 (Study Day 198) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US317-2374 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 16 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 13 Nov 2020 (Study Day 29)
First Dose of Vaccine in Part B: 26 Jan 2021 (Study Day 103)
Second Dose of Vaccine in Part B: 26 Feb 2021 (Study Day 134)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Decubitus Ulcer/Left Feet Second Toe Pressure Ulcer Stage Iii	SAE	Grade 3/ severe	Not related	19 Apr 2021 (Study Day 186) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2374, a 61-year-old Hispanic or Latino male, received the first dose of Placebo in the left arm on 16 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 13 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 26 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 26 Jan 2021 (Study Day 103). The second dose was administered in the left arm on 26 Feb 2021 (Study Day 134).

Event Details

On 19 Apr 2021 (Study Day 186), 185 days after the first dose in Part A/83 days after the first dose in Part B and 157 days after the second dose in Part A/52 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of decubitus ulcer. Action taken with the IP was not applicable. The event of left feet second toe pressure ulcer stage III was considered to be ongoing. The investigator assessed the event of decubitus ulcer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-093652	Decubitus ulcer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 1 diabetes mellitus	Diabetes type 1	1966 - Ongoing
Arthralgia	Chronic hip pain	1990 - Ongoing
Bipolar disorder	Bipolar disorder	1990 - Ongoing
Constipation	Constipation	1990 - Ongoing
Depression	Depression	1990 - Ongoing
Gastroesophageal reflux disease	Acid reflux	1990 - Ongoing
Insomnia	Insomnia	1990 - Ongoing
Anxiety	Anxiety	1999 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	1999 - Ongoing
Diabetic neuropathy	Diabetic polyneuropathy (sensorial bilateral lower extremities)	1999 - Ongoing
Hyperlipidaemia	Hyperlipidemia	1999 - Ongoing
Hypertension	Hypertension	1999 - Ongoing
Osteoporosis	Osteoporosis	1999 - Ongoing
Penile prosthesis insertion	Penile implant	2009 - 2009
Impaired gastric emptying	Gastroparesis	2010 - Ongoing
Cataract	Left eye cataracts (planning surgery next year)	2017 - Ongoing
Cataract operation	Cataract right eye surgery	2017 - 2017
Injury	Physical trauma	Apr 2020 - Apr 2020
Localised infection	Left foot infection	Apr 2020 - Apr 2020
Toe amputation	Left foot 3rd toe amputation due to physical trauma surgery	Apr 2020 - Apr 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	1990 - Ongoing	Acid Relux
Gabapentin	1999 - Ongoing	Diabetic Polynueropathy
Lisinopril	1999 - Ongoing	Hypertension
Simvastatin	1999 - Ongoing	Hyperlipidemia
Budesonide; formoterol fumarate	2000 - Ongoing	Chronic Obstructive Pulmonary Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxycodone	2000 - Ongoing	Chronic Hip Pain
Quetiapine fumarate	2000 - Ongoing	Bip[olar/ Depression/ Insomnia
Brexpiprazole	2015 - Ongoing	Anxiety
Insulin lispro	2016 - Ongoing	Diabetes Type 1
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	02 Feb 2021 (Study Day 110) - 04 Feb 2021 (Study Day 112)	Upper Respiratory Infection - Uri

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 1/mild	Not related	31 Jan 2021 (Study Day 108) - 08 Feb 2021 (Study Day 116)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US317-2406 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 19 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Nov 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Patella Fracture/Left Knee Patella Fracture	SAE	Grade 3/severe	Not related	31 Jan 2021 (Study Day 105) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2406, a 60-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 19 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 16 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 04 Mar 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 31 Jan 2021 (Study Day 105), 104 days after the first dose in Part A and 76 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of patella fracture. Action taken with the IP was not applicable. The event of left knee patella fracture was considered to be ongoing. The investigator assessed the event of patella fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014621	Patella fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hysterectomy	Partial hysterectomy	1998 - 1998
Menorrhagia	Heavy menstrual bleeding (related to uterine fibroids)	1998 - 1998
Uterine leiomyoma	Uterine fibroids	1998 - 1998
Foot fracture	Right second toe fracture	2000 - 2000
Fracture treatment	Right 2nd toe fracture surgery	2000 - 2000
Hypertension	Hypertension	2000 - Ongoing
Obesity	Obese	2000 - Ongoing
Presbyopia	Presbyopia	2000 - Ongoing
Chronic gastritis	Chronic gastritis	2010 - Ongoing
Drug hypersensitivity	Aspirin allergy (hypotension) (no anaphalaxis)	2010 - Ongoing
Osteoarthritis	Generalized osteoarthritis	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Aliskiren fumarate	2004 - Ongoing	Hypertension
Metoprolol	2004 - Ongoing	Hypertension
Vitamin d nos	2018 - Ongoing	Nutritional Supplement
Paracetamol	19 Oct 2020 (Study Day 1) - Ongoing	Left Arm Pain At Injection Site (Solicited Adverse Reaction) (Not An A/E)
Paracetamol	17 Nov 2020 (Study Day 30) - 18 Nov 2020 (Study Day 31)	Headache, Chills, Body Ache, Myalgia, Arthralgia, Injection Site Pain (Solicited Adverse Reaction) (Not An A/E)
Paracetamol	31 Jan 2021 (Study Day 105) - 08 Feb 2021 (Study Day 113)	Left Knee Pain Secondary To Fracture - Sae
Codeine phosphate; paracetamol	09 Feb 2021 (Study Day 114) - Ongoing	Left Knee Fracture - Sae

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US317-2469 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 21 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 18 Nov 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pain In Extremity/Left Thigh Pain Worsening	SAE	Grade 3/ severe	Not related	22 Mar 2021 (Study Day 153) – 12 Apr 2021 (Study Day 174)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2469, a 59-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 21 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 18 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 05 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 22 Mar 2021 (Study Day 153), 152 days after the first dose in Part A and 124 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of pain in extremity. Action taken with the IP was not applicable. The event of left thigh pain worsening lasted for 22 days, after which it was considered to be recovered/resolved on 12 Apr 2021 (Study Day 174). The investigator assessed the event of pain in extremity to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-075737	Pain in extremity

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Mild asthma	1966 - Ongoing
Appendectomy	Appendectomy	1982 - 1982
Appendicitis	Acute appendicitis	1982 - 1982
Presbyopia	Bilateral presbyopia	2013 - Ongoing
Deafness bilateral	Hearing loss mild bilateral	2015 - Ongoing
Pain in extremity	Left thigh pain (secondary to fall)	03 Sep 2020 (Study Day -48) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1999 - Ongoing	Mild Asthma
Ibuprofen	14 Nov 2020 (Study Day 25) - Ongoing	Left Thigh Pain
Bicalutamide	18 Dec 2020 (Study Day 59) - Ongoing	Prostate Cancer
Gabapentin	18 Dec 2020 (Study Day 59) - Ongoing	Bilateral Left Extremities Numbness
Oxycodone hydrochloride	18 Dec 2020 (Study Day 59) - Ongoing	Left Thigh Pain
Diclofenac	21 Jan 2021 (Study Day 93) - Ongoing	Knee Pain
Leuporelin acetate	22 Jan 2021 (Study Day 94) - Ongoing	Prostate Cancer

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US318-2065 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 29 Jul 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Aug 2020 (Study Day 31)
First Dose of Vaccine in Part B: 14 Jan 2021 (Study Day 170)
Second Dose of Vaccine in Part B: 24 Feb 2021 (Study Day 211)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pancreatic Carcinoma Stage IV/Stage 4 Pancreatic Cancer.	SAE	Grade 3/ severe	Not related	11 Feb 2021 (Study Day 198) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US318-2065, a 60-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 29 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 28 Aug 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 14 Jan 2021 (Study Day 170). The second dose was administered in the left arm on 24 Feb 2021 (Study Day 211).

Event Details

On 11 Feb 2021 (Study Day 198), 197 days after the first dose in Part A/28 days after the first dose in Part B and 167 days after the second dose in Part A/13 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of pancreatic carcinoma stage iv. The IP dose was not changed due to the stage 4 pancreatic cancer. The event of stage 4 pancreatic cancer. was considered to be ongoing. The investigator assessed the event of pancreatic carcinoma stage IV to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014637	Pancreatic carcinoma stage IV

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1966 - 1966
Tonsillitis	Tonsillitis	1966 - 1966
Myopia	Bilateral myopia	1973 - Ongoing
Seasonal allergy	Seasonal allergies	1974 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Botulinum toxin type a	2015 - Jun 2020	Cosmetic Facial Filler
Durapatite	2015 - Jun 2020	Cosmetic Facial Filler
Hyaluronic acid	2015 - Jun 2020	Cosmetic Facial Filler
Vitamin d nos	Jan 2020 - Ongoing	Health Maintenance
Ibuprofen	30 Aug 2020 (Study Day 33) - 30 Aug 2020 (Study Day 33)	Headache
All other therapeutic products	17 Mar 2021 (Study Day 232) - Ongoing	Pancreatic Cancer

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US318-2114 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 31 Jul 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 31 Aug 2020 (Study Day 32)
First Dose of Vaccine in Part B: 27 Jan 2021 (Study Day 181)
Second Dose of Vaccine in Part B: 23 Feb 2021 (Study Day 208)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abdominal Pain/Abdominal Pain	SAE	Grade 4	Not related	05 Apr 2021 (Study Day 249) – Ongoing	Unknown

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US318-2114, a 53-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 31 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 31 Aug 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 27 Jan 2021. The participant was unblinded on 27 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 27 Jan 2021 (Study Day 181). The second dose was administered in the left arm on 23 Feb 2021 (Study Day 208).

Event Details

On 05 Apr 2021 (Study Day 249), 248 days after the first dose in Part A/68 days after the first dose in Part B and 217 days after the second dose in Part A/41 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of abdominal pain. Action taken with the IP was not applicable. The outcome of the event was unknown. The investigator assessed the event of abdominal pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-071903	Shigella sepsis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Sinus operation	Sinus surgery	1995 - 1995
Sinusitis	Frequent sinus infections	1995 - 1995
Malignant melanoma	Left thigh melanoma	2000 - 2000
Anxiety	Anxiety	2015 - Ongoing
Blood cholesterol increased	High cholesterol	2015 - Ongoing
Depression	Depression	2015 - Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing
Hypertension	Hypertension	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Alprazolam	2015 - Ongoing	Anxiety
Pravastatin	2015 - Ongoing	High Cholesterol
Temazepam	2015 - Ongoing	Depression
Emtricitabine; tenofovir disoproxil fumarate	2018 - Ongoing	Hiv Prep
Lisinopril	2019 - Ongoing	Hypertension
Vilazodone hydrochloride	2019 - Ongoing	Depression
Ibuprofen	02 Aug 2020 (Study Day 3) - 03 Aug 2020 (Study Day 4)	Headache
Influenza vaccine	15 Oct 2020 (Study Day 77) - 15 Oct 2020 (Study Day 77)	Health Maintenance
Ibuprofen	16 Nov 2020 (Study Day 109) - 24 Nov 2020 (Study Day 117)	Headache
Pseudoephedrine hydrochloride	16 Nov 2020 (Study Day 109) - 26 Nov 2020 (Study Day 119)	Sinus Congestion

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Muscle Injury	Grade 2/moderate	Not related	16 Mar 2021 (Study Day 229) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US319-2575 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 29 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 26 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 21 Jan 2021 (Study Day 146)
Second Dose of Vaccine in Part B: 24 Feb 2021 (Study Day 180)
Reason for Narrative: AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chills/Chills	AE leading to withdrawal from study vaccine	Grade 1/ mild	Related	24 Feb 2021 (Study Day 180) – 26 Feb 2021 (Study Day 182)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US319-2575, a 30-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 29 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 26 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Jan 2021. The participant was unblinded on 21 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 21 Jan 2021 (Study Day 146). The second dose was administered in the left arm on 24 Feb 2021 (Study Day 180).

Event Details

On 24 Feb 2021 (Study Day 180), 179 days after the first dose in Part A/34 days after the first dose in Part B and 151 days after the second dose in Part A/on the day of the second dose in Part B of the IP, the participant experienced a Grade 1/mild non-serious adverse event of chills. The IP dose was withdrawn due to the chills. The event of chills lasted for 3 days, after which it was considered to be recovered/resolved on 26 Feb 2021 (Study Day 182). The investigator assessed the event of chills to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tension headache	Tension headaches	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Magnesium oxide	2015 - Ongoing	Tension Headaches
Ethinylestradiol; norethisterone acetate	Jun 2020 - Ongoing	Birth Control
Ibuprofen	27 Sep 2020 (Study Day 30) - 27 Sep 2020 (Study Day 30)	Soreness At The Injection Site
Influenza vaccine	06 Oct 2020 (Study Day 39) - 06 Oct 2020 (Study Day 39)	Flu Prevention
Ibuprofen	22 Jan 2021 (Study Day 147) - 22 Jan 2021 (Study Day 147)	Tenderness At Injection Site
Paracetamol	24 Feb 2021 (Study Day 180) - 24 Feb 2021 (Study Day 180)	Chills, Body Aches And Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 1/mild	Related	21 Jan 2021 (Study Day 146) - 21 Jan 2021 (Study Day 146)
Injection Site Pain	Grade 1/mild	Related	22 Jan 2021 (Study Day 147) - 23 Jan 2021 (Study Day 148)
Chills	Grade 1/mild	Related	24 Feb 2021 (Study Day 180) - 26 Feb 2021 (Study Day 182)
Headache	Grade 1/mild	Related	24 Feb 2021 (Study Day 180) - 26 Feb 2021 (Study Day 182)
Pain	Grade 1/mild	Related	24 Feb 2021 (Study Day 180) - 26 Feb 2021 (Study Day 182)
Injection Site Rash	Grade 1/mild	Related	25 Feb 2021 (Study Day 181) - 28 Feb 2021 (Study Day 184)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US320-2025 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 06 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Back Pain/Worsening Of Back Pain	SAE	Grade 2/ moderate	Not related	28 Apr 2021 (Study Day 266) – Ongoing	Unknown

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The MedDRA Preferred Term/ Verbatim Term of Back Pain/Worsening Of Back Pain was updated to Spinal Synovial Cyst/Worsening of Back Pain (L2-3 Spinal Stenosis) and Lumbar Spinal Stenosis/ Lumbar Facet Cyst after the database lock.

Participant US320-2025, a 71-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 22 Jan 2021. The participant was unblinded on 22 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 28 Apr 2021 (Study Day 266), 265 days after the first dose in Part A and 237 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of back pain. Action taken with the IP was not applicable. The outcome of the event was unknown. The investigator assessed the event of back pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-097072	Spinal synovial cyst
MOD-2021-097072	Lumbar spinal stenosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vasectomy	Vasectomy	1972 - 1972
Seasonal allergy	Seasonal allergies	2005 - Ongoing
Coronary arterial stent insertion	Cardiac stent placed	2008 - 2008
Coronary artery disease	Coronary artery disease	2008 - Ongoing
Back pain	Chronic back pain	2010 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2011 - Ongoing
Hypertension	Hypertension	2011 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2011 - Ongoing
Anxiety	Anxiety	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Clopidogrel	2008 - Ongoing	Coronary Artery Disease
Atorvastatin	2011 - Ongoing	Hyperlipidemia
Hydrochlorothiazide; lisinopril	2011 - Ongoing	Hypertension
Metformin	2011 - Ongoing	Type 2 Diabetes
Gabapentin	2014 - Ongoing	Chronic Back Pain
Hydrocodone; paracetamol	2014 - Ongoing	Chronic Back Pain
Sitagliptin	2014 - Ongoing	Type 2 Diabetes
Sertraline	2015 - Ongoing	Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US320-2042 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 06 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 36)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Jugular Vein Thrombosis/Deep Vein Thrombosis Left Internal Jugular - Partially Occlusive	SAE	Grade 3/ severe	Not related	06 Jan 2021 (Study Day 154) – 11 Jan 2021 (Study Day 159)	Recovered/ resolved
Subclavian Vein Thrombosis/ Dvt- Occlusive Left Subclavian Vein	SAE	Grade 3/ severe	Not related	06 Jan 2021 (Study Day 154) – 11 Jan 2021 (Study Day 159)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2042, a 49-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Jan 2021. The participant was unblinded on 04 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 06 Jan 2021 (Study Day 154), 153 days after the first dose in Part A and 118 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of jugular vein thrombosis. Action taken with the IP was not applicable. The event of deep vein thrombosis left internal jugular - partially occlusive lasted for 6 days, after which it was considered to be recovered/resolved on 11 Jan 2021 (Study Day 159). The investigator assessed the event of jugular vein thrombosis to be not related to the IP.

On 06 Jan 2021 (Study Day 154), 153 days after the first dose in Part A and 118 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of subclavian vein thrombosis. Action taken with the IP was not applicable. The event of dvt-occlusive left subclavian vein lasted for 6 days, after which it was considered to be

recovered/resolved on 11 Jan 2021 (Study Day 159). The investigator assessed the event of subclavian vein thrombosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002924	Jugular vein thrombosis
MOD-2021-002924	Subclavian vein thrombosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy to nsoids	Not reported - Ongoing
Back pain	Back pain	2006 - Ongoing
Hysterectomy	Hysterectomy	2011 - 2011
Nephrolithiasis	Kidney stones	2011 - 2011
Insomnia	Insomnia	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Trazodone	2017 - Ongoing	Insomnia
Topiramate	2019 - Ongoing	Back Pain
Bilateral brachioplasty*	05 Jan 2021 (Study Day 153) - 05 Jan 2021 (Study Day 153)	Other, Cosmetic
Bilateral thigh lift*	05 Jan 2021 (Study Day 153) - 05 Jan 2021 (Study Day 153)	Other, Cosmetic
Heparin	07 Jan 2021 (Study Day 155) - 09 Jan 2021 (Study Day 157)	Deep Vein Thrombosis Left Internal Jugular And Subclavian Veins
Heparin porcine	07 Jan 2021 (Study Day 155) - 08 Jan 2021 (Study Day 156)	Deep Vein Thrombosis Left Internal Jugular And Subclavian Veins
Rivaroxaban	07 Jan 2021 (Study Day 155) - 14 Feb 2021 (Study Day 193)	Deep Vein Thrombosis Left Internal Jugular And Subclavian Veins
Anesthetics, general	12 Jan 2021 (Study Day 160) - 12 Jan 2021 (Study Day 160)	Right Groin Hematoma

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Incision and drainage of right groin hematoma*	12 Jan 2021 (Study Day 160) - 12 Jan 2021 (Study Day 160)	Adverse Event
Morphine	12 Jan 2021 (Study Day 160) - 12 Jan 2021 (Study Day 160)	Right Leg Hematoma
Ondansetron	12 Jan 2021 (Study Day 160) - 12 Jan 2021 (Study Day 160)	Right Leg Hematoma
Sodium chloride	12 Jan 2021 (Study Day 160) - 12 Jan 2021 (Study Day 160)	Right Groin Hematoma
Fentanyl	19 Jan 2021 (Study Day 167) - 19 Jan 2021 (Study Day 167)	Right Leg Painful Swelling
Ondansetron	19 Jan 2021 (Study Day 167) - 19 Jan 2021 (Study Day 167)	Painful Leg Swelling
Tramadol	19 Jan 2021 (Study Day 167) - 22 Jan 2021 (Study Day 170)	Right Leg Painful Swelling
Rivaroxaban	15 Feb 2021 (Study Day 194) - Ongoing	Phlebitis In Both Legs

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Haematoma	Grade 3/severe	Not related	12 Jan 2021 (Study Day 160) - 12 Jan 2021 (Study Day 160)
Peripheral Swelling	Grade 2/moderate	Not related	19 Jan 2021 (Study Day 167) - 22 Jan 2021 (Study Day 170)
Phlebitis	Grade 1/mild	Not related	15 Feb 2021 (Study Day 194) - 16 Mar 2021 (Study Day 223)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US320-2070 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 08 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Sep 2020 (Study Day 38)
First Dose of Vaccine in Part B: 14 Jan 2021 (Study Day 160)
Second Dose of Vaccine in Part B: 11 Feb 2021 (Study Day 188)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cervical Dysplasia/Recurrent Cervical Dysplasia (With High Risk Hpv)	SAE	Grade 2/ moderate	Not related	19 Feb 2021 (Study Day 196) – 20 Feb 2021 (Study Day 197)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2070, a 48-year-old not Hispanic or Latino female, received the first dose of Placebo in the right arm on 08 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 14 Sep 2020 (Study Day 38). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 14 Jan 2021 (Study Day 160). The second dose was administered in the right arm on 11 Feb 2021 (Study Day 188).

Event Details

On 19 Feb 2021 (Study Day 196), 195 days after the first dose in Part A/36 days after the first dose in Part B and 158 days after the second dose in Part A/8 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of cervical dysplasia. Action taken with the IP was not applicable. The event of recurrent cervical dysplasia (with high risk hpv) lasted for 2 days, after which it was considered to be recovered/resolved on 20 Feb 2021 (Study Day 197). The investigator assessed the event of cervical dysplasia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-045404	Cervical dysplasia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Caesarean section	Cesarean section	2001 - 2001
Female sterilisation	Bilateral tubal ligation	03 Jan 2003 (Study Day -6427) - 03 Jan 2003 (Study Day -6427)
Hypothyroidism	Hypothyroidism	01 Jun 2003 (Study Day -6278) - Ongoing
Multiple sclerosis	Multiple sclerosis	01 Dec 2006 (Study Day -4999) - Ongoing
Endometrial ablation	Uterine ablation- irregular periods	2016 - 2016
Hot flush	Hot flashes	2019 - Ongoing
Obesity	Obesity (bmi- 33.5)	2019 - Ongoing
Smear cervix abnormal	Cold knife cone- abnormal pap smear	2019 - 2019
Anxiety	Anxiety	01 Jan 2019 (Study Day -585) - Ongoing
Depression	Depression	01 Jan 2019 (Study Day -585) - Ongoing
Insulin resistance	Insulin resistance	01 Jun 2019 (Study Day -434) - Ongoing
Seasonal allergy	Seasonal allergies	01 Jan 2020 (Study Day -220) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Thyroid	01 Jun 2003 (Study Day -6278) - Ongoing	Hypothyroid
Colecalciferol	01 Jan 2007 (Study Day -4968) - Ongoing	Multiple Sclerosis
Fish oil	01 Jan 2007 (Study Day -4968) - Ongoing	Multiple Sclerosis
Botulinum toxin type a	2010 - Ongoing	Cosmetic
Hyaluronic acid	2010 - Ongoing	Cosmetic
Ubidecarenone	2010 - Ongoing	Multiple Scrosis
Calcium citrate; vitamin d nos	2015 - Ongoing	Supplement
Lactobacillus nos	2015 - Ongoing	Pobiotic Gut Health
Zeaxanthin	2017 - Ongoing	Eye Prophlaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Phentermine	2019 - Ongoing	Obesity
Progesterone	01 Jan 2019 (Study Day -585) - Ongoing	Hot Flashes
Sertraline	01 Jan 2019 (Study Day -585) - Ongoing	Anxiety/Depression
Teriflunomide	01 Jan 2019 (Study Day -585) - Ongoing	Multiple Sclerosis
Dulaglutide	01 Jun 2019 (Study Day -434) - Ongoing	Insulin Resistance
Empagliflozin; metformin hydrochloride	01 Jun 2019 (Study Day -434) - Ongoing	Insulin Resistance
Fexofenadine	2020 - Ongoing	Seasonal Allergies
Donepezil hydrochloride	01 Jan 2020 (Study Day -220) - Ongoing	Multiple Sclerosis
Estradiol	Sep 2020 - Ongoing	Hot Flashes
Influenza vaccine	29 Sep 2020 (Study Day 53) - 29 Sep 2020 (Study Day 53)	Flu Prevention
Anesthetics, general	19 Feb 2021 (Study Day 196) - 19 Feb 2021 (Study Day 196)	Recurrent Cervical Dysplasia (With High Risk Hpv) Surgical Medication
Bilateral salpingo-oophorectomy*	19 Feb 2021 (Study Day 196) - 19 Feb 2021 (Study Day 196)	Adverse Event
Bupivacaine	19 Feb 2021 (Study Day 196) - 19 Feb 2021 (Study Day 196)	Benign Lipoma Left Buttock
Calcium chloride; potassium chloride; sodium lactate	19 Feb 2021 (Study Day 196) - 19 Feb 2021 (Study Day 196)	Procedural Medication (To Maintain Iv Line)
Calcium chloride; potassium chloride; sodium lactate	19 Feb 2021 (Study Day 196) - 19 Feb 2021 (Study Day 196)	Procedural Medication To Maintain Iv
Cefazolin sodium	19 Feb 2021 (Study Day 196) - 19 Feb 2021 (Study Day 196)	Surgical Procedure For Infection Prophylaxis
Docusate sodium	19 Feb 2021 (Study Day 196) - 20 Feb 2021 (Study Day 197)	Prevention Of Opioid-Induced Constipation Post Surgical Procedure
Dronabinol	19 Feb 2021 (Study Day 196) - 19 Feb 2021 (Study Day 196)	Nausea Prevention Prior To Surgery
Excision of 1 buttock lipoma*	19 Feb 2021 (Study Day 196) - 19 Feb 2021 (Study Day 196)	Adverse Event
Gabapentin	19 Feb 2021 (Study Day 196) - 19 Feb 2021 (Study Day 196)	Pain Prophylaxis Pre-Surgery
Hydrocodone bitartrate; paracetamol	19 Feb 2021 (Study Day 196) - 20 Feb 2021 (Study Day 197)	Post-Surgical Pain
Metoclopramide	19 Feb 2021 (Study Day 196) - 19 Feb 2021 (Study Day 196)	Pre-Surgical Nausea Prevention
Paracetamol	19 Feb 2021 (Study Day 196) - 19 Feb 2021 (Study Day 196)	Pre-Surgical Pain Prevention
Total hysterectomy*	19 Feb 2021 (Study Day 196) - 19 Feb 2021 (Study Day 196)	Adverse Event
Ketorolac tromethamine	20 Feb 2021 (Study Day 197) - 20 Feb 2021 (Study Day 197)	Post-Surgical Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Lipoma	Grade 1/mild	Not related	15 Feb 2021 (Study Day 192) - 19 Feb 2021 (Study Day 196)
Procedural Pain	Grade 1/mild	Not related	19 Feb 2021 (Study Day 196) - 26 Feb 2021 (Study Day 203)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US320-2179 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 14 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 24 Sep 2020 (Study Day 42)
First Dose of Vaccine in Part B: 01 Feb 2021 (Study Day 172)
Second Dose of Vaccine in Part B: 01 Mar 2021 (Study Day 200)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Coronary Syndrome/ Acute Coronary Syndrome >24 Hrs Duration	SAE	Grade 2/ moderate	Not related	19 Mar 2021 (Study Day 218) – 22 Mar 2021 (Study Day 221)	Recovered/resolved
Coronary Artery Disease/ Worsening Of Coronary Artery Disease	SAE	Grade 2/ moderate	Not related	19 Mar 2021 (Study Day 218) – 22 Mar 2021 (Study Day 221)	Recovered/resolved
Ventricular Tachycardia/ Wide Complex Ventricular Tachycardia	SAE	Grade 2/ moderate	Not related	20 Mar 2021 (Study Day 219) – 21 Mar 2021 (Study Day 220)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2179, a 76-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 42). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 01 Feb 2021. The participant was unblinded on 01 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 01 Feb 2021 (Study Day 172). The second dose was administered in the left arm on 01 Mar 2021 (Study Day 200).

Event Details

On 19 Mar 2021 (Study Day 218), 217 days after the first dose in Part A/46 days after the first dose in Part B and 176 days after the second dose in Part A/18 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of acute coronary syndrome. Action taken with the IP was not applicable. The event of acute coronary syndrome >24 hrs duration lasted for 4 days, after which it was considered to be recovered/resolved on 22 Mar 2021 (Study Day 221). The investigator assessed the event of acute coronary syndrome to be not related to the IP.

On 19 Mar 2021 (Study Day 218), 217 days after the first dose in Part A/46 days after the first dose in Part B and 176 days after the second dose in Part A/18 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of coronary artery disease. Action taken with the IP was not applicable. The event of worsening of coronary artery disease lasted for 4 days, after which it was considered to be recovered/resolved on 22 Mar 2021 (Study Day 221). The investigator assessed the event of coronary artery disease to be not related to the IP.

On 20 Mar 2021 (Study Day 219), 218 days after the first dose in Part A/47 days after the first dose in Part B and 177 days after the second dose in Part A/19 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of ventricular tachycardia. Action taken with the IP was not applicable. The event of wide complex ventricular tachycardia lasted for 2 days, after which it was considered to be recovered/resolved on 21 Mar 2021 (Study Day 220). The investigator assessed the event of ventricular tachycardia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-062981	Acute coronary syndrome
MOD-2021-062981	Coronary artery disease
MOD-2021-062981	Ventricular tachycardia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Angina pectoris	Angina	Not reported - Ongoing
Atrial fibrillation	Atrial fib	Not reported - Ongoing
Cardiac failure congestive	Congestive heart failure	Not reported - Ongoing
Chronic kidney disease	Chronic kidney disease	Not reported - Ongoing
Chronic obstructive pulmonary disease	Copd	Not reported - Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Migraine	Migraine headaches	2000 - Ongoing
Coronary artery disease	Coronary artery disease (3 stents)	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	2000 - Ongoing	Migraines
Apixaban	Sep 2020 - Ongoing	Atrial Fibrillation
Influenza vaccine	09 Oct 2020 (Study Day 57) - 09 Oct 2020 (Study Day 57)	Prevent Flu
Piperacillin sodium; tazobactam sodium	19 Mar 2021 (Study Day 218) - 24 Mar 2021 (Study Day 223)	Appendicitis
Heparin	21 Mar 2021 (Study Day 220) - 22 Mar 2021 (Study Day 221)	Acute Coronary Syndrome
Acetylsalicylic acid	22 Mar 2021 (Study Day 221) - Ongoing	Coronary Artery Disease
Atorvastatin	22 Mar 2021 (Study Day 221) - Ongoing	Cad
Cardiac stent placement*	22 Mar 2021 (Study Day 221) - 22 Mar 2021 (Study Day 221)	Adverse Event
Carvedilol	22 Mar 2021 (Study Day 221) - Ongoing	Cad Chf
Clopidogrel bisulfate	22 Mar 2021 (Study Day 221) - Ongoing	Cad Stent Placement
Diphenhydramine	22 Mar 2021 (Study Day 221) - 22 Mar 2021 (Study Day 221)	Prophylaxis
Fentanyl	22 Mar 2021 (Study Day 221) - 22 Mar 2021 (Study Day 221)	Procedure Sedation For Cad Stent
Metoprolol tartrate	22 Mar 2021 (Study Day 221) - 22 Mar 2021 (Study Day 221)	Prophylaxis
Midazolam	22 Mar 2021 (Study Day 221) - 22 Mar 2021 (Study Day 221)	Procedure Sedation For Cad Stent
Amoxicillin; clavulanic acid	24 Mar 2021 (Study Day 223) - 01 Apr 2021 (Study Day 231)	Appendicitis
Docusate	24 Mar 2021 (Study Day 223) - Ongoing	Prophylaxis
Furosemide	24 Mar 2021 (Study Day 223) - Ongoing	Chf
Gabapentin	24 Mar 2021 (Study Day 223) - Ongoing	L4 Vertebral Compression Fx
Hydrocodone bitartrate; paracetamol	24 Mar 2021 (Study Day 223) - Ongoing	L4 Compression Fx
Macrogol 3350	24 Mar 2021 (Study Day 223) - Ongoing	Prophylaxis
Methocarbamol	24 Mar 2021 (Study Day 223) - Ongoing	L4 Compression Fx
Metoprolol	24 Mar 2021 (Study Day 223) - Ongoing	Cad Arrhythmias- At Fib Wide-Complex Ventricular Tachycardia
Potassium chloride	24 Mar 2021 (Study Day 223) - Ongoing	Prophylaxis
Vitamins nos	24 Mar 2021 (Study Day 223) - Ongoing	Supplement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Appendicitis	Grade 2/moderate	Not related	19 Mar 2021 (Study Day 218) - Ongoing
Lumbar Vertebral Fracture	Grade 2/moderate	Not related	19 Mar 2021 (Study Day 218) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US320-2183 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 14 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 22 Sep 2020 (Study Day 40)
First Dose of Vaccine in Part B: 13 Jan 2021 (Study Day 153)
Second Dose of Vaccine in Part B: 24 Feb 2021 (Study Day 195)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intervertebral Disc Degeneration/ Worsening Of Cervical Degenerative Disc Disease	SAE	Grade 2/ moderate	Not related	01 Mar 2021 (Study Day 200) – 01 Mar 2021 (Study Day 200)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2183, a 70-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 40). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 13 Jan 2021. The participant was unblinded on 13 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 13 Jan 2021 (Study Day 153). The second dose was administered in the left arm on 24 Feb 2021 (Study Day 195).

Event Details

On 01 Mar 2021 (Study Day 200), 199 days after the first dose in Part A/47 days after the first dose in Part B and 160 days after the second dose in Part A/5 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of intervertebral disc degeneration. Action taken with the IP was not applicable. The event of worsening of cervical degenerative disc disease lasted for 1 day, after which it was considered to be recovered/resolved on 01 Mar 2021 (Study Day 200). The investigator assessed the event of intervertebral disc degeneration to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-058512	Intervertebral disc degeneration

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Osteoarthritis	1970 - Ongoing
Sleep apnoea syndrome	Sleep apnea	1970 - Ongoing
Hypertension	Hypertension	1975 - Ongoing
Menorrhagia	Menorrhagia	1988 - 1990
Hysterectomy	Hysterectomy	1990 - 1990
Hyperlipidaemia	Hyperlipidemia	2017 - Ongoing
Depression	Depression	2018 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	2019 - Ongoing
Intervertebral disc degeneration	Degenerative disc disease	2020 - Ongoing
Sciatica	Sciatica	2020 - Ongoing
Scoliosis	Scoliosis	2020 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	Feb 2020 - Ongoing
Seasonal allergy	Seasonal allergies	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	1970 - Ongoing	General Health Supplement
Vitamins nos	1970 - Ongoing	General Health Supplement
Amlodipine besilate; benazepril hydrochloride	2010 - Ongoing	Hypertension
Celecoxib	2015 - 22 Feb 2021 (Study Day 193)	Osteoarthritis
Gabapentin	2015 - Ongoing	Osteoarthritis
Chondroitin sulfate; glucosamine hydrochloride	2016 - 22 Feb 2021 (Study Day 193)	General Health Supplement
Colecalciferol	2016 - 22 Feb 2021 (Study Day 193)	General Health Supplement
Vitamin b complex	2016 - 22 Feb 2021 (Study Day 193)	General Health Supplement
Atorvastatin	2017 - Ongoing	Hyperlipidemia
Trazodone	2018 - Ongoing	Depression
Cinnamomum verum oil	2019 - Ongoing	General Health Supplement
Hydrochlorothiazide	2019 - Nov 2020	Hypertension
Biotin	2020 - Ongoing	General Health Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Baclofen	Mar 2020 - 02 Mar 2021 (Study Day 201)	Osteoarthritis
Pantoprazole	Mar 2020 - Ongoing	Gastroesophageal Reflux Disease
Memantine	May 2020 - Ongoing	Memory Supplement
Colestipol	28 May 2020 (Study Day -78) - Ongoing	Hyperlipedemia
Influenza vaccine	18 Sep 2020 (Study Day 36) - 18 Sep 2020 (Study Day 36)	Prophylaxis- Flu
Pneumococcal vaccine 13v	18 Sep 2020 (Study Day 36) - 18 Sep 2020 (Study Day 36)	Prophylaxis- Pneumonia
Tetanus vaccine	18 Sep 2020 (Study Day 36) - 18 Sep 2020 (Study Day 36)	Prophylaxis- Tetanus
Anesthetics, general	01 Mar 2021 (Study Day 200) - 01 Mar 2021 (Study Day 200)	Worsening Of Cervical Degenerative Disc Disease
Cervical disc replacement*	01 Mar 2021 (Study Day 200) - 01 Mar 2021 (Study Day 200)	Adverse Event
Cyclobenzaprine	02 Mar 2021 (Study Day 201) - Ongoing	Acute Post Surgical Cervical Neck Pain
Tramadol	02 Mar 2021 (Study Day 201) - 09 Mar 2021 (Study Day 208)	Post Surgical Cervical Neck Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Procedural Pain	Grade 1/mild	Not related	02 Mar 2021 (Study Day 201) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US320-2185 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 14 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Sep 2020 (Study Day 32)
First Dose of Vaccine in Part B: 01 Feb 2021 (Study Day 172)
Second Dose of Vaccine in Part B: 01 Mar 2021 (Study Day 200)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Asthenia/Weakness	SAE	Grade 2/ moderate	Not related	06 Apr 2021 (Study Day 236) – 13 Apr 2021 (Study Day 243)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2185, a 56-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 01 Feb 2021. The participant was unblinded on 01 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 01 Feb 2021 (Study Day 172). The second dose was administered in the left arm on 01 Mar 2021 (Study Day 200).

Event Details

On 06 Apr 2021 (Study Day 236), 235 days after the first dose in Part A/64 days after the first dose in Part B and 204 days after the second dose in Part A/36 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of asthenia. Action taken with the IP was not applicable. The event of weakness lasted for 8 days, after which it was considered to be recovered/resolved on 13 Apr 2021 (Study Day 243). The investigator assessed the event of asthenia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-075681	Asthenia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Chronic back pain	1990 - Ongoing
Seasonal allergy	Seasonal allergies	1992 - Ongoing
Gout	Gout	1996 - Ongoing
Alopecia	Hair loss	2019 - Ongoing
Depression	Depression	2019 - Ongoing
Folate deficiency	Folic acid deficiency	2019 - Ongoing
Hyperammonaemia	Hyperammonemia	2019 - Ongoing
Hypokalaemia	Potassium deficiency	2019 - Ongoing
Insomnia	Insomnia	2019 - Ongoing
Nephrolithiasis	Kidney stone	2019 - Ongoing
Oedema peripheral	Bilateral edema legs	2019 - Ongoing
Onychomycosis	Toenail fungus	2019 - Ongoing
Hepatic cirrhosis	Elevated liver tests- cirrhosis	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Allopurinol	2011 - Ongoing	Gout
Citalopram	2019 - Ongoing	Depression
Folic acid	2019 - Ongoing	Folic Acid Deficiency
Rifaximin	2019 - Ongoing	High Blood Ammonia Level/Hyperammonemia
Potassium chloride	2020 - Ongoing	Potassium Deficiency
Spironolactone	2020 - Ongoing	Bilateral Edema Legs
Trazodone	2020 - Ongoing	Insomnia
Finasteride	17 Mar 2020 (Study Day -150) - Ongoing	Hair Loss
Furosemide	25 Apr 2020 (Study Day -111) - Ongoing	Bilateral Edema Legs
Paracentesis*	04 Jan 2021 (Study Day 144) - 04 Jan 2021 (Study Day 144)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US320-2197 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 15 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Sep 2020 (Study Day 31)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Carotid Artery Stenosis/Left Carotid Stenosis	SAE	Grade 2/moderate	Not related	19 Jan 2021 (Study Day 158) – 19 Jan 2021 (Study Day 158)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2197, a 73-year-old race not reported male, received the first dose of mRNA-1273 in the left arm on 15 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 19 Jan 2021 (Study Day 158), 157 days after the first dose in Part A and 127 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of carotid artery stenosis. Action taken with the IP was not applicable. The event of left carotid stenosis lasted for 1 day, after which it was considered to be recovered/resolved on 19 Jan 2021 (Study Day 158). The investigator assessed the event of carotid artery stenosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-068078	Carotid artery stenosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Arthralgia	Chronic hip pain bilateral	Not reported - Ongoing
Back pain	Chronic back pain	Not reported - Ongoing
Hypertension	Hypertension	1995 - Ongoing
Gastroesophageal reflux disease	Heartburn/acid reflux	2000 - Ongoing
Sleep apnoea syndrome	Sleep apnea- uses a c-pap	2000 - Ongoing
Hypothyroidism	Hypothyroidism	2001 - Ongoing
Gout	General gout	2005 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2010 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Drug hypersensitivity	Allergic to statins- caused kidney disease	2011 - Ongoing
Nephropathy toxic	Kidney disease- caused by allergic reaction to statins	2011 - Ongoing
Aortic aneurysm	Abdominal aortic aneurysm	2014 - 2014
Cardiac pacemaker insertion	Placement of cardiac pacemaker	2014 - 2014
Coronary artery disease	Coronary artery disease	2014 - Ongoing
Implantable defibrillator insertion	Placement of cardiac pacemaker defibrillator	2015 - 2015
Carotid artery stenosis	Left carotid artery stenosis	Jan 2020 - Ongoing
Carotid artery stenosis	Right carotid artery stenosis	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole sodium sesquihydrate	2000 - Ongoing	Acid Reflux
Allopurinol	2005 - Ongoing	Gouty Arthritis
Levothyroxine	2011 - Ongoing	Hypothyroidism
Terazosin	2011 - Ongoing	Benign Prostatic Hyperplasia
Carvedilol	2015 - Ongoing	Hypertension
Lisinopril	2015 - Ongoing	Hypertension
Anesthetics, general	21 Oct 2020 (Study Day 68) - 21 Oct 2020 (Study Day 68)	Right Carotid Stenosis
Heparin	21 Oct 2020 (Study Day 68) - 21 Oct 2020 (Study Day 68)	Right Carotid Endarterectomy Procedural Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Right carotid endarterectomy with bovine patch angioplasty*	21 Oct 2020 (Study Day 68) - 21 Oct 2020 (Study Day 68)	Medical History
Anesthetics, general	19 Jan 2021 (Study Day 158) - 19 Jan 2021 (Study Day 158)	Left Carotid Stenosis (Procedural Anesthesia For Left Carotid Endarterectomy)
Heparin	19 Jan 2021 (Study Day 158) - 19 Jan 2021 (Study Day 158)	Left Carotid Endarterectomy Procedural Prophylaxis
Left carotid endarterectomy with bovine patch angioplasty*	19 Jan 2021 (Study Day 158) - 19 Jan 2021 (Study Day 158)	Medical History
Alirocumab	08 Feb 2021 (Study Day 178) - Ongoing	Hyperlipidemia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US320-2217 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 17 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 25 Jan 2021 (Study Day 162)
Second Dose of Vaccine in Part B: 01 Mar 2021 (Study Day 197)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening Right Knee Osteoarthritis	SAE	Grade 2/ moderate	Not related	11 Feb 2021 (Study Day 179) – 12 Feb 2021 (Study Day 180)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2217, a 75-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 25 Jan 2021. The participant was unblinded on 25 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 25 Jan 2021 (Study Day 162). The second dose was administered in the left arm on 01 Mar 2021 (Study Day 197).

Event Details

On 11 Feb 2021 (Study Day 179), 178 days after the first dose in Part A/17 days after the first dose in Part B and 150 days after the second dose in Part A/18 days before the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of osteoarthritis. The IP dose was not changed due to the worsening right knee osteoarthritis. The event of worsening right knee osteoarthritis lasted for 2 days, after which it was considered to be recovered/resolved on 12 Feb 2021 (Study Day 180). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-079718	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy to doxycycline	Not reported - Ongoing
Food allergy	Allergy to brazil nuts	Not reported - Ongoing
Sciatica	Sciatica	Not reported - Ongoing
Gout	Gout	2005 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Barrett's oesophagus	Barrett's esophagus	2012 - Ongoing
Insomnia	Insomnia	2012 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2012 - Ongoing
Neuralgia	Chronic neuropathic pain- left hand	2015 - Ongoing
Neuralgia	Chronic neuropathic pain left leg	2017 - Ongoing
Arrhythmia	Cardiac arrhythmia	2018 - Ongoing
Arthralgia	Chronic pain right knee	2019 - Ongoing
Osteoarthritis	Osteoarthritis right knee	2019 - Ongoing
Squamous cell carcinoma	Squamous cell skin cancer right elbow	Feb 2020 - Aug 2020
Meniscus operation	Right knee torn meniscus repair surgery	Apr 2020 - Apr 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Allopurinol	2005 - Ongoing	Gout
Rosuvastatin	2010 - Ongoing	Hyperlipidemia
Amlodipine	2012 - Ongoing	Hypertension
Losartan	2012 - Ongoing	Hypertension
Omeprazole	2012 - Ongoing	Barrett's Esophagus
Spironolactone	2012 - Ongoing	Hypertension
Trazodone	2012 - Ongoing	Insomnia
Oxycodone hydrochloride; paracetamol	2017 - 12 Feb 2021 (Study Day 180)	Chronic Neuropathic Pain
Apixaban	2018 - 11 Feb 2021 (Study Day 179)	Cardiac Arrhythmia
Carvedilol	2018 - Ongoing	Cardiac Arrhythmia
Gabapentin	Jun 2020 - Ongoing	Chronic Neuropathic Pain
Diclofenac	Nov 2020 - Ongoing	Chronic Pain Right Knee

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydralazine	04 Jan 2021 (Study Day 141) - Ongoing	Hypertension
Bupropion	30 Jan 2021 (Study Day 167) - Ongoing	Chronic Neuropathic Pain In Left Leg And Left Hand
Anesthetics, general	11 Feb 2021 (Study Day 179) - 11 Feb 2021 (Study Day 179)	Worsening Of Right Knee Osteoarthritis
Calcium chloride; potassium chloride; sodium lactate	11 Feb 2021 (Study Day 179) - 12 Feb 2021 (Study Day 180)	Worsening Right Knee Osteoarthritis
Dexamethasone	11 Feb 2021 (Study Day 179) - 11 Feb 2021 (Study Day 179)	Worsening Right Knee Osteoarthritis
Right knee arthroplasty (right total knee replacement)*	11 Feb 2021 (Study Day 179) - 11 Feb 2021 (Study Day 179)	Adverse Event
Sodium chloride	11 Feb 2021 (Study Day 179) - 12 Feb 2021 (Study Day 180)	Worsening Of Right Knee Osteoarthritis
Tranexamic acid	11 Feb 2021 (Study Day 179) - 11 Feb 2021 (Study Day 179)	Surgical Prophylaxis (To Prevent Blood Loss Due To Anticoagulant Use)
Diphenhydramine	12 Feb 2021 (Study Day 180) - 12 Feb 2021 (Study Day 180)	Insomnia
Docusate sodium	12 Feb 2021 (Study Day 180) - 12 Feb 2021 (Study Day 180)	Prevention Of Opioid-Induced Constipation Post-Surgery
Famotidine	12 Feb 2021 (Study Day 180) - 12 Feb 2021 (Study Day 180)	Barrett's Esophagus
Hydrocodone bitartrate; paracetamol	12 Feb 2021 (Study Day 180) - 12 Feb 2021 (Study Day 180)	Worsening Of Right Knee Osteoarthritis
Oxycodone	12 Feb 2021 (Study Day 180) - 26 Feb 2021 (Study Day 194)	Acute Post-Operative Pain
Warfarin	12 Feb 2021 (Study Day 180) - 29 Mar 2021 (Study Day 225)	Blood Clot Prophylaxis
Prednisolone	18 Mar 2021 (Study Day 214) - 28 Mar 2021 (Study Day 224)	Chronic Back Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Procedural Pain	Grade 2/moderate	Not related	12 Feb 2021 (Study Day 180) - 26 Feb 2021 (Study Day 194)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US320-2366 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 31 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Uterine Leiomyoma/ Worsening Of Uterine Fibroid	SAE	Grade 2/ moderate	Not related	01 Apr 2021 (Study Day 214) – 03 Apr 2021 (Study Day 216)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2366, a 30-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 23 Feb 2021. The participant was unblinded on 23 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 01 Apr 2021 (Study Day 214), 213 days after the first dose in Part A and 185 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of uterine leiomyoma. Action taken with the IP was not applicable. The event of worsening of uterine fibroid lasted for 3 days, after which it was considered to be recovered/resolved on 03 Apr 2021 (Study Day 216). The investigator assessed the event of uterine leiomyoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-065714	Uterine leiomyoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1995 - Ongoing
Eczema	Eczema	2000 - Ongoing
Drug eruption	Allergy to keflex reaction- entire body rash	2010 - Ongoing
Fatigue	Chronic fatigue	2015 - Ongoing
Gastroesophageal reflux disease	Chronic acid reflux	2015 - Ongoing
Menorrhagia	Heavy menstrual bleeding	2015 - Ongoing
Hiatus hernia	Hiatal hernia	Aug 2015 - Ongoing
Diarrhoea	Chronic diarrhea- controlled with diet	2018 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome- controlled with diet	2018 - Ongoing
Glucose tolerance impaired	Pre-diabetes	Jul 2018 - Ongoing
Ovarian cyst	Left ovarian cyst	2019 - Ongoing
Uterine leiomyoma	Uterine fibroid	2019 - Ongoing
Blood testosterone increased	Elevated testosterone level	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Biotin	2010 - Ongoing	General Health Supplement
Vitamins nos	2010 - 01 Dec 2020 (Study Day 93)	General Health Supplement
Paracetamol	2015 - Ongoing	Heavy Menstrual Bleeding
Fexofenadine hydrochloride	May 2017 - 15 Feb 2021 (Study Day 169)	Seasonal Allergies
Metformin	Jul 2018 - 15 Feb 2021 (Study Day 169)	Pre-Diabetes
Fluticasone propionate	Apr 2020 - Ongoing	Seasonal Allergies
Magnesium	Jun 2020 - Ongoing	General Health Supplement
Fluconazole	03 Sep 2020 (Study Day 4) - 03 Sep 2020 (Study Day 4)	Vaginal Candidiasis
Sulfamethoxazole; trimethoprim	03 Sep 2020 (Study Day 4) - 08 Sep 2020 (Study Day 9)	Urinary Tract Infection
Urine pregnancy test*	02 Dec 2020 (Study Day 94) - 02 Dec 2020 (Study Day 94)	Other, Confirmation Of Pregnancy
Vaginal ultrasound*	02 Dec 2020 (Study Day 94) - 02 Dec 2020 (Study Day 94)	Other, Confirmation Of Pregnancy

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	02 Dec 2020 (Study Day 94) - Ongoing	Pregnancy
Nystatin	29 Dec 2020 (Study Day 121) - 30 Dec 2020 (Study Day 122)	Candidiasis Under Left Arm
Fluconazole	30 Dec 2020 (Study Day 122) - 30 Dec 2020 (Study Day 122)	Under Arm Yeast Infection-Left Arm
Sulfamethoxazole; trimethoprim	02 Feb 2021 (Study Day 156) - 08 Feb 2021 (Study Day 162)	Benign Cyst Left Labia Majora
Fluconazole	15 Feb 2021 (Study Day 169) - 15 Feb 2021 (Study Day 169)	Candidiasis Left Axilla
Crisaborole	15 Mar 2021 (Study Day 197) - Ongoing	Eczema
Pantoprazole	15 Mar 2021 (Study Day 197) - Ongoing	Intermittent Acid Reflux

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Rhinovirus Infection	Grade 1/mild	Not related	25 Mar 2021 (Study Day 207) - 04 Apr 2021 (Study Day 217)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US320-2395 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 07 Oct 2020 (Study Day 35)
First Dose of Vaccine in Part B: 01 Feb 2021 (Study Day 152)
Second Dose of Vaccine in Part B: 01 Mar 2021 (Study Day 180)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dyspnoea Exertional/ Dyspnea On Exertion	SAE	Grade 2/ moderate	Not related	06 Apr 2021 (Study Day 216) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2395, a 76-year-old not Hispanic or Latino female, received the first dose of Placebo in the right arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 07 Oct 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 01 Feb 2021. The participant was unblinded on 01 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 01 Feb 2021 (Study Day 152). The second dose was administered in the right arm on 01 Mar 2021 (Study Day 180).

Event Details

On 06 Apr 2021 (Study Day 216), 215 days after the first dose in Part A/64 days after the first dose in Part B and 181 days after the second dose in Part A/36 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of dyspnoea exertional. Action taken with the IP was not applicable. The event of dyspnea on exertion was considered to be ongoing. The investigator assessed the event of dyspnoea exertional to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-074307	Dyspnoea exertional

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1950 - Ongoing
Female sterilisation	Bilateral tubal ligation	1980 - 1980
Basal cell carcinoma	Left breast basal cell cancer	1993 - 1993
Breast conserving surgery	Lumpectomy left breast	1993 - 1993
Hypothyroidism	Hypothyroidism	1993 - Ongoing
Sciatica	Sciatic nerve pain	2000 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2004 - Ongoing
Back pain	Back pain	2008 - Ongoing
Hypertension	Hypertension	2008 - Ongoing
Spinal fusion surgery	Lumbar fusion	2009 - 2009
Vitamin D deficiency	Vitamin d deficiency	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	1993 - Ongoing	Hypothyroidism
Simvastatin	2004 - Ongoing	Hypercholesterolemia
Hydrochlorothiazide; triamterene	2008 - Ongoing	Hypertension
Tramadol	2008 - Ongoing	Sciatic Nerve Pain
Bioflavonoids nos	2010 - Ongoing	Supplement
Choline bitartrate	2010 - Ongoing	Supplement
Colecalciferol; menaquinone-7	2010 - Ongoing	Supplement
Curcuma longa	2010 - Ongoing	Supplement
DL-alpha tocopheryl acetate; retinol palmitate; xantofyl; zeaxanthin; zinc oxide	2010 - Ongoing	Supplement
Fish oil	2010 - Ongoing	Supplement
Ginkgo biloba	2010 - Ongoing	Supplement
Glucosamine sulfate	2010 - Ongoing	Supplement
Magnesium citrate	2010 - Ongoing	Supplement
Nicotinamide	2010 - Ongoing	Supplement
Ubidecarenone	2010 - Ongoing	Supplement
Vitamin b12 nos	2010 - Ongoing	Supplement
Gabapentin	Mar 2020 - Ongoing	Sciatic Nerve Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Silybum marianum	Mar 2020 - Ongoing	Supplement
Paracetamol	13 Oct 2020 (Study Day 41) - Ongoing	Back Pain Diary Entry Headache Con Med
Ibuprofen	15 Oct 2020 (Study Day 43) - Ongoing	Chronic Back Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US321-2049 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 05 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 36)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Prostate Cancer/Prostate Cancer	SAE	Grade 3/ severe	Not related	01 Feb 2021 (Study Day 181) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US321-2049, a 72-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 01 Feb 2021 (Study Day 181), 180 days after the first dose in Part A and 145 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of prostate cancer. Action taken with the IP was not applicable. The event of prostate cancer was considered to be ongoing. The investigator assessed the event of prostate cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-021795	Prostate cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastric cancer	Cancerous stomach tumor	2010 - 2010
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2010 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Obesity	Obesity	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Cardiac Health Prophylaxis
Atorvastatin	2010 - Ongoing	Hypercholesterolemia
Lisinopril	2010 - Ongoing	Hypertension
Omeprazole	2010 - Ongoing	Gastroesophageal Reflux Disease
Vitamin d nos	2010 - Ongoing	General Health
Vitamins nos	2010 - Ongoing	General Health
Influenza vaccine	25 Aug 2020 (Study Day 21) - 25 Aug 2020 (Study Day 21)	Vaccination
Ofloxacin	30 Nov 2020 (Study Day 118) - Ongoing	Bilateral Bacterial Conjunctivitis
Prostate biopsy*	01 Feb 2021 (Study Day 181) - 01 Feb 2021 (Study Day 181)	Other, Elevated Psa

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US321-2121 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 11 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 06 Jan 2021 (Study Day 149)
Second Dose of Vaccine in Part B: 20 Feb 2021 (Study Day 194)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Oesophageal Candidiasis/ Esophageal Candidiasis	SAE	Grade 3/ severe	Not related	23 Apr 2021 (Study Day 256) – Ongoing	Recovering/ resolving
Oesophageal Rupture/Esophageal Tear	SAE	Grade 3/ severe	Not related	23 Apr 2021 (Study Day 256) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US321-2121, a 53-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 06 Jan 2021 (Study Day 149). The second dose was administered in the left arm on 20 Feb 2021 (Study Day 194).

Event Details

On 23 Apr 2021 (Study Day 256), 255 days after the first dose in Part A/107 days after the first dose in Part B and 227 days after the second dose in Part A/62 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of oesophageal candidiasis. The IP dose was not changed due to the esophageal candidiasis. The event of esophageal candidiasis was considered to be ongoing. The investigator assessed the event of oesophageal candidiasis to be not related to the IP.

On 23 Apr 2021 (Study Day 256), 255 days after the first dose in Part A/107 days after the first dose in Part B and 227 days after the second dose in Part A/62 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of oesophageal rupture. The IP dose was not changed due to the esophageal tear. The event of esophageal tear was

considered to be ongoing. The investigator assessed the event of oesophageal rupture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-091053	Oesophageal candidiasis
MOD-2021-091053	Oesophageal rupture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraines	1976 - Ongoing
Food allergy	Onion allergy	1977 - Ongoing
Wrist fracture	Fracture left wrist	Apr 1981 - May 1981
Hyperthyroidism	Hyperthyroidism	Aug 1998 - Jan 1999
Drug hypersensitivity	Morphine allergy	1999 - Ongoing
Hypothyroidism	Hypothyroidism	Jan 1999 - Ongoing
Thyroidectomy	Thyroidectomy	Jan 1999 - Jan 1999
Arthralgia	Knee pain (right)	2001 - Ongoing
Appendectomy	Appendectomy (prophylactic, during hysterectomy)	2005 - 2005
Haemorrhage	Uncontrolled post-partum hemorrhage	2005 - 2005
Hysterectomy	Hysterectomy	2005 - 2005
Cholelithiasis	Gallstones	2008 - 2012
Insomnia	Insomnia	2008 - Ongoing
Cholecystectomy	Cholecystectomy	2012 - 2012
Iodine allergy	Iodine allergy	2012 - Ongoing
Osteoarthritis	Osteoarthritis of bilateral shoulders	2016 - Ongoing
Osteoarthritis	Osteoarthritis of right knee	2016 - Ongoing
Nephrolithiasis	Kidney stones (bilateral)	May 2017 - May 2017
Obesity	Obesity	2018 - Ongoing
Pruritus	Generalized pruritus	Jul 2019 - Nov 2019
Rubber sensitivity	Latex allergy	Jan 2020 - Ongoing
Oedema peripheral	Trace ankle edema bilateral	12 Mar 2020 (Study Day -152) - 15 Apr 2020 (Study Day -118)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid; caffeine; paracetamol	1980 - Ongoing	Migraines
Ibuprofen	1990 - Ongoing	Migraines
Levothyroxine	1999 - Ongoing	Hypothyroidism
Topiramate	2009 - Ongoing	Migraine
Botulinum toxin type a	2015 - Ongoing	Migraines
Duloxetine hydrochloride	2016 - Ongoing	Knee Pain (Right)
Eszopiclone	2016 - Ongoing	Insomnia
Sumatriptan	2019 - Ongoing	Migraine Headaches
Liothyronine	Nov 2019 - Ongoing	Hypothyroidism
Hydrocodone bitartrate; paracetamol	08 Apr 2020 (Study Day -125) - Ongoing	Osteoarthritis (Right Knee And Bilateral Shoulders)
Influenza vaccine	26 Oct 2020 (Study Day 77) - 26 Oct 2020 (Study Day 77)	Immunization
Paracetamol	06 Jan 2021 (Study Day 149) - Ongoing	Fever/Pain Reactogenicity
Nitrofurantoin	08 Jan 2021 (Study Day 151) - 12 Jan 2021 (Study Day 155)	Urinary Tract Infection
Root canal*	26 Jan 2021 (Study Day 169) - 26 Jan 2021 (Study Day 169)	Other, Replace Porcelain Filling
Rimegepant	01 Feb 2021 (Study Day 175) - Ongoing	Migraine Headache
Root canal*	02 Feb 2021 (Study Day 176) - 02 Feb 2021 (Study Day 176)	Other, Replace Porcelain Filling
Paracetamol	21 Feb 2021 (Study Day 195) - Ongoing	Tension Headache
Paracetamol	25 Mar 2021 (Study Day 227) - 27 Mar 2021 (Study Day 229)	Body Aches

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	08 Jan 2021 (Study Day 151) - 12 Jan 2021 (Study Day 155)
Tension Headache	Grade 2/moderate	Related	21 Feb 2021 (Study Day 195) - 15 Mar 2021 (Study Day 217)
Rhinovirus Infection	Grade 1/mild	Not related	19 Mar 2021 (Study Day 221) - 28 Mar 2021 (Study Day 230)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US321-2166 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 65 Years
First Dose of Vaccine in Part A: 13 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 28)
First Dose of Vaccine in Part B: 20 Jan 2021 (Study Day 161)
Second Dose of Vaccine in Part B: 18 Feb 2021 (Study Day 190)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Ischaemic Cerebral Infarction/ Ischemic Cerebrovascular Accident	SAE	Grade 3/ severe	Not related	18 Apr 2021 (Study Day 249) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US321-2166, a 68-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 20 Jan 2021. The participant was unblinded on 20 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 20 Jan 2021 (Study Day 161). The second dose was administered in the right arm on 18 Feb 2021 (Study Day 190).

Event Details

On 18 Apr 2021 (Study Day 249), 248 days after the first dose in Part A/88 days after the first dose in Part B and 221 days after the second dose in Part A/59 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of ischaemic cerebral infarction. The IP dose was not changed due to the ischemic cerebrovascular accident. The event of ischemic cerebrovascular accident was considered to be ongoing. The investigator assessed the event of ischaemic cerebral infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-090061	Ischaemic cerebral infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1964 - Ongoing
Migraine	Migraines	1980 - Ongoing
Menopause	Menopause	1983 - Ongoing
Spinal osteoarthritis	Osteoarthritis of lumbar spine	2008 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Hypertension	Hypertension	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	1964 - Ongoing	Seasonal Allergies
Rosuvastatin	2010 - Ongoing	Hypercholesterolemia
Topiramate	2017 - Ongoing	Migraine Prophylaxis
Amlodipine	2018 - Ongoing	Hypertension
Azelastine hydrochloride	Mar 2020 - Ongoing	Seasonal Allergies
Montelukast	26 May 2020 (Study Day -79) - 28 May 2020 (Study Day -77)	Seasonal Allergies
Paracetamol	14 Aug 2020 (Study Day 2) - 14 Aug 2020 (Study Day 2)	Fever/Pain Reactogenicity
Acetylsalicylic acid	14 Sep 2020 (Study Day 33) - 14 Sep 2020 (Study Day 33)	Fever/Pain Reactogenicity
Tramadol	16 Sep 2020 (Study Day 35) - Ongoing	Osteoarthritis Of Lumbar Spine
Botulinum toxin type a	23 Sep 2020 (Study Day 42) - Ongoing	Migraine Prophylaxis
Influenza vaccine	28 Sep 2020 (Study Day 47) - 28 Sep 2020 (Study Day 47)	Influenza Prevention
Skin tag removal*	30 Sep 2020 (Study Day 49) - 30 Sep 2020 (Study Day 49)	Other, Routine Skin Tag Removal
Doxycycline hyclate	13 Nov 2020 (Study Day 93) - 02 Dec 2020 (Study Day 112)	Acute Sinusitis
Montelukast sodium	13 Nov 2020 (Study Day 93) - 20 Nov 2020 (Study Day 100)	Acute Sinusitis
Pseudoephedrine hydrochloride	21 Nov 2020 (Study Day 101) - 21 Nov 2020 (Study Day 101)	Acute Sinusitis
Hydrocodone bitartrate; paracetamol	11 Jan 2021 (Study Day 152) - 14 Jan 2021 (Study Day 155)	Left Shoulder Fracture

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	11 Jan 2021 (Study Day 152) - 13 Jan 2021 (Study Day 154)	Left Shoulder Fracture
X-ray of left shoulder*	11 Jan 2021 (Study Day 152) - 11 Jan 2021 (Study Day 152)	Adverse Event
Calcium citrate; colecalciferol	01 Mar 2021 (Study Day 201) - Ongoing	Bone Health

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US321-2181 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 14 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 02 Oct 2020 (Study Day 50)
First Dose of Vaccine in Part B: 21 Jan 2021 (Study Day 161)
Second Dose of Vaccine in Part B: 23 Feb 2021 (Study Day 194)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Depression/Worsening Of Depression	SAE	Grade 3/ severe	Not related	05 Mar 2021 (Study Day 204) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US321-2181, a 57-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 50). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Jan 2021. The participant was unblinded on 21 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 21 Jan 2021 (Study Day 161). The second dose was administered in the right arm on 23 Feb 2021 (Study Day 194).

Event Details

On 05 Mar 2021 (Study Day 204), 203 days after the first dose in Part A/43 days after the first dose in Part B and 154 days after the second dose in Part A/10 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of depression. Action taken with the IP was not applicable. The event of worsening of depression was considered to be ongoing. The investigator assessed the event of depression to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-058736	Depression

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	Feb 2016 - Sep 2016

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	22 Oct 2020 (Study Day 70) - 22 Oct 2020 (Study Day 70)	Immunization
Escitalopram	06 Mar 2021 (Study Day 205) - Ongoing	Worsening Of Depression
Trazodone	12 Mar 2021 (Study Day 211) - Ongoing	Insomnia
Aripiprazole	25 Mar 2021 (Study Day 224) - Ongoing	Depression/Anxiety
Duloxetine hydrochloride	25 Mar 2021 (Study Day 224) - Ongoing	Depression/Anxiety
Mirtazapine	25 Mar 2021 (Study Day 224) - Ongoing	Depression/Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Insomnia	Grade 2/moderate	Not related	05 Mar 2021 (Study Day 204) - Ongoing
Anxiety	Grade 2/moderate	Not related	24 Mar 2021 (Study Day 223) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US321-2250 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 19 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Enterovesical Fistula/ Colovesical Fistula	SAE	Grade 3/ severe	Not related	11 Feb 2021 (Study Day 177) – 05 Apr 2021 (Study Day 230)	Recovered/ resolved
Enterovesical Fistula/ Colovesicular Fistula (Sigmoid Colectomy Surgery)	SAE	Grade 3/ severe	Not related	05 Apr 2021 (Study Day 230) – 08 Apr 2021 (Study Day 233)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US321-2250, a 75-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 19 Jan 2021. The participant was unblinded on 19 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 11 Feb 2021 (Study Day 177), 176 days after the first dose in Part A and 148 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of enterovesical fistula. Action taken with the IP was not applicable. The event of colovesical fistula lasted for 54 days, after which it was considered to be recovered/resolved on 05 Apr 2021 (Study Day 230). The investigator assessed the event of enterovesical fistula to be not related to the IP.

On 05 Apr 2021 (Study Day 230), 229 days after the first dose in Part A and 201 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of enterovesical fistula. Action taken with the IP was not applicable. The event of colovesicular fistula (sigmoid colectomy surgery) was considered to be Recovered/ resolved on 08 Apr 2021

(Study Day 233). The investigator assessed the event of enterovesical fistula to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014110	Enterovesical fistula
MOD-2021-014110	Enterovesical fistula

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Aspirin hypersensitivity	Not reported - Ongoing
Drug hypersensitivity	Penicillin (allergy)	Not reported - Ongoing
Drug hypersensitivity	Sulfa (allergy)	Not reported - Ongoing
Drug hypersensitivity	Tramadol allergy	Not reported - Ongoing
Iodine allergy	Iodine (allergy)	Not reported - Ongoing
Renal aplasia	Renal agenesis, left side	(b) (6) 1945 (Study Day (b) (6) - Ongoing
Hypertension	Hypertension	1965 - Ongoing
Hysterectomy	Hysterectomy	1977 - 1977
Uterine leiomyoma	Uterine fibroids	1977 - 1977
Back pain	Recurrent back pain	1989 - Ongoing
Tinnitus	Bilateral tinnitus	1990 - Ongoing
Cataract	Bilateral cataracts	1995 - 2019
Obesity	Morbid obesity	2000 - 2010
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Elbow operation	Right elbow surgery	2001 - 2001
Joint injury	Right elbow injury	2001 - 2001
Musculoskeletal pain	Right shoulder pain	2003 - Ongoing
Dyspnoea	Shortness of breath	2007 - Ongoing
Lung neoplasm malignant	Lung cancer	2007 - 2011
Pulmonary resection	Wedge resection of right lung	2007 - 2007
Gastric banding	Gastric banding	2010 - 2010
Transient ischaemic attack	Transient ischemic attack	2010 - 2010
Lung lobectomy	Upper lobe lobotomy, left lung	2011 - 2011
Diverticulum	Diverticulosis	2016 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2016 - 2017

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Urinary incontinence	Urinary incontinence	2016 - Ongoing
Atrial fibrillation	Atrial fibrillation	2017 - 2018
Medical device implantation	Watchman implant	2018 - 2018
Spinal operation	Back surgery	2018 - 2018
Cataract operation	Bilateral cataract surgery	2019 - 2019
Insomnia	Insomnia	Mar 2020 - Ongoing
Muscle strain	Neck strain, intermittent	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol	2000 - 04 Mar 2021 (Study Day 198)	Hypertension
Vitamins nos	2010 - Ongoing	General Health
Influenza vaccine	07 Oct 2020 (Study Day 50) - 07 Oct 2020 (Study Day 50)	Immunization
Paracetamol	04 Nov 2020 (Study Day 78) - 30 Nov 2020 (Study Day 104)	Left Ac Joint Soreness
Meloxicam	24 Nov 2020 (Study Day 98) - 30 Nov 2020 (Study Day 104)	Left Ac Joint Soreness
Tizanidine	24 Nov 2020 (Study Day 98) - 30 Nov 2020 (Study Day 104)	Left Ac Joint Soreness
Lidocaine	03 Dec 2020 (Study Day 107) - 03 Dec 2020 (Study Day 107)	Bursitis Of Left Shoulder
Methylprednisolone	03 Dec 2020 (Study Day 107) - 03 Dec 2020 (Study Day 107)	Bursitis Of Left Shoulder
Ciprofloxacin	07 Feb 2021 (Study Day 173) - 10 Feb 2021 (Study Day 176)	Urinary Tract Infection
Codeine phosphate; paracetamol	07 Feb 2021 (Study Day 173) - Ongoing	Fractured Right Elbow
Ct scan of head*	07 Feb 2021 (Study Day 173) - 07 Feb 2021 (Study Day 173)	Adverse Event
X-ray of right upper extremity*	07 Feb 2021 (Study Day 173) - 07 Feb 2021 (Study Day 173)	Adverse Event
Cefdinir	11 Feb 2021 (Study Day 177) - Ongoing	Colonic Fistula
Metoprolol	04 Mar 2021 (Study Day 198) - Ongoing	Worsening Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fall	Grade 2/moderate	Not related	07 Feb 2021 (Study Day 173) - 07 Feb 2021 (Study Day 173)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hand Fracture	Grade 2/moderate	Not related	07 Feb 2021 (Study Day 173) - 30 Mar 2021 (Study Day 224)
Rib Fracture	Grade 2/moderate	Not related	07 Feb 2021 (Study Day 173) - 30 Mar 2021 (Study Day 224)
Rib Fracture	Grade 2/moderate	Not related	07 Feb 2021 (Study Day 173) - 30 Mar 2021 (Study Day 224)
Upper Limb Fracture	Grade 2/moderate	Not related	07 Feb 2021 (Study Day 173) - 30 Mar 2021 (Study Day 224)
Urinary Tract Infection	Grade 2/moderate	Not related	07 Feb 2021 (Study Day 173) - 11 Feb 2021 (Study Day 177)
Hypertension	Grade 2/moderate	Not related	04 Mar 2021 (Study Day 198) - 01 Apr 2021 (Study Day 226)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US322-2422 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 31 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 25 Feb 2021 (Study Day 179)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 2/ moderate	Not related	28 Jan 2021 (Study Day 151) – 25 Feb 2021 (Study Day 179)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US322-2422, a 62-year-old Hispanic or Latino male, received the first dose of Placebo in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 28 Jan 2021. The participant was unblinded on 28 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 25 Feb 2021 (Study Day 179). The second dose was not administered.

Severe COVID-19 Details

On 28 Jan 2021 (Study Day 151), 150 days after the first dose in Part A/28 days before the first dose in Part B and 122 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 28 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 28 Jan 2021 (Study Day 151), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
28 Jan 2021 (Study Day 151)	Sore Throat	Mild
29 Jan 2021 (Study Day 152)	Cough	Moderate
29 Jan 2021 (Study Day 152)	Nasal Congestion	Moderate
30 Jan 2021 (Study Day 153)	Body Aches	Moderate
30 Jan 2021 (Study Day 153)	Cough	Moderate
30 Jan 2021 (Study Day 153)	Headache	Moderate
30 Jan 2021 (Study Day 153)	Nasal Congestion	Moderate
30 Jan 2021 (Study Day 153)	O2 Saturation (%)	93
31 Jan 2021 (Study Day 154)	Body Aches	Moderate
31 Jan 2021 (Study Day 154)	Cough	Moderate
31 Jan 2021 (Study Day 154)	Headache	Moderate
31 Jan 2021 (Study Day 154)	Nasal Congestion	Moderate
01 Feb 2021 (Study Day 155)	Body Aches	Mild
01 Feb 2021 (Study Day 155)	Cough	Moderate
02 Feb 2021 (Study Day 156)	Body Aches	Mild
02 Feb 2021 (Study Day 156)	Cough	Moderate
03 Feb 2021 (Study Day 157)	Body Aches	Mild
03 Feb 2021 (Study Day 157)	Cough	Mild
04 Feb 2021 (Study Day 158)	Body Aches	Mild
04 Feb 2021 (Study Day 158)	Cough	Mild
05 Feb 2021 (Study Day 159)	Cough	Mild
06 Feb 2021 (Study Day 160)	Body Aches	Moderate
06 Feb 2021 (Study Day 160)	Cough	Moderate
06 Feb 2021 (Study Day 160)	Runny Nose (Rhinorrhea)	Moderate
07 Feb 2021 (Study Day 161)	Cough	Mild
07 Feb 2021 (Study Day 161)	Runny Nose (Rhinorrhea)	Mild
08 Feb 2021 (Study Day 162)	Cough	Mild
08 Feb 2021 (Study Day 162)	Runny Nose (Rhinorrhea)	Mild
09 Feb 2021 (Study Day 163)	Cough	Mild
10 Feb 2021 (Study Day 164)	Body Aches	Mild
10 Feb 2021 (Study Day 164)	Cough	Mild
10 Feb 2021 (Study Day 164)	Runny Nose (Rhinorrhea)	Mild
11 Feb 2021 (Study Day 165)	Cough	Mild
12 Feb 2021 (Study Day 166)	Cough	Mild
12 Feb 2021 (Study Day 166)	Runny Nose (Rhinorrhea)	Mild
13 Feb 2021 (Study Day 167)	Cough	Mild
13 Feb 2021 (Study Day 167)	Runny Nose (Rhinorrhea)	Mild
13 Feb 2021 (Study Day 167)	Sore Throat	Mild
14 Feb 2021 (Study Day 168)	Cough	Mild
14 Feb 2021 (Study Day 168)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
15 Feb 2021 (Study Day 169)	Cough	Mild
15 Feb 2021 (Study Day 169)	Fatigue	Mild
16 Feb 2021 (Study Day 170)	Body Aches	Moderate
16 Feb 2021 (Study Day 170)	Cough	Mild
16 Feb 2021 (Study Day 170)	Headache	Mild
17 Feb 2021 (Study Day 171)	Cough	Mild
18 Feb 2021 (Study Day 172)	Cough	Mild
19 Feb 2021 (Study Day 173)	Cough	Mild
19 Feb 2021 (Study Day 173)	Nasal Congestion	Mild
20 Feb 2021 (Study Day 174)	Cough	Mild
20 Feb 2021 (Study Day 174)	Headache	Mild
21 Feb 2021 (Study Day 175)	Body Aches	Moderate
21 Feb 2021 (Study Day 175)	Cough	Mild
21 Feb 2021 (Study Day 175)	Headache	Mild
22 Feb 2021 (Study Day 176)	Body Aches	Mild
22 Feb 2021 (Study Day 176)	Headache	Mild
23 Feb 2021 (Study Day 177)	Body Aches	Moderate
23 Feb 2021 (Study Day 177)	Fatigue	Mild
23 Feb 2021 (Study Day 177)	Sore Throat	Mild
24 Feb 2021 (Study Day 178)	Body Aches	Moderate
24 Feb 2021 (Study Day 178)	Fatigue	Mild
24 Feb 2021 (Study Day 178)	Headache	Mild
24 Feb 2021 (Study Day 178)	Nasal Congestion	Mild
24 Feb 2021 (Study Day 178)	Sore Throat	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
30 Jan 2021 (Study Day 153)	Oxygen Saturation	93%
30 Jan 2021 - 31 Jan 2021 (Study Day 153-154)	Oxygen Saturation of SpO2 <= 93% on room air at sea level	Yes

The IP dose was not changed due to the COVID-19. The event of COVID-19 lasted for 29 days, after which it was considered to be recovered/resolved on 25 Feb 2021 (Study Day 179). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-055689	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	1994 - Ongoing
Seasonal allergy	Allergies seasonal	2014 - Ongoing
Hypertension	Hypertension	01 Feb 2016 (Study Day -1673) - Ongoing
Osteoarthritis	Osteoarthritis, unknown	2017 - Ongoing
Type 2 diabetes mellitus	Diabetes type ii	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	2014 - Ongoing	Seasonal Allergies
Nebivolol	2016 - Ongoing	Hypertension
Hydrochlorothiazide	01 Feb 2016 (Study Day -1673) - Ongoing	Hypertension
Naproxen	2017 - Ongoing	Osteoarthritis Pain
Semaglutide	01 Mar 2020 (Study Day -183) - Ongoing	Diabetes Mellitus Typeii
Paracetamol	28 Jan 2021 (Study Day 151) - 22 Feb 2021 (Study Day 176)	Fever/Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US323-2050 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 14 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Gastrointestinal Haemorrhage/ Gastrointestinal Bleed	SAE	Grade 3/ severe	Not related	04 Mar 2021 (Study Day 203) – 05 Mar 2021 (Study Day 204)	Recovered/ resolved
Hypotension/ Hypotension	SAE	Grade 3/ severe	Not related	04 Mar 2021 (Study Day 203) – 06 Mar 2021 (Study Day 205)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US323-2050, a 73-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Jan 2021. The participant was unblinded on 21 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 04 Mar 2021 (Study Day 203), 202 days after the first dose in Part A and 174 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of gastrointestinal haemorrhage. Action taken with the IP was not applicable. The event of gastrointestinal bleed lasted for 2 days, after which it was considered to be recovered/resolved on 05 Mar 2021 (Study Day 204). The investigator assessed the event of gastrointestinal haemorrhage to be not related to the IP.

On 04 Mar 2021 (Study Day 203), 202 days after the first dose in Part A and 174 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of hypotension. Action taken with the IP was not applicable. The event of hypotension lasted for 3 days, after which it was considered to be recovered/resolved on 06 Mar 2021 (Study Day 205). The investigator assessed the event of hypotension to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-036426	Gastrointestinal haemorrhage
MOD-2021-036426	Hypotension

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hepatic cirrhosis	Cirrhosis	Not reported - Ongoing
Portal hypertensive gastropathy	Portal hypertensive gastropathy	Not reported - Ongoing
Hepatic steatosis	Fatty liver	23 Mar 2009 (Study Day -4162) - Ongoing
Anaemia	Chronic anemia	23 May 2013 (Study Day -2640) - Ongoing
Vision correction operation	Laser vision correction	2015 - 2015
Colonoscopy	Colonoscopy secondary diverticulosis	2018 - 2018
Diverticulum	Diverticulosis	05 Jan 2018 (Study Day -952) - Ongoing
Denture wearer	Dentures	2020 - 2020
Type V hyperlipidaemia	Mixed hyperlipidemia	30 Jan 2020 (Study Day -197) - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	02 Feb 2020 (Study Day -194) - Ongoing
Type 2 diabetes mellitus	Diabetes (type ii)	20 Feb 2020 (Study Day -176) - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	20 Feb 2020 (Study Day -176) - Ongoing
Hypertension	Hypertension	16 Apr 2020 (Study Day -120) - Ongoing
Tendonitis	Left elbow tendonitis	15 Jul 2020 (Study Day -30) - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	10 Aug 2020 (Study Day -4) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Cardiac Prophylactic
Glimepiride	16 Apr 2020 (Study Day -120) - Ongoing	Diabetes
Lisinopril	16 Apr 2020 (Study Day -120) - Ongoing	Hypertension
Metformin; sitagliptin	16 Apr 2020 (Study Day -120) - Ongoing	Diabetes
Tamsulosin	10 Aug 2020 (Study Day -4) - Ongoing	Benign Prostatic Hyperplasia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Blood transfusion (packed red blood cells)*	04 Mar 2021 (Study Day 203) - 04 Mar 2021 (Study Day 203)	Adverse Event
Lovastatin	04 Mar 2021 (Study Day 203) - Ongoing	Worsening Mixed Hyperlipidemia
Octreotide acetate	04 Mar 2021 (Study Day 203) - 04 Mar 2021 (Study Day 203)	Upper Gastrointestinal Bleed
Octreotide acetate	04 Mar 2021 (Study Day 203) - 06 Mar 2021 (Study Day 205)	Upper Gastrointestinal Bleed
Ondansetron	04 Mar 2021 (Study Day 203) - 05 Mar 2021 (Study Day 204)	Nausea (Gastritis)
Pantoprazole sodium sesquihydrate	04 Mar 2021 (Study Day 203) - 04 Mar 2021 (Study Day 203)	Upper Gastrointestinal Bleed/Ulcer Of Duodenum
Pantoprazole sodium sesquihydrate	04 Mar 2021 (Study Day 203) - 06 Mar 2021 (Study Day 205)	Upper Gastrointestinal Bleed/Ulcer Of Duodenum
Paracetamol	04 Mar 2021 (Study Day 203) - 06 Mar 2021 (Study Day 205)	Pain (Stomach) Secondary To Gi Bleed
Promethazine	04 Mar 2021 (Study Day 203) - 06 Mar 2021 (Study Day 205)	Nausea (Gastritis)
Red blood cells	04 Mar 2021 (Study Day 203) - 05 Mar 2021 (Study Day 204)	Upper Gastrointestinal Bleed/Worsening Severe Acute Chronic Symptomatic Anemia/Esophageal Varices
Sodium chloride	04 Mar 2021 (Study Day 203) - 06 Mar 2021 (Study Day 205)	Hypotension
Sodium chloride	04 Mar 2021 (Study Day 203) - 06 Mar 2021 (Study Day 205)	Peripheral Iv Flush (Preventive)
Chlorhexidine gluconate	05 Mar 2021 (Study Day 204) - 05 Mar 2021 (Study Day 204)	Pre-Operative Protocol (Egd)
Esophagogastroduodenoscopy*	05 Mar 2021 (Study Day 204) - 05 Mar 2021 (Study Day 204)	Adverse Event
Fentanyl	05 Mar 2021 (Study Day 204) - 05 Mar 2021 (Study Day 204)	Pain(Stomach) /Anesthesia (Egd)
Flumazenil	05 Mar 2021 (Study Day 204) - 05 Mar 2021 (Study Day 204)	Preventive Of Anesthesia Overdose
Lidocaine	05 Mar 2021 (Study Day 204) - 05 Mar 2021 (Study Day 204)	Esophagogastroduodenoscopy
Midazolam hydrochloride	05 Mar 2021 (Study Day 204) - 05 Mar 2021 (Study Day 204)	Anesthesia (Egd)
Naloxone hydrochloride	05 Mar 2021 (Study Day 204) - 05 Mar 2021 (Study Day 204)	Preventive Of Anesthesia Overdose
Propofol	05 Mar 2021 (Study Day 204) - 05 Mar 2021 (Study Day 204)	Esophagogastroduodenoscopy

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anaemia	Grade 3/severe	Not related	04 Mar 2021 (Study Day 203) - Ongoing

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Duodenal Ulcer	Grade 3/severe	Not related	04 Mar 2021 (Study Day 203) - 05 Mar 2021 (Study Day 204)
Type V Hyperlipidaemia	Grade 2/moderate	Not related	04 Mar 2021 (Study Day 203) - Ongoing
Gastritis	Grade 3/severe	Not related	05 Mar 2021 (Study Day 204) - 06 Mar 2021 (Study Day 205)
Hepatic Cirrhosis	Grade 2/moderate	Not related	05 Mar 2021 (Study Day 204) - Ongoing
Portal Hypertensive Gastropathy	Grade 2/moderate	Not related	05 Mar 2021 (Study Day 204) - Ongoing
Varices Oesophageal	Grade 3/severe	Not related	05 Mar 2021 (Study Day 204) - 06 Mar 2021 (Study Day 205)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US323-2063 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 18 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 25 Sep 2020 (Study Day 39)
First Dose of Vaccine in Part B: 29 Jan 2021 (Study Day 165)
Second Dose of Vaccine in Part B: 26 Feb 2021 (Study Day 193)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Meningitis/Acute Meningitis	SAE	Grade 2/ moderate	Not related	13 Apr 2021 (Study Day 239) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US323-2063, a 66-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 18 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 39). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 29 Jan 2021. The participant was unblinded on 29 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 29 Jan 2021 (Study Day 165). The second dose was administered in the right arm on 26 Feb 2021 (Study Day 193).

Event Details

On 13 Apr 2021 (Study Day 239), 238 days after the first dose in Part A/74 days after the first dose in Part B and 200 days after the second dose in Part A/46 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of meningitis. Action taken with the IP was not applicable. The event of acute meningitis was considered to be ongoing. The investigator assessed the event of meningitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-079879	Meningitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	1980 - Ongoing
Depression	Depression	1986 - Ongoing
Anaemia	Anemia	2000 - Ongoing
Osteoarthritis	Osteoarthritis	2003 - 2004
Postmenopause	Post menopausal	2010 - Ongoing
Cataract	Cataracts	2018 - Ongoing
Asthma	Asthma	2019 - Ongoing
Blood cholesterol increased	Elevated cholesterol	2019 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2019 - Ongoing
Hypertension	High blood pressure	2019 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	2019 - Ongoing
Migraine	Migraine headaches	2019 - Ongoing
Seasonal allergy	Seasonal allergic rhinitis	2019 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2019 - Ongoing
Nausea	Nausea	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Nortriptyline	2016 - Ongoing	Depression
Atorvastatin	2019 - Ongoing	Hyperlipidemia
Baclofen	2019 - Ongoing	Migraine
Bupropion hydrochloride	2019 - Ongoing	Migraine
Calcium citrate; vitamin d nos	2019 - Ongoing	Maintenance
Cetirizine	2019 - Ongoing	Seasonal Allergic Rhinitis
Erenumab	2019 - Ongoing	Migraine
Lubiprostone	2019 - Ongoing	Irritable Bowel Syndrome
Metoprolol	2019 - Ongoing	Hypertension
Ramipril	2019 - 18 Jan 2021 (Study Day 154)	Hypertension
Triamcinolone acetonide	2019 - Ongoing	Seasonal Allergic Rhinitis
Vitamin d nos	2019 - Ongoing	Bone Health Prophylactic
Prochlorperazine	25 Jun 2020 (Study Day -54) - Ongoing	Nausea

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Apixaban	27 Aug 2020 (Study Day 10) - 09 Oct 2020 (Study Day 53)	Atrial Fibrillation
Influenza vaccine inact split 3v	11 Sep 2020 (Study Day 25) - 11 Sep 2020 (Study Day 25)	Immunization
Doxylamine; phenylephrine	28 Oct 2020 (Study Day 72) - 14 Nov 2020 (Study Day 89)	Rhinorrhea
Warfarin sodium	10 Dec 2020 (Study Day 115) - 10 Jan 2021 (Study Day 146)	Atrial Fibrillation
Diphenhydramine hydrochloride	05 Jan 2021 (Study Day 141) - 21 Jan 2021 (Study Day 157)	Runny Nose
Warfarin sodium	11 Jan 2021 (Study Day 147) - 11 Jan 2021 (Study Day 147)	Atrial Fibrillation
Warfarin sodium	12 Jan 2021 (Study Day 148) - 14 Jan 2021 (Study Day 150)	Atrial Fibrillation
Warfarin sodium	15 Jan 2021 (Study Day 151) - 15 Jan 2021 (Study Day 151)	Atrial Fibrillation
Warfarin sodium	16 Jan 2021 (Study Day 152) - 24 Jan 2021 (Study Day 160)	Atrial Fibrillation
Warfarin sodium	25 Jan 2021 (Study Day 161) - 25 Jan 2021 (Study Day 161)	Atrial Fibrillation
Warfarin sodium	26 Jan 2021 (Study Day 162) - Ongoing	Atrial Fibrillation
Sulfamethoxazole; trimethoprim	02 Feb 2021 (Study Day 169) - 13 Feb 2021 (Study Day 180)	Nasal Vestibulitis
Doxycycline monohydrate	03 Feb 2021 (Study Day 170) - 13 Feb 2021 (Study Day 180)	Nasal Vestibulitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nasal Vestibulitis	Grade 1/mild	Not related	02 Feb 2021 (Study Day 169) - 13 Feb 2021 (Study Day 180)
Injection Site Pain	Grade 1/mild	Related	26 Feb 2021 (Study Day 193) - 05 Mar 2021 (Study Day 200)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US323-2157 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 07 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 11 Feb 2021 (Study Day 156)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pancreatic Carcinoma Metastatic/Metastatic Pancreatic Cancer	SAE, AE leading to withdrawal from IP	Grade 3/severe	Not related	22 Mar 2021 (Study Day 195) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US323-2157, a 62-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Feb 2021. The participant was unblinded on 11 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 11 Feb 2021 (Study Day 156). The second dose was not administered.

Event Details

On 22 Mar 2021 (Study Day 195), 194 days after the first dose in Part A/39 days after the first dose in Part B and 166 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of pancreatic carcinoma metastatic. The IP dose was withdrawn due to the metastatic pancreatic cancer. The event of metastatic pancreatic cancer was considered to be ongoing. The investigator assessed the event of pancreatic carcinoma metastatic to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-070902	Pancreatic carcinoma metastatic

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraine headaches	1980 - Ongoing
Neck surgery	Cervical surgery	1998 - 1998
Hyperlipidaemia	Hyperlipidemia	2000 - Ongoing
Vision correction operation	Laser vision correction	2005 - 2005
Herpes simplex	Herpes simplex virus 2 (face)	29 Aug 2013 (Study Day -2568) - Ongoing
Back pain	Recurrent back pain	2016 - Ongoing
Osteoarthritis	Osteoarthritis	2016 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2018 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2018 - Ongoing
Cataract	Cataracts	2019 - 2019
Blood donor	Frequent blood donor	15 Mar 2020 (Study Day -178) - 15 Mar 2020 (Study Day -178)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2000 - Ongoing	Cardiac Prophylactic
Atorvastatin	2000 - Ongoing	Hyperlipidemia
Famotidine	2018 - Ongoing	Reflux
Pantoprazole	2018 - Ongoing	Gerd
Valaciclovir	05 Apr 2019 (Study Day -523) - Ongoing	Herpes Simplex Virus 2 (Face)
Ascorbic acid	08 Jan 2021 (Study Day 122) - 22 Jan 2021 (Study Day 136)	COVID-19
Azithromycin	08 Jan 2021 (Study Day 122) - 08 Jan 2021 (Study Day 122)	COVID-19
Azithromycin	08 Jan 2021 (Study Day 122) - 12 Jan 2021 (Study Day 126)	COVID-19
Budesonide	08 Jan 2021 (Study Day 122) - Ongoing	Pulmonary Infiltrates
Colecalciferol	08 Jan 2021 (Study Day 122) - 22 Jan 2021 (Study Day 136)	COVID-19
Melatonin	08 Jan 2021 (Study Day 122) - 22 Jan 2021 (Study Day 136)	COVID-19
Zinc	08 Jan 2021 (Study Day 122) - 22 Jan 2021 (Study Day 136)	COVID-19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dietary supplement	15 Feb 2021 (Study Day 160) - Ongoing	Gastroenteritis
Simeticone	15 Feb 2021 (Study Day 160) - Ongoing	Gastroenteritis
Naproxen sodium	25 Feb 2021 (Study Day 170) - 10 Mar 2021 (Study Day 183)	Abdominal Pain
Dicycloverine	08 Mar 2021 (Study Day 181) - Ongoing	Gastric Emptying Secondary To Cholangitis
Fentanyl	11 Mar 2021 (Study Day 184) - Ongoing	Abdominal Pain (Pancreatic Mass)
Metoclopramide	11 Mar 2021 (Study Day 184) - Ongoing	Gastric Emptying Secondary To Cholangitis
Mirtazapine	11 Mar 2021 (Study Day 184) - Ongoing	Insomnia
Tramadol hydrochloride	11 Mar 2021 (Study Day 184) - 11 Mar 2021 (Study Day 184)	Abdominal Pain
Enoxaparin sodium	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)	Prophylactic Cardiac
Esophagogastroduodenoscopy*	12 Mar 2021 (Study Day 185) - 12 Mar 2021 (Study Day 185)	Adverse Event
Lidocaine hydrochloride	12 Mar 2021 (Study Day 185) - 12 Mar 2021 (Study Day 185)	Pre-Op Egd
Morphine	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)	Abdominal Pain
Paracetamol	12 Mar 2021 (Study Day 185) - 12 Mar 2021 (Study Day 185)	Fever
Piperacillin; tazobactam	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)	Cholangitis/Sepsis
Promethazine	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)	Nausea Secondary To Worsening Gastroesophageal Reflux Disease
Propofol	12 Mar 2021 (Study Day 185) - 12 Mar 2021 (Study Day 185)	Anesthesia Egd Secondary To Abdominal Pain
Sodium chloride	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)	Fluid Resuscitation Secondary To Dehydration
Endoscopic retrograde cholangiopancreatography*	13 Mar 2021 (Study Day 186) - 13 Mar 2021 (Study Day 186)	Adverse Event
Levofloxacin	13 Mar 2021 (Study Day 186) - 23 Mar 2021 (Study Day 196)	Cholangitis/Sepsis
Metronidazole	13 Mar 2021 (Study Day 186) - 23 Mar 2021 (Study Day 196)	Sepsis/Cholangitis
Ondansetron	13 Mar 2021 (Study Day 186) - Ongoing	Nausea Secondary To Worsening Gastroesophageal Reflux Disease
Promethazine	13 Mar 2021 (Study Day 186) - Ongoing	Nausea Secondary To Worsening Gastroesophageal Reflux Disease
Laparoscopic biopsy of peritoneal and omental masses with frozen section and infusaport placement*	25 Mar 2021 (Study Day 198) - 25 Mar 2021 (Study Day 198)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pancreatic Carcinoma	Grade 3/severe	Not related	26 Feb 2021 (Study Day 171) - Ongoing
Abdominal Pain	Grade 2/moderate	Not related	07 Mar 2021 (Study Day 180) - Ongoing
Insomnia	Grade 2/moderate	Not related	11 Mar 2021 (Study Day 184) - Ongoing
Pyrexia	Grade 2/moderate	Not related	11 Mar 2021 (Study Day 184) - 13 Mar 2021 (Study Day 186)
Bile Duct Obstruction	Grade 3/severe	Not related	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)
Cholangitis	Grade 3/severe	Not related	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)
Early Satiety	Grade 3/severe	Not related	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)
Gastroesophageal Reflux Disease	Grade 3/severe	Not related	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)
Sepsis	Grade 3/severe	Not related	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)
Transaminases Increased	Grade 3/severe	Not related	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US323-2162 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardiac Failure Congestive/ Acute Exacerbation Of Congestive Heart Failure	SAE	Grade 3/ severe	Not related	29 Jan 2021 (Study Day 141) – 02 Feb 2021 (Study Day 145)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US323-2162, a 68-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 15 Jan 2021. The participant was unblinded on 15 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 29 Jan 2021 (Study Day 141), 140 days after the first dose in Part A and 112 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of cardiac failure congestive. Action taken with the IP was not applicable. The event of acute exacerbation of congestive heart failure lasted for 5 days, after which it was considered to be recovered/resolved on 02 Feb 2021 (Study Day 145). The investigator assessed the event of cardiac failure congestive to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012506	Cardiac failure congestive

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Diverticulum	Diverticulosis	2010 - Ongoing
Hypertension	Hypertension	01 Oct 2012 (Study Day -2902) - Ongoing
Cataract	Cataracts bilateral eyes	2015 - 2015
Myopia	Myopia (eyeglasses)	2015 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2015 - Ongoing
Prostatic operation	Prostate surgery	2019 - 2019
Benign prostatic hyperplasia	Benign prostatic hyperplasia	04 Nov 2019 (Study Day -312) - Ongoing
Cardiac failure congestive	Chronic diastolic and systolic congestive heart failure	21 May 2020 (Study Day -113) - Ongoing
Basal cell carcinoma	Basal cell skin cancer	10 Sep 2020 (Study Day -1) - 10 Sep 2020 (Study Day -1)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	2015 - 31 Jan 2021 (Study Day 143)	Type 2 Diabetes
Losartan	Nov 2019 - 29 Jan 2021 (Study Day 141)	Prophylactic Renal Protection
Carvedilol	31 Jan 2021 (Study Day 143) - 24 Feb 2021 (Study Day 167)	Worsened Hypertension
Cta of chest with echocardiogram*	31 Jan 2021 (Study Day 143) - 31 Jan 2021 (Study Day 143)	Adverse Event
Dapagliflozin propanediol monohydrate	31 Jan 2021 (Study Day 143) - 08 Feb 2021 (Study Day 151)	Worsening Of Diabetes
Furosemide	31 Jan 2021 (Study Day 143) - Ongoing	Acute Exacerbation Of Congestive Heart Failure
Furosemide	31 Jan 2021 (Study Day 143) - 31 Jan 2021 (Study Day 143)	Acute Exacerbation Of Congestive Heart Failure
Sacubitril	31 Jan 2021 (Study Day 143) - 14 Mar 2021 (Study Day 185)	Acute Exacerbation Of Congestive Heart Failure
Spironolactone	31 Jan 2021 (Study Day 143) - Ongoing	Acute Exacerbation Of Congestive Heart Failure
Valsartan	31 Jan 2021 (Study Day 143) - 14 Mar 2021 (Study Day 185)	Acute Exacerbation Of Congestive Heart Failure
Carvedilol	25 Feb 2021 (Study Day 168) - Ongoing	Worsened Chronic Essential Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sacubitril	15 Mar 2021 (Study Day 186) - Ongoing	Chronic Congestive Heart Failure
Valsartan	15 Mar 2021 (Study Day 186) - Ongoing	Chronic Diastolic And Systolic Combined Congestive Heart Failure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Bundle Branch Block Right	Grade 1/mild	Not related	31 Jan 2021 (Study Day 143) - 25 Feb 2021 (Study Day 168)
Essential Hypertension	Grade 2/moderate	Not related	31 Jan 2021 (Study Day 143) - Ongoing
Type 2 Diabetes Mellitus	Grade 2/moderate	Not related	31 Jan 2021 (Study Day 143) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US324-2081 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 13 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Sepsis/Severe Sepsis	SAE	Grade 4	Not related	01 Apr 2021 (Study Day 232) – 03 Apr 2021 (Study Day 234)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US324-2081, a 76-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 01 Apr 2021 (Study Day 232), 231 days after the first dose in Part A and 202 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of sepsis. Action taken with the IP was not applicable. The event of severe sepsis lasted for 3 days, after which it was considered to be recovered/resolved on 03 Apr 2021 (Study Day 234). The investigator assessed the event of sepsis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-067824	Sepsis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cardiac pacemaker insertion	Pacemaker placement	1994 - 1994
Coronary artery bypass	Coronary artery bypass graft	1994 - 1994
Coronary artery disease	Coronary artery disease	1994 - Ongoing
Hypertension	Hypertension	1994 - Ongoing
Neuropathy peripheral	Neuropathy, bilateral feet	1995 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2000 - Ongoing
Coronary artery bypass	Coronary artery bypass graft	2010 - 2010
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2015 - Ongoing
Arrhythmia	Arrhythmia	10 May 2018 (Study Day -826) - 10 May 2018 (Study Day -826)
Implantable defibrillator insertion	Defibrillator placement	10 May 2018 (Study Day -826) - 10 May 2018 (Study Day -826)
Cardiac arrest	Cardiac arrest	18 May 2018 (Study Day -818) - 18 May 2018 (Study Day -818)
Musculoskeletal pain	Shoulder pain, right	13 May 2020 (Study Day -92) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	1994 - Ongoing	Heart Health
Atenolol	1994 - Ongoing	Hypertension
Atorvastatin	2000 - Ongoing	Hypercholesterolemia
Lisinopril	2000 - Ongoing	Hypertension
Pregabalin	2005 - Ongoing	Neuropathy, Bilateral Feet
Clopidogrel	2012 - Ongoing	Cad
Vitamins nos	2012 - Ongoing	Vitamin Supplement
Omeprazole	2015 - Ongoing	Gerd
Colecalciferol	2019 - Ongoing	Vitamin Supplement
Vitamin b12 nos	2019 - Ongoing	Vitamin Supplement
Methylprednisolone sodium succinate	09 Sep 2020 (Study Day 28) - 09 Sep 2020 (Study Day 28)	Insect Bites To Left Leg

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US324-2102 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 15 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Sep 2020 (Study Day 31)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Left Ventricular Failure/Acute Diastolic Congestive Heart Failure	SAE	Grade 4	Not related	04 Apr 2021 (Study Day 233) – 14 Apr 2021 (Study Day 243)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US324-2102, a 79-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 15 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 04 Apr 2021 (Study Day 233), 232 days after the first dose in Part A and 202 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of acute left ventricular failure. Action taken with the IP was not applicable. The event of acute diastolic congestive heart failure lasted for 11 days, after which it was considered to be recovered/resolved on 14 Apr 2021 (Study Day 243). The investigator assessed the event of acute left ventricular failure to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-069275	Acute left ventricular failure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1990 - Ongoing
Benign prostatic hyperplasia	Benign prostate hyperplasia	1996 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2008 - Ongoing
Hypothyroidism	Hypothyroidism	2010 - Ongoing
Neck pain	Neck pain	2010 - Ongoing
Atrial fibrillation	Atrial fibrillation	2015 - Ongoing
Bradycardia	Bradycardia	2015 - Ongoing
Cataract	Cataracts, bilateral	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Losartan	1990 - Ongoing	Hypertension
Doxazosin	1996 - Ongoing	Benign Prostatic Hyperplasia
Atorvastatin	2008 - Ongoing	Hyperlipidemia
Nicotinic acid	2008 - Ongoing	Hypercholesterolemia
Atenolol	2010 - Ongoing	Hypertension
Carisoprodol	2010 - Ongoing	Neck Pain
Cinnamomum verum bark	2010 - Ongoing	Gastrointestinal Health
Levothyroxine	2010 - Ongoing	Hypothyroidism
Acetylsalicylic acid	2015 - Ongoing	Atrial Fibrillation
Furosemide	2015 - 07 Apr 2021 (Study Day 236)	Hypertension
Propafenone	2015 - Ongoing	Atrial Fibrillation
Warfarin sodium	2015 - Ongoing	Atrial Fibrillation
Nifedipine	2017 - 03 Apr 2021 (Study Day 232)	Hypertension
Lactobacillus rhamnosus	2019 - Ongoing	Gastrointestinal Health
Paracetamol	14 Sep 2020 (Study Day 31) - 15 Sep 2020 (Study Day 32)	Fever / Chills
Bromfenac; gatifloxacin; prednisolone acetate	23 Mar 2021 (Study Day 221) - Ongoing	Cataracts, Bilateral
Bromfenac; prednisolone	23 Mar 2021 (Study Day 221) - Ongoing	Cataracts, Bilateral
Cataract removal, left eye*	23 Mar 2021 (Study Day 221) - 23 Mar 2021 (Study Day 221)	Medical History

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Macrogol 400	23 Mar 2021 (Study Day 221) - Ongoing	Cataracts, Bilateral

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US325-2215 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 17 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 07 Jan 2021 (Study Day 144)
Second Dose of Vaccine in Part B: 04 Feb 2021 (Study Day 172)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Peripheral Arterial Occlusive Disease/Worsening Peripheral Artery Disease	SAE	Grade 2/ moderate	Not related	01 Mar 2021 (Study Day 197) – 23 Mar 2021 (Study Day 219)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2215, a 65-year-old Hispanic or Latino male, received the first dose of Placebo in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 07 Jan 2021. The participant was unblinded on 07 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 07 Jan 2021 (Study Day 144). The second dose was administered in the left arm on 04 Feb 2021 (Study Day 172).

Event Details

On 01 Mar 2021 (Study Day 197), 196 days after the first dose in Part A/53 days after the first dose in Part B and 168 days after the second dose in Part A/25 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of peripheral arterial occlusive disease. The IP dose was not changed due to the worsening peripheral artery disease. The event of worsening peripheral artery disease lasted for 23 days, after which it was considered to be recovered/resolved on 23 Mar 2021 (Study Day 219). The investigator assessed the event of peripheral arterial occlusive disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-077537	Peripheral arterial occlusive disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hernia repair	Hernia repair	Jan 1995 - Jan 1995
Hypertension	Hypertension	2010 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2010 - Ongoing
Asthma	Asthma	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Allopurinol	2010 - Ongoing	Type 2 Diabetes
Atenolol	2010 - Ongoing	Hypertension
Glibenclamide; metformin	2010 - Ongoing	Type 2 Diabetes
Lisinopril	2010 - Ongoing	Hypertension
Fluticasone propionate; salmeterol xinafoate	2015 - Ongoing	Asthma
Linagliptin	2017 - Ongoing	Type 2 Diabetes
Influenza vaccine	28 Sep 2020 (Study Day 43) - 28 Sep 2020 (Study Day 43)	Influenza Prophylaxis
Femoral endarterectomy*	23 Mar 2021 (Study Day 219) - 23 Mar 2021 (Study Day 219)	Adverse Event
Rivaroxaban	23 Mar 2021 (Study Day 219) - Ongoing	Post Femoral Endarterectomy

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US325-2382 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 29 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 26 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 09 Mar 2021 (Study Day 193)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chest Pain/Atypical Chest Pain	SAE	Grade 2/ moderate	Not related	13 Apr 2021 (Study Day 228) – 15 Apr 2021 (Study Day 230)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2382, a 58-year-old Hispanic or Latino female, received the first dose of Placebo in the right arm on 29 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 26 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 09 Mar 2021. The participant was unblinded on 09 Mar 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 09 Mar 2021 (Study Day 193). The second dose was not administered.

Event Details

On 13 Apr 2021 (Study Day 228), 227 days after the first dose in Part A/35 days after the first dose in Part B and 199 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 2/moderate serious adverse event of chest pain. Action taken with the IP was not applicable. The event of atypical chest pain lasted for 3 days, after which it was considered to be recovered/resolved on 15 Apr 2021 (Study Day 230). The investigator assessed the event of chest pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-078777	Chest pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Menopause	Menopause	1990 - Ongoing
Adenomyosis	Adenomyosis	Jan 1990 - Jan 1990
Hysterectomy	Hysterectomy	Jan 1990 - Jan 1990
Uterine leiomyoma	Uterine fibroids	Jan 1990 - Jan 1990
Breast conserving surgery	Cancerous lumpectomy of left breast	Jan 2015 - Jan 2015
Lymphadenectomy	Lymphadenectomy of upper left extremity	Jan 2015 - Jan 2015
Breast cancer	Breast cancer on left breast in remission	May 2015 - 25 Mar 2016 (Study Day -1618)
Osteoporosis	Osteoporosis	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Anastrozole	2016 - Ongoing	Estrogen Control For Breast Cancer
Denosumab	2016 - Ongoing	Osteoporosis
Venlafaxine	2016 - Ongoing	Menopause
Calcium	Mar 2016 - Ongoing	General Health
Ascorbic acid	May 2020 - Ongoing	General Health
Vitamin b1 nos	May 2020 - Ongoing	General Health
Vitamin d nos	May 2020 - Ongoing	General Health

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US325-2399 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Sep 2020 (Study Day 28)
First Dose of Vaccine in Part B: 22 Jan 2021 (Study Day 144)
Second Dose of Vaccine in Part B: 26 Feb 2021 (Study Day 179)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cervical Dysplasia/ Cervical Dysplasia	SAE	Grade 4	Not related	08 Mar 2021 (Study Day 189) – 09 Mar 2021 (Study Day 190)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2399, a 47-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 22 Jan 2021. The participant was unblinded on 22 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 22 Jan 2021 (Study Day 144). The second dose was administered in the left arm on 26 Feb 2021 (Study Day 179).

Event Details

On 08 Mar 2021 (Study Day 189), 188 days after the first dose in Part A/45 days after the first dose in Part B and 161 days after the second dose in Part A/10 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of cervical dysplasia. Action taken with the IP was not applicable. The event of cervical dysplasia lasted for 2 days, after which it was considered to be recovered/resolved on 09 Mar 2021 (Study Day 190). The investigator assessed the event of cervical dysplasia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-060187	Cervical dysplasia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hysterectomy	Hysterectomy	Jan 2013 - Jan 2013
Polycystic ovaries	Polycystic ovary syndrome	Jan 2013 - Jan 2013
Keratomileusis	Lasik	Mar 2017 - Mar 2017
Myopia	Myopia	Mar 2017 - Mar 2017
Glucose tolerance impaired	Prediabetes	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Mar 2020 - Ongoing	General Health
Ascorbic acid	Mar 2020 - Ongoing	General Health
Zinc	Mar 2020 - Ongoing	General Health
Trachelectomy surgery*	08 Mar 2021 (Study Day 189) - 08 Mar 2021 (Study Day 189)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US325-2624 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 05 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 04 Nov 2020 (Study Day 31)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia Bacterial/Bacterial Pneumonia	SAE	Grade 3/ severe	Not related	12 Apr 2021 (Study Day 190) – 17 Apr 2021 (Study Day 195)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2624, a 33-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 05 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 04 Nov 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 17 Mar 2021. The participant was unblinded on 17 Mar 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 12 Apr 2021 (Study Day 190), 189 days after the first dose in Part A and 159 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of pneumonia bacterial. Action taken with the IP was not applicable. The event of bacterial pneumonia lasted for 6 days, after which it was considered to be recovered/resolved on 17 Apr 2021 (Study Day 195). The investigator assessed the event of pneumonia bacterial to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-084398	Pneumonia bacterial

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2016 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	Mar 2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide; valsartan	2016 - Ongoing	Hypertension
Ibuprofen	06 Oct 2020 (Study Day 2) - 06 Oct 2020 (Study Day 2)	Arm Pain
Ibuprofen	04 Nov 2020 (Study Day 31) - 04 Nov 2020 (Study Day 31)	Arm Pain
Dulaglutide	23 Dec 2020 (Study Day 80) - Ongoing	Diabetes Type 2
Metformin	23 Dec 2020 (Study Day 80) - Ongoing	Diabetes Type 2

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US326-2027 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 28 Jul 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 21 Sep 2020 (Study Day 56)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia/Pneumonia	SAE	Grade 3/severe	Not related	08 Apr 2021 (Study Day 255) – 11 Apr 2021 (Study Day 258)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US326-2027, a 72-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 28 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 56). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Feb 2021. The participant was unblinded on 04 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 08 Apr 2021 (Study Day 255), 254 days after the first dose in Part A and 199 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of pneumonia lasted for 4 days, after which it was considered to be recovered/resolved on 11 Apr 2021 (Study Day 258). The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-080955	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Chronic back pain	2014 - Ongoing
Muscle spasms	Muscle spasms	2014 - Ongoing
Depression	Depression	2018 - Ongoing
Onychomycosis	Onychomycosis of toes bilaterally	Apr 2019 - Ongoing
Cardiac failure congestive	Congestive heart failure	Apr 2020 - Ongoing
Oedema peripheral	Bilateral lower extremity edema	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Baclofen	2014 - Ongoing	Muscle Spasms
Morphine sulfate	2014 - Ongoing	Chronic Back Pain
Escitalopram	2018 - Ongoing	Depression
Furosemide	Apr 2020 - Ongoing	Lower Extremity Edema
Potassium chloride	Apr 2020 - Ongoing	Nutritional Support
Terbinafine	Apr 2020 - Ongoing	Onychomycosis Of Toes
Ibuprofen	22 Aug 2020 (Study Day 26) - Ongoing	Headache
Ibuprofen	22 Aug 2020 (Study Day 26) - Ongoing	Muscle Body Aches

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US326-2115 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 06 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pulmonary Embolism/ Pulmonary Embolism	SAE	Grade 3/ severe	Not related	03 Apr 2021 (Study Day 241) – 06 Apr 2021 (Study Day 244)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US326-2115, a 57-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Jan 2021. The participant was unblinded on 21 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 03 Apr 2021 (Study Day 241), 240 days after the first dose in Part A and 212 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of pulmonary embolism. The IP dose was not changed due to the pulmonary embolism. The event of pulmonary embolism lasted for 4 days, after which it was considered to be recovered/resolved on 06 Apr 2021 (Study Day 244). The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-073161	Pulmonary embolism

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dyslipidaemia	Dyslipidemia	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2019 - Ongoing	Dyslipidemia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US326-2133 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 07 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 05 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Biliary Colic/Epigastric Pain Due To Recurrent Biliary Colic	SAE	Grade 3/ severe	Not related	08 Mar 2021 (Study Day 214) – 10 Mar 2021 (Study Day 216)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US326-2133, a 58-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 05 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 28 Jan 2021. The participant was unblinded on 28 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 08 Mar 2021 (Study Day 214), 213 days after the first dose in Part A and 184 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of biliary colic. Action taken with the IP was not applicable. The event of epigastric pain due to recurrent biliary colic lasted for 3 days, after which it was considered to be recovered/resolved on 10 Mar 2021 (Study Day 216). The investigator assessed the event of biliary colic to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-053779	Biliary colic

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1990 - Ongoing
Gastroesophageal reflux disease	Gastric esophageal reflex disease	2001 - Ongoing
Depression	Depression	2002 - Ongoing
Hysterectomy	Complete hysterectomy	2002 - Dec 2002
Food allergy	Allergy to food (shellfish)	2008 - Ongoing
Colitis	Intermittent colitis	Jul 2012 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	Jan 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fexofenadine hydrochloride	2010 - Ongoing	Asthma
Lansoprazole	2010 - Ongoing	Gastric Esophageal Reflux Disease
Amlodipine	2015 - Ongoing	Hypertension
Citalopram	2018 - Jan 2021	Depression
Famotidine	Jan 2020 - Ongoing	Gastric Esophageal Reflux Disease
Lisinopril	Jan 2020 - Ongoing	Hypertension
Fluticasone furoate; vilanterol trifenate	Jun 2020 - Jan 2021	Asthma
Naproxen sodium	08 Aug 2020 (Study Day 2) - 08 Aug 2020 (Study Day 2)	Pain At Injection Site
Naproxen sodium	06 Sep 2020 (Study Day 31) - 07 Sep 2020 (Study Day 32)	Fever And Pain At Injection Site, Headache
Cefdinir	29 Sep 2020 (Study Day 54) - Ongoing	Sinus Infection
Epinephrine	07 Nov 2020 (Study Day 93) - 07 Nov 2020 (Study Day 93)	Anaphylaxis Reaction
Citalopram	Jan 2021 - Ongoing	Depression
Fluticasone propionate; salmeterol xinafoate	Jan 2021 - Ongoing	Asthma
Nitrofurantoin	Feb 2021 - Feb 2021	Urinary Tract Infection
Doxycycline	15 Feb 2021 (Study Day 193) - 24 Feb 2021 (Study Day 202)	Urinary Tract Infection
Robot xi assisted cholecystectomy*	09 Mar 2021 (Study Day 215) - 09 Mar 2021 (Study Day 215)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 179) - 24 Feb 2021 (Study Day 202)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US326-2259 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 07 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 26 Jan 2021 (Study Day 140)
Second Dose of Vaccine in Part B: 03 Mar 2021 (Study Day 176)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diarrhoea/Diarrhea Of Unknown Etiology	SAE	Grade 3/ severe	Not related	01 May 2021 (Study Day 235) – Ongoing	Unknown

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The MedDRA Preferred Term/ Verbatim Term of Diarrhoea/Diarrhea Of Unknown Etiology was updated to Atrial fibrillation/New Onset Atrial Fibrillation after the database lock.

Participant US326-2259, a 54-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 26 Jan 2021. The participant was unblinded on 26 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 26 Jan 2021 (Study Day 140). The second dose was administered in the left arm on 03 Mar 2021 (Study Day 176).

Event Details

On 01 May 2021 (Study Day 235), 234 days after the first dose in Part A/95 days after the first dose in Part B and 206 days after the second dose in Part A/59 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of diarrhoea. The IP dose was not changed due to the diarrhea of unknown etiology. The outcome of the event was unknown. The investigator assessed the event of diarrhoea to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-101439	Atrial fibrillation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	2000 - Ongoing
Overweight	Overweight	2005 - Ongoing
Hypertension	Hypertension	2012 - Ongoing
Nerve compression	Pinched nerve	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2012 - Ongoing	Hypertension
Benazepril	2016 - Ongoing	Hypertension
Hydrochlorothiazide	2016 - Ongoing	Hypertension
Gabapentin	2019 - Mar 2021	Pinched Nerve

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US327-2060 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 06 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Suicide Attempt/Suicide Attempt	SAE	Grade 3/ severe	Not related	21 Feb 2021 (Study Day 200) – 21 Feb 2021 (Study Day 200)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US327-2060, a 22-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 15 Jan 2021. The participant was unblinded on 15 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 21 Feb 2021 (Study Day 200), 199 days after the first dose in Part A and 171 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of suicide attempt. Action taken with the IP was not applicable. The event of suicide attempt lasted for 1 day, after which it was considered to be recovered/resolved on 21 Feb 2021 (Study Day 200). The investigator assessed the event of suicide attempt to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-026615	Suicide attempt

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2002 - Ongoing
Depression	Depression	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Aripiprazole	2010 - Ongoing	Attention Deficit Hyperactive Disorder
Atomoxetine hydrochloride	2010 - Ongoing	Attention Deficit Hyperactivity Disorder
Buspirone hydrochloride	2010 - Ongoing	Depression
Clonidine	2010 - Ongoing	Attention Deficit Hyperactivity Disorder
Clozapine	2010 - Ongoing	Attention Deficit Hyperactivity Disorder
Fluvoxamine	2010 - Ongoing	Depression
Melatonin	2019 - Ongoing	Attention Deficit Hyperactivity Disorder
Lithium carbonate	22 Feb 2021 (Study Day 201) - Ongoing	Worsening Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Depression	Grade 3/severe	Not related	21 Feb 2021 (Study Day 200) - Ongoing
Autism Spectrum Disorder	Grade 1/mild	Not related	23 Feb 2021 (Study Day 202) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US327-2078 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 07 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Post Procedural Haematoma/ Postoperative Hematoma Of Breast, Left	SAE	Grade 4	Not related	25 Mar 2021 (Study Day 231) – 28 Mar 2021 (Study Day 234)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US327-2078, a 39-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 15 Jan 2021. The participant was unblinded on 15 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 25 Mar 2021 (Study Day 231), 230 days after the first dose in Part A and 202 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of post procedural haematoma. Action taken with the IP was not applicable. The event of postoperative hematoma of breast, left lasted for 4 days, after which it was considered to be recovered/resolved on 28 Mar 2021 (Study Day 234). The investigator assessed the event of post procedural haematoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-073295	Post procedural haematoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Back ache	2005 - Ongoing
Anxiety	Anxiety	2017 - Ongoing
Menopause	Perimenopause	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram oxalate	2017 - Ongoing	Anxiety
Botulinum toxin type a	2018 - Ongoing	Cosmetic Injection
Testosterone	Feb 2020 - Ongoing	Premenopausal
Ibuprofen	05 Sep 2020 (Study Day 30) - 05 Sep 2020 (Study Day 30)	Headache
Evacuation of hematoma, left breast*	25 Mar 2021 (Study Day 231) - 25 Mar 2021 (Study Day 231)	Adverse Event
Liposuction*	25 Mar 2021 (Study Day 231) - 25 Mar 2021 (Study Day 231)	Other, Cosmetic
Oxycodone	25 Mar 2021 (Study Day 231) - Ongoing	Reduction Mammoplasty
Reduction mammoplasty*	25 Mar 2021 (Study Day 231) - 25 Mar 2021 (Study Day 231)	Medical History
Tramadol hydrochloride	25 Mar 2021 (Study Day 231) - Ongoing	Reduction Mammoplasty

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US327-2291 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 22 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 23 Sep 2020 (Study Day 33)
First Dose of Vaccine in Part B: 14 Jan 2021 (Study Day 146)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Urticaria/Hives, Fully Body	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	15 Jan 2021 (Study Day 147) – 18 Jan 2021 (Study Day 150)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US327-2291, a 27-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 22 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 14 Jan 2021 (Study Day 146). The second dose was not administered.

Event Details

On 15 Jan 2021 (Study Day 147), 146 days after the first dose in Part A/1 day after the first dose in Part B and 114 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of urticaria. The IP dose was withdrawn due to the hives, fully body. The event of hives, fully body lasted for 4 days, after which it was considered to be recovered/resolved on 18 Jan 2021 (Study Day 150). The investigator assessed the event of urticaria to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Insomnia	Insomnia	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine	21 Sep 2020 (Study Day 31) - Ongoing	Insomnia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urticaria	Grade 2/moderate	Related	15 Jan 2021 (Study Day 147) - 18 Jan 2021 (Study Day 150)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US327-2315 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 23 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 26 Sep 2020 (Study Day 35)
First Dose of Vaccine in Part B: 08 Jan 2021 (Study Day 139)
Second Dose of Vaccine in Part B: 04 Feb 2021 (Study Day 166)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Aortic Stenosis/Aortic Stenosis	SAE	Grade 4	Not related	01 Feb 2021 (Study Day 163) – 31 Mar 2021 (Study Day 221)	Recovered/resolved
Cardiac Failure/Reduced Ejection Fraction Heart Failure	SAE	Grade 4	Not related	15 Feb 2021 (Study Day 177) – 03 Mar 2021 (Study Day 193)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US327-2315, a 75-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 23 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 26 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 08 Jan 2021. The participant was unblinded on 08 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 08 Jan 2021 (Study Day 139). The second dose was administered in the left arm on 04 Feb 2021 (Study Day 166).

Event Details

On 01 Feb 2021 (Study Day 163), 162 days after the first dose in Part A/24 days after the first dose in Part B and 128 days after the second dose in Part A/3 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of aortic stenosis. The IP dose was not changed due to the aortic stenosis. The event of aortic stenosis lasted for 59 days, after which it was considered to be recovered/resolved on 31 Mar 2021 (Study Day 221). The investigator assessed the event of aortic stenosis to be not related to the IP.

On 15 Feb 2021 (Study Day 177), 176 days after the first dose in Part A/38 days after the first dose in Part B and 142 days after the second dose in Part A/11 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of cardiac failure. Action taken with the IP was not applicable. The event of reduced ejection fraction heart failure lasted for 17 days, after which it was considered to be recovered/resolved on 03 Mar 2021 (Study Day 193). The investigator assessed the event of cardiac failure to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-079706	Aortic stenosis
MOD-2021-079706	Cardiac failure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Codeine allergy	1975 - Ongoing
Menopause	Menopause	1985 - 1986
Postmenopause	Post-menopausal	1986 - Ongoing
Menorrhagia	Menorrhagia	1989 - 1990
Gastroesophageal reflux disease	Gastroesophageal reflux disease	1990 - Ongoing
Hysterectomy	Hysterectomy	1990 - 1990
Type 2 diabetes mellitus	Diabetes mellitus (type 2)	1990 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2000 - Ongoing
Oophorectomy bilateral	Bilateral oophorectomy	2004 - 2004
Lumbar spinal stenosis	Spinal stenosis (lumbar region)	2017 - Ongoing
Hypothyroidism	Hypothyroidism	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	1990 - Ongoing	Gastroesophageal Reflux Disease
Metformin	2000 - Ongoing	Diabetes Mellitus (Type 2)
Lisinopril	2010 - Ongoing	Hyperlipidemia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Simvastatin	2010 - Ongoing	Hyperlipidemia
Cyclobenzaprine hydrochloride	2017 - Ongoing	Spinal Stenosis (Lumbar Region)
Paracetamol	2017 - Ongoing	Spinal Stenosis (Lumbar Region)
Glipizide	2018 - Ongoing	Diabetes Mellitus (Type 2)
Levothyroxine	2018 - Ongoing	Hypothyroidism
Meloxicam	2018 - Ongoing	Spinal Stenosis (Lumbar Region)
Influenza vaccine	10 Nov 2020 (Study Day 80) - 10 Nov 2020 (Study Day 80)	Influenza Prophylaxis
Doxycycline	08 Feb 2021 (Study Day 170) - Ongoing	Sinusitis And Som Bilaterally
Prednisone	08 Feb 2021 (Study Day 170) - Ongoing	Sinusitis And Som Bilaterally
Furosemide	19 Mar 2021 (Study Day 209) - Ongoing	Worsening Of Aortic Stenosis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Oedema Peripheral	Grade 1/mild	Not related	12 Jan 2021 (Study Day 143) - 15 Jan 2021 (Study Day 146)
Dyspnoea	Grade 1/mild	Not related	15 Jan 2021 (Study Day 146) - 15 Jan 2021 (Study Day 146)
Aortic Stenosis	Grade 3/severe	Not related	01 Feb 2021 (Study Day 163) - 31 Mar 2021 (Study Day 221)
Otitis Media	Grade 1/mild	Not related	05 Feb 2021 (Study Day 167) - 06 Mar 2021 (Study Day 196)
Otitis Media	Grade 1/mild	Not related	05 Feb 2021 (Study Day 167) - 06 Mar 2021 (Study Day 196)
Sinusitis	Grade 2/moderate	Not related	08 Feb 2021 (Study Day 170) - 06 Mar 2021 (Study Day 196)
Dyspnoea	Grade 3/severe	Not related	15 Feb 2021 (Study Day 177) - 31 Mar 2021 (Study Day 221)
Exercise Tolerance Decreased	Grade 3/severe	Not related	15 Feb 2021 (Study Day 177) - 04 Apr 2021 (Study Day 225)
Syncope	Grade 3/severe	Not related	01 Mar 2021 (Study Day 191) - 01 Mar 2021 (Study Day 191)
Oedema Peripheral	Grade 3/severe	Not related	15 Mar 2021 (Study Day 205) - 03 Apr 2021 (Study Day 224)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US329-2128 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 11 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 19 Jan 2021 (Study Day 162)
Second Dose of Vaccine in Part B: 26 Feb 2021 (Study Day 200)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Animal Bite/Dog Bite R Arm	SAE	Grade 2/ moderate	Not related	03 Mar 2021 (Study Day 205) – 01 Apr 2021 (Study Day 234)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2128, a 74-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 19 Jan 2021. The participant was unblinded on 19 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 19 Jan 2021 (Study Day 162). The second dose was administered in the left arm on 26 Feb 2021 (Study Day 200).

Event Details

On 03 Mar 2021 (Study Day 205), 204 days after the first dose in Part A/43 days after the first dose in Part B and 176 days after the second dose in Part A/5 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of animal bite. Action taken with the IP was not applicable. The event of dog bite r arm lasted for 30 days, after which it was considered to be recovered/resolved on 01 Apr 2021 (Study Day 234). The investigator assessed the event of animal bite to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-036272	Animal bite

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vasectomy	Vasectomy	1972 - Ongoing
Hypersensitivity	Environmental allergies	1987 - Ongoing
Hypertension	Hypertension	1990 - Ongoing
Visual acuity reduced	Decreased visual acuity	1990 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	1997 - Ongoing
Gout	Generalized gout	2004 - Ongoing
Rotator cuff repair	R rotator cuff surgery	May 2017 - May 2017
Rotator cuff syndrome	Right torn rotator cuff	May 2017 - May 2017
Vitamin D deficiency	Vitamin d deficiency	12 Feb 2020 (Study Day -181) - Ongoing
Rotator cuff repair	L rotator cuff repair	May 2020 - May 2020
Rotator cuff syndrome	Left torn rotator cuff	May 2020 - May 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Allopurinol	2004 - Ongoing	Generalized Gout
Vitamins nos	2005 - Ongoing	Supplement
Atenolol	2010 - Ongoing	Hypertension
Calcium carbonate; vitamin d nos	2015 - Ongoing	Supplement
Lisinopril	2015 - Ongoing	Hypertension
Atorvastatin	2016 - Ongoing	Hypercholesterolemia
Colecalciferol	12 Feb 2020 (Study Day -181) - Ongoing	Vitamin D Deficiency
Influenza vaccine	11 Nov 2020 (Study Day 93) - 11 Nov 2020 (Study Day 93)	Prophylaxis
Amoxicillin trihydrate; clavulanate potassium	05 Mar 2021 (Study Day 207) - 22 Mar 2021 (Study Day 224)	Dog Bite R Arm
Docusate	05 Mar 2021 (Study Day 207) - 22 Mar 2021 (Study Day 224)	Dog Bite R Arm
Hydrocodone bitartrate; paracetamol	05 Mar 2021 (Study Day 207) - 22 Mar 2021 (Study Day 224)	Dog Bite R Arm
Naproxen	05 Mar 2021 (Study Day 207) - 22 Mar 2021 (Study Day 224)	Dog Bite R Arm

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ondansetron	05 Mar 2021 (Study Day 207) - 22 Mar 2021 (Study Day 224)	Dog Bite R Arm
Paracetamol	05 Mar 2021 (Study Day 207) - 22 Mar 2021 (Study Day 224)	Dog Bite R Arm

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US329-2149 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 13 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 12 Sep 2020 (Study Day 31)
First Dose of Vaccine in Part B: 12 Jan 2021 (Study Day 153)
Second Dose of Vaccine in Part B: 09 Feb 2021 (Study Day 181)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Sinus Node Dysfunction/Sick Sinus Syndrome	SAE	Grade 3/ severe	Not related	01 Feb 2021 (Study Day 173) – 03 Feb 2021 (Study Day 175)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2149, a 69-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 12 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 12 Jan 2021 (Study Day 153). The second dose was administered in the right arm on 09 Feb 2021 (Study Day 181).

Event Details

On 01 Feb 2021 (Study Day 173), 172 days after the first dose in Part A/20 days after the first dose in Part B and 142 days after the second dose in Part A/8 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of sinus node dysfunction. The IP dose was not changed due to the sick sinus syndrome. The event of sick sinus syndrome lasted for 3 days, after which it was considered to be recovered/resolved on 03 Feb 2021 (Study Day 175). The investigator assessed the event of sinus node dysfunction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012066	Sinus node dysfunction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Visual acuity reduced	Decreased visual acuity	2000 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2002 - Ongoing
Hypertension	Hypertension	2002 - Ongoing
Volvulus	Twisted colon	2003 - 2004
Colectomy	Colon resection	2004 - 2004
Anal sphincterotomy	Sphincterotomy - colon	Apr 2004 - Apr 2004
Eczema	Generalized eczema	2008 - Ongoing
Erectile dysfunction	Erectile dysfunction	2008 - Ongoing
Colonoscopy	Routine colonoscopy	Oct 2011 - Oct 2011
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2015 - Ongoing
Rhinitis	Rhinitis	2015 - Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing
Inguinal hernia	Inguinal hernia	2016 - 2016
Inguinal hernia repair	Inguinal hernia repair	Dec 2016 - Dec 2016
Cataract	Bilateral cataracts	2017 - 2020
Eye operation	Eye surgery	Mar 2017 - Mar 2017
Drug hypersensitivity	Drug allergy to amoxicillin	Aug 2019 - Ongoing
Eye operation	Eye surgery - right eye	Jan 2020 - Jan 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Heart Health
Benazepril	2012 - 02 Jan 2021 (Study Day 143)	Hypertension
Simvastatin	2012 - Ongoing	Hypercholesterolemia
Colecalciferol	2015 - Ongoing	Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	2015 - Ongoing	Seasonal Allergy
Tamsulosin	2015 - Ongoing	Benign Prostatic Hyperplasia
Sildenafil	2018 - Ongoing	Erectile Dysfunction
Influenza vaccine	16 Oct 2020 (Study Day 65) - 16 Oct 2020 (Study Day 65)	Influenza Vaccine
Benazepril	03 Jan 2021 (Study Day 144) - Ongoing	Hypertension
Atropine sulfate	01 Feb 2021 (Study Day 173) - 02 Feb 2021 (Study Day 174)	Sick Sinus Syndrome
Enalapril	01 Feb 2021 (Study Day 173) - 03 Feb 2021 (Study Day 175)	Sick Sinus Syndrome
Isoprenaline hydrochloride	01 Feb 2021 (Study Day 173) - 01 Feb 2021 (Study Day 173)	Sick Sinus Syndrome
Ondansetron	01 Feb 2021 (Study Day 173) - 02 Feb 2021 (Study Day 174)	Sick Sinus Syndrome
Paracetamol	01 Feb 2021 (Study Day 173) - 03 Feb 2021 (Study Day 175)	Sick Sinus Syndrome
Sodium chloride	01 Feb 2021 (Study Day 173) - 02 Feb 2021 (Study Day 174)	Sick Sinus Syndrome
Cefazolin sodium	02 Feb 2021 (Study Day 174) - 02 Feb 2021 (Study Day 174)	Sick Sinus Syndrome
Fentanyl	02 Feb 2021 (Study Day 174) - 02 Feb 2021 (Study Day 174)	Sick Sinus Syndrome
Midazolam hydrochloride	02 Feb 2021 (Study Day 174) - 02 Feb 2021 (Study Day 174)	Sick Sinus Syndrome
Pace maker insertion*	02 Feb 2021 (Study Day 174) - 02 Feb 2021 (Study Day 174)	Adverse Event
Nifedipine	03 Feb 2021 (Study Day 175) - 05 Apr 2021 (Study Day 236)	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US329-2158 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 13 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 12 Sep 2020 (Study Day 31)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chronic Obstructive Pulmonary Disease/Exacerbation Of Copd	SAE	Grade 3/severe	Not related	26 Mar 2021 (Study Day 226) – 29 Mar 2021 (Study Day 229)	Recovered/resolved
Chronic Obstructive Pulmonary Disease/Exacerbation Of Copd	SAE	Grade 3/severe	Not related	07 Apr 2021 (Study Day 238) – 09 Apr 2021 (Study Day 240)	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2158, a 58-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 12 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was Not reported. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Jan 2021. The participant was unblinded on 21 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 26 Mar 2021 (Study Day 226), 225 days after the first dose in Part A and 195 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of chronic obstructive pulmonary disease. Action taken with the IP was not applicable. The event of exacerbation of copd lasted for 4 days, after which it was considered to be recovered/resolved on 29 Mar 2021 (Study Day 229). The investigator assessed the event of chronic obstructive pulmonary disease to be not related to the IP.

On 07 Apr 2021 (Study Day 238), 237 days after the first dose in Part A and 207 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of chronic obstructive pulmonary disease. Action taken with the IP was not applicable. The event of exacerbation of copd lasted for 3 days, after which it was considered to be not recovered/not

resolved on 09 Apr 2021 (Study Day 240). The investigator assessed the event of chronic obstructive pulmonary disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-061232	Chronic obstructive pulmonary disease
MOD-2021-061232	Chronic obstructive pulmonary disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypercholesterolaemia	Hypercholesterolemia	Not reported - Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Rhinorrhoea	Rhionrrhea	1972 - Ongoing
Seasonal allergy	Seasonal allergies	1972 - Ongoing
Cryptorchism	Undescended testicles	1973 - 1973
Testicular operation	Testicle surgery	1973 - 1973
Tonsillectomy	Tonsillectomy	1973 - 1973
Tonsillitis	Tonsillitis	1986 - 1986
Nasal operation	Nasal mucus overproduction surgery	1988 - Nov 1988
Rhinorrhoea	Nasal mucus over production	1988 - 2018
Drug intolerance	Codeine intolerance	1990 - Ongoing
Drug intolerance	Gabapentin intolerance	1990 - Ongoing
Drug intolerance	Valium intolerance	1990 - Ongoing
Joint surgery	Cervical degenerative joint disease surgery	2002 - 2002
Spinal osteoarthritis	C5-c7 degenerative joint disease	2002 - 2002
Spinal osteoarthritis	Cervical degenerative joint disease	2002 - 2002
Tinnitus	Bilateral tinnitus	2005 - Ongoing
Coronary artery bypass	Cabg	2012 - 2012
Coronary artery disease	Cad	2012 - Ongoing
Hypermetropia	Farsighted	2012 - Ongoing
Myocardial infarction	Myocardial infarct	2012 - 2012
Peripheral arterial occlusive disease	Peripheral arterial disease	2012 - Ongoing
Gastroesophageal reflux disease	Gerd	2013 - Ongoing
Carpal tunnel syndrome	Carpal tunnel syndrome	2014 - Ongoing
Drug hypersensitivity	Drug allergy to statins	2015 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Type 2 diabetes mellitus	2016 - Ongoing
Hypoacusis	Bilateral hearing imparied	2017 - Ongoing
Nasal operation	Nasal mucus overproduction surgery	2018 - 2018
Chronic obstructive pulmonary disease	Copd	Apr 2018 - Ongoing
Cystitis	Uti (cystitis)	2019 - 2019
Depression	Depression	2019 - Ongoing
Generalised oedema	Generalized edema	2019 - Ongoing
Iron deficiency anaemia	Iron defecency anmeia	2019 - Ongoing
Dry eye	Dry eyes	Dec 2019 - Ongoing
Erectile dysfunction	Erectile dysfunction	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone	2015 - Ongoing	Rhinorrhea
Enalapril	2016 - Ongoing	Hypertension
Nicotinic acid	Feb 2017 - Ongoing	Hypertension
Colecalciferol	2018 - Ongoing	Supplement
Metformin	2018 - Ongoing	Type Ii Diabetes
Montelukast	2018 - Ongoing	Rhinorrhea
Budesonide; formoterol	May 2018 - Ongoing	Copd
Salbutamol	May 2018 - Ongoing	Copd
Tiotropium	May 2018 - Ongoing	Copd
Bupropion	2019 - Ongoing	Depression
Ferrous gluconate	2019 - Ongoing	Anemia
Furosemide	2019 - Ongoing	Generalized Edema
Mirtazapine	2019 - Ongoing	Depression
Trazodone	2019 - Ongoing	Depression
Carmellose	Dec 2019 - Ongoing	Dry Eyes
Ezetimibe	May 2020 - Ongoing	Hypercholesterlemia
Famotidine	May 2020 - Ongoing	Gerd
Pantoprazole	May 2020 - Ongoing	Gerd
Tadalafil	Jul 2020 - Ongoing	Erectile Dysfunction
Testosterone	20 Feb 2021 (Study Day 192) - 20 Feb 2021 (Study Day 192)	Erectile Dysfunction

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US329-2172 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 13 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Uterine Cancer/Uterine Cancer	SAE	Grade 3/severe	Not related	19 Feb 2021 (Study Day 191) – 07 Apr 2021 (Study Day 238)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2172, a 53-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 15 Jan 2021. The participant was unblinded on 15 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 19 Feb 2021 (Study Day 191), 190 days after the first dose in Part A and 162 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of uterine cancer. The IP dose was not changed due to the uterine cancer. The event of uterine cancer lasted for 48 days, after which it was considered to be recovered/resolved on 07 Apr 2021 (Study Day 238). The investigator assessed the event of uterine cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-090704	Uterine cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Intermittent headache	1980 - Ongoing
Bunion operation	Bunion removal	1982 - 1982
Bunion operation	Bunionectomy	1982 - 1982
Visual acuity reduced	Bilateral decreased visual acuity	1983 - Ongoing
Mammoplasty	Breast reduction	1987 - 1987
Seasonal allergy	Seasonal allergy	1990 - Ongoing
Caesarean section	C-section	1992 - 1992
Delivery	Vaginal delivery	1997 - 1997
Organ donor	Left kidney donation surgery	2010 - 2010
Rotator cuff syndrome	Right rotator cuff injury	2010 - 2010
Rotator cuff repair	Right rotator cuff repair	2013 - 2013
Tendon injury	Left achilles tendon damage	2013 - 2013
Tenoplasty	Left achilles tendon surgery	2013 - 2013
Rotator cuff repair	Left rotator cuff repair	2014 - 2014
Rotator cuff syndrome	Left rotator cuff injury	2014 - 2014
Drug hypersensitivity	Lidocaine allergy	2015 - Ongoing
Bone lesion excision	Right foot osteophytes removal	2016 - 2016
Exostosis	Right foot osteophytes	2016 - 2016
Postmenopause	Post menopausal	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	1985 - Ongoing	Headache
Cetirizine hydrochloride; pseudoephedrine hydrochloride	2010 - Ongoing	Seasonal Allergy
Paracetamol	11 Sep 2020 (Study Day 30) - 11 Sep 2020 (Study Day 30)	Reactogenicity - Pain At Injection Site
Pap smear*	19 Feb 2021 (Study Day 191) - 19 Feb 2021 (Study Day 191)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US329-2173 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 13 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 12 Sep 2020 (Study Day 31)
First Dose of Vaccine in Part B: 09 Feb 2021 (Study Day 181)
Second Dose of Vaccine in Part B: 09 Mar 2021 (Study Day 209)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cholecystitis/Cholecystitis	SAE	Grade 3/ severe	Not related	28 Apr 2021 (Study Day 259) – 28 Apr 2021 (Study Day 259)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2173, a 61-year-old not Hispanic or Latino male, received the first dose of Placebo in the right arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 12 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 09 Feb 2021. The participant was unblinded on 09 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 09 Feb 2021 (Study Day 181). The second dose was administered in the right arm on 09 Mar 2021 (Study Day 209).

Event Details

On 28 Apr 2021 (Study Day 259), 258 days after the first dose in Part A/78 days after the first dose in Part B and 228 days after the second dose in Part A/50 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of cholecystitis. The IP dose was not changed due to the cholecystitis. The event of cholecystitis lasted for 1 days, after which it was considered to be recovered/resolved on 28 Apr 2021 (Study Day 259). The investigator assessed the event of cholecystitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-101470	Cholecystitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendectomy	Appendectomy	1973 - 1973
Appendectomy	Appendectomy	1973 - 1973
Appendicitis	Appendicitis	1973 - 1973
Appendicitis perforated	Ruptured appendix	1973 - 1973
Oral pain	Mouth pain	1981 - 1981
Wisdom teeth removal	Wisdom teeth removal	1981 - 1981
Rhinitis	Rhinitis	1986 - Ongoing
Tonsillectomy	Tonsillectomy	1995 - 1995
Tonsillitis	Tonsil infection	1995 - 1995
Gastroesophageal reflux disease	Acid reflux	2004 - Ongoing
Erectile dysfunction	Erectile dysfunction	2009 - Ongoing
Intestinal obstruction	Intestinal blockage	2016 - 2016
Knee operation	Left knee surgery	2017 - 2017
Ligament rupture	Left knee anterior cruciate ligament tear	2017 - 2017
Ligament rupture	Left knee medial collateral ligament tear	2017 - 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	1980 - Ongoing	General Health
Loratadine	2004 - Ongoing	Rhinitis (Allergic)
Omeprazole	2004 - Ongoing	Acid Reflux
Plantago ovata	2004 - Ongoing	Digestive Health
Tadalafil	2009 - Ongoing	Erectile Dysfunction
Ibuprofen	2018 - Ongoing	Generalized Muscle Aches
Acetylsalicylic acid	Apr 2020 - Ongoing	General Health
Nicotinic acid	Apr 2020 - Ongoing	General Health
Influenza vaccine	27 Sep 2020 (Study Day 46) - 27 Sep 2020 (Study Day 46)	Influenza

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Syncope	Grade 1/mild	Not applicable	09 Feb 2021 (Study Day 181) - 09 Feb 2021 (Study Day 181)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US329-2259 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 20 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 17 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 28 Jan 2021 (Study Day 162)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Post Procedural Infection/Abdominal Hernia Repair Infection	SAE	Grade 4	Not related	02 Feb 2021 (Study Day 167) – 18 Feb 2021 (Study Day 183)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2259, a 50-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 28 Jan 2021. The participant was unblinded on 28 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 28 Jan 2021 (Study Day 162). The second dose was not administered.

Event Details

On 02 Feb 2021 (Study Day 167), 166 days after the first dose in Part A/5 days after the first dose in Part B and 138 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 4 serious adverse event of post procedural infection. Action taken with the IP was not applicable. The event of abdominal hernia repair infection lasted for 17 days, after which it was considered to be recovered/resolved on 18 Feb 2021 (Study Day 183). The investigator assessed the event of post procedural infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004569	Post procedural infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Low back pain	1998 - Ongoing
Spinal operation	Low back surgery	1998 - 1998
Spinal operation	Low back surgery	1999 - 1999
Abdominal hernia	Ventral hernia	2009 - 2017
Abdominal hernia repair	Ventral hernia repair	2011 - 2011
Abdominal hernia repair	Ventral hernia repair	2017 - 2017
Type 2 diabetes mellitus	Diabetes type II	Nov 2019 - Ongoing
Contusion	Head contusion	15 May 2020 (Study Day -97) - 15 May 2020 (Study Day -97)
Headache	Headaches secondary to head contusion	15 May 2020 (Study Day -97) - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	15 Aug 2020 (Study Day -5) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrocodone bitartrate; paracetamol	1998 - Ongoing	Low Back Pain
Sitagliptin	Nov 2019 - Ongoing	Diabetes Type II
Topiramate	09 Aug 2020 (Study Day -11) - Ongoing	Headache
Atorvastatin	15 Aug 2020 (Study Day -5) - Ongoing	Hypercholesterolemia
Paracetamol	21 Aug 2020 (Study Day 2) - 25 Aug 2020 (Study Day 6)	Mild Fever
Prednisolone	01 Sep 2020 (Study Day 13) - 17 Sep 2020 (Study Day 29)	Eye Infection
Baclofen	07 Nov 2020 (Study Day 80) - Ongoing	Muscle Aches
Baclofen	07 Nov 2020 (Study Day 80) - 16 Nov 2020 (Study Day 89)	Muscle Soreness
Varicella zoster vaccine	06 Dec 2020 (Study Day 109) - 06 Dec 2020 (Study Day 109)	Prophylaxis
Varicella zoster vaccine	06 Dec 2020 (Study Day 109) - 06 Dec 2020 (Study Day 109)	Shingles
Bilat myocut flaps*	29 Dec 2020 (Study Day 132) - 29 Dec 2020 (Study Day 132)	Adverse Event
Exploratory laparotomy*	29 Dec 2020 (Study Day 132) - 29 Dec 2020 (Study Day 132)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omentectomy*	29 Dec 2020 (Study Day 132) - 29 Dec 2020 (Study Day 132)	Adverse Event
Removal of fb*	29 Dec 2020 (Study Day 132) - 29 Dec 2020 (Study Day 132)	Adverse Event
Ventral hernia repair*	29 Dec 2020 (Study Day 132) - 29 Dec 2020 (Study Day 132)	Adverse Event
Paracetamol	28 Jan 2021 (Study Day 162) - Ongoing	Pain At Injection Site
Cat scan - abdomen/pelvis*	13 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 178)	Adverse Event
Cefepime hydrochloride	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Ceftriaxone	13 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 178)	Abdominal Hernia Repair Infection
Glucagon	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Hydrocodone; paracetamol	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Insulin lispro	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Magnesium oxide	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Magnesium sulfate	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Metronidazole	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Morphine sulfate	13 Feb 2021 (Study Day 178) - 15 Feb 2021 (Study Day 180)	Abdominal Hernia Repair Infection
Ondansetron hydrochloride	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Paracetamol	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Potassium chloride	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Sodium chloride	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Abdominal Hernia Repair Infection
Vancomycin	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Ultrasound guided needle aspiration*	15 Feb 2021 (Study Day 180) - 15 Feb 2021 (Study Day 180)	Adverse Event
Ciprofloxacin	17 Feb 2021 (Study Day 182) - 26 Feb 2021 (Study Day 191)	Abdominal Hernia Repair Infection
Metronidazole	17 Feb 2021 (Study Day 182) - 26 Feb 2021 (Study Day 191)	Abdominal Hernia Repair Infection
Broken incisor repair*	20 Mar 2021 (Study Day 213) - 20 Mar 2021 (Study Day 213)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 2/moderate	Related	28 Jan 2021 (Study Day 162) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US330-2105 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 07 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/ Myocardial Infarction	SAE	Grade 3/ severe	Not related	19 Feb 2021 (Study Day 197) – 19 Feb 2021 (Study Day 197)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US330-2105, a 71-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 07 Jan 2021. The participant was unblinded on 07 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 19 Feb 2021 (Study Day 197), 196 days after the first dose in Part A and 168 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction lasted for 1 day, after which it was considered to be recovered/resolved on 19 Feb 2021 (Study Day 197). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-017223	Myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1953 - 1953
Tonsillitis	Tonsillitis	1953 - 1953
Arthritis	Arthritis	1990 - Ongoing
Postmenopause	Post menopausal	2000 - Ongoing
Hypertension	Hypertension	2014 - Ongoing
Knee arthroplasty	Knee replacement (left knee)	2016 - 2016
Knee arthroplasty	Knee replacement (right knee)	2016 - 2016

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	1990 - Ongoing	Arthritis
Paracetamol	1990 - Ongoing	Arthritis
Hydrochlorothiazide; triamterene	2014 - Ongoing	Hypertension
Amoxicillin; clavulanic acid	18 Jan 2021 (Study Day 165) - 19 Jan 2021 (Study Day 166)	Tooth Abscess
Azithromycin	19 Jan 2021 (Study Day 166) - 19 Jan 2021 (Study Day 166)	Tooth Abscess
Azithromycin	20 Jan 2021 (Study Day 167) - 30 Jan 2021 (Study Day 177)	Tooth Abscess
Acetylsalicylic acid; clopidogrel	19 Feb 2021 (Study Day 197) - 19 Feb 2021 (Study Day 197)	Coronary Artery Disease (Cad)
Atorvastatin	19 Feb 2021 (Study Day 197) - Ongoing	Hyperlipidemia
Carvedilol	19 Feb 2021 (Study Day 197) - Ongoing	Congestive Heart Failure (Ae)
Colecalciferol	19 Feb 2021 (Study Day 197) - Ongoing	Coronary Artery Disease
Enoxaparin sodium	19 Feb 2021 (Study Day 197) - 22 Feb 2021 (Study Day 200)	Dvt Prophylaxis
Diphenhydramine hydrochloride	20 Feb 2021 (Study Day 198) - 20 Feb 2021 (Study Day 198)	Heart Cath
Fentanyl	20 Feb 2021 (Study Day 198) - 20 Feb 2021 (Study Day 198)	Heart Cath
Heart cath*	20 Feb 2021 (Study Day 198) - 20 Feb 2021 (Study Day 198)	Other, Myocardial Infarction (Sae)
Hydrocortisone sodium succinate	20 Feb 2021 (Study Day 198) - 20 Feb 2021 (Study Day 198)	Heart Cath
Lidocaine	20 Feb 2021 (Study Day 198) - 20 Feb 2021 (Study Day 198)	Heart Cath
Midazolam hydrochloride	20 Feb 2021 (Study Day 198) - 20 Feb 2021 (Study Day 198)	Heart Cath

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	23 Feb 2021 (Study Day 201) - Ongoing	Coronary Artery Disease (Cad)
Atorvastatin	23 Feb 2021 (Study Day 201) - Ongoing	Hyperlipidemia
Carvedilol	23 Feb 2021 (Study Day 201) - Ongoing	Congestive Heart Failure (Chf)
Clopidogrel	23 Feb 2021 (Study Day 201) - Ongoing	Coronary Artery Disease (Cad)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Tooth Abscess	Grade 1/mild	Not related	18 Jan 2021 (Study Day 165) - 30 Jan 2021 (Study Day 177)
Chest Discomfort	Grade 2/moderate	Not related	19 Feb 2021 (Study Day 197) - 19 Feb 2021 (Study Day 197)
Coronary Artery Disease	Grade 2/moderate	Not related	19 Feb 2021 (Study Day 197) - Ongoing
Hyperglycaemia	Grade 2/moderate	Not related	20 Feb 2021 (Study Day 198) - Ongoing
Hyperlipidaemia	Grade 2/moderate	Not related	20 Feb 2021 (Study Day 198) - Ongoing
Mitral Valve Incompetence	Grade 2/moderate	Not related	20 Feb 2021 (Study Day 198) - Ongoing
Cardiac Failure Congestive	Grade 2/moderate	Not related	22 Feb 2021 (Study Day 200) - Ongoing
Cardiomyopathy	Grade 2/moderate	Not related	22 Feb 2021 (Study Day 200) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US330-2455 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 21 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 19 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 14 Jan 2021 (Study Day 116)
Second Dose of Vaccine in Part B: 11 Feb 2021 (Study Day 144)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cerebrovascular Accident/Acute Cva	SAE	Grade 4	Not related	06 Mar 2021 (Study Day 167) – 10 Mar 2021 (Study Day 171)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US330-2455, a 67-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 21 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 19 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 14 Jan 2021 (Study Day 116). The second dose was administered in the left arm on 11 Feb 2021 (Study Day 144).

Event Details

On 06 Mar 2021 (Study Day 167), 166 days after the first dose in Part A/51 days after the first dose in Part B and 138 days after the second dose in Part A/23 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of cerebrovascular accident. Action taken with the IP was not applicable. The event of acute cva lasted for 5 days, after which it was considered to be recovered/resolved on 10 Mar 2021 (Study Day 171). The investigator assessed the event of cerebrovascular accident to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-041521	Cerebrovascular accident

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hiatus hernia	Hiatal hernia	1997 - 1997
Anxiety	Anxiety	1999 - Ongoing
Bipolar disorder	Bio polar disorder (in remission)	1999 - Ongoing
Depression	Depression	1999 - Ongoing
Chronic obstructive pulmonary disease	Copd	2000 - Ongoing
Sleep apnoea syndrome	Sleep apnea (no c-pap)	2003 - Ongoing
Anaemia	Anemia (unspecified)	2005 - 2005
Vitamin D deficiency	Vitamin d deficiency	2005 - Ongoing
Back pain	Back pain (lower back)	2010 - 2010
Overdose	Overdose of opiate agonist	2010 - 2010
Insomnia	Insomnia	2015 - Ongoing
Postmenopause	Post menopausal	2015 - Ongoing
Cardiac murmur	Heart murmur	2018 - Ongoing
Hyperkeratosis	Callus of foot (right)	2018 - 2018
Chronic kidney disease	Chronic kidney disease (stage 3)	2019 - Ongoing
Dementia Alzheimer's type	Alzheimer's disease	2019 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2019 - Ongoing
Hypertension	Hypertension	2019 - Ongoing
Hyponatraemia	Hyponatremia (secondary to kidney disease)	2019 - Ongoing
Renal failure	Renal insufficiency (secondary kidney disease)	2019 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2019 - Ongoing
Dependence on oxygen therapy	O2 dependent	2020 - Ongoing
Onychomycosis	Onychomycosis (bilateral feet/ intermittent)	2020 - Ongoing
Gastroesophageal reflux disease	Gerd	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	2019 - Ongoing	Hypertension
Simvastatin	2019 - 06 Mar 2021 (Study Day 167)	Hypercholesterolemia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glipizide	May 2020 - Ongoing	Diabetes Type 2
Indapamide	May 2020 - Ongoing	Hypertension
Liraglutide	May 2020 - Ongoing	Diabetes Type 2
Pantoprazole	Jun 2020 - Ongoing	Gerd
Clonidine	11 Feb 2021 (Study Day 144) - 11 Feb 2021 (Study Day 144)	Hypertension
Acetylsalicylic acid	06 Mar 2021 (Study Day 167) - Ongoing	Dvt Prophylaxis
Amlodipine	06 Mar 2021 (Study Day 167) - Ongoing	Hypertension
Atorvastatin	06 Mar 2021 (Study Day 167) - Ongoing	Hypercholesterolemia
Benzatropine mesilate	06 Mar 2021 (Study Day 167) - Ongoing	Anxiety
Heparin	06 Mar 2021 (Study Day 167) - 07 Mar 2021 (Study Day 168)	Dvt Prophylaxis
Hydralazine	06 Mar 2021 (Study Day 167) - 06 Mar 2021 (Study Day 167)	Hypertension
Insulin glargine	06 Mar 2021 (Study Day 167) - Ongoing	Diabetes Type II
Insulin glargine	06 Mar 2021 (Study Day 167) - 09 Mar 2021 (Study Day 170)	Diabetes Type II
Insulin lispro	06 Mar 2021 (Study Day 167) - 10 Mar 2021 (Study Day 171)	Diabetes Type II
Lisinopril	06 Mar 2021 (Study Day 167) - 08 Mar 2021 (Study Day 169)	Hypertension
Lisinopril	06 Mar 2021 (Study Day 167) - 10 Mar 2021 (Study Day 171)	Hypertension
Memantine	06 Mar 2021 (Study Day 167) - Ongoing	Alzheimer's Disease
Olanzapine	06 Mar 2021 (Study Day 167) - Ongoing	Bi-Polar Disease
Sodium chloride	06 Mar 2021 (Study Day 167) - 10 Mar 2021 (Study Day 171)	Cva
Sodium chloride	06 Mar 2021 (Study Day 167) - 16 Mar 2021 (Study Day 177)	Hyponatremia
Tuberculin	06 Mar 2021 (Study Day 167) - 06 Mar 2021 (Study Day 167)	Tb Skin Test
Clopidogrel	07 Mar 2021 (Study Day 168) - Ongoing	Dvt Prophylaxis
Paroxetine	07 Mar 2021 (Study Day 168) - Ongoing	Menopause
Hydralazine	10 Mar 2021 (Study Day 171) - 10 Mar 2021 (Study Day 171)	Hypertension
Clobetasol propionate	11 Mar 2021 (Study Day 172) - Ongoing	Onychomycosis
Indapamide	11 Mar 2021 (Study Day 172) - Ongoing	Hypertension
Liraglutide	11 Mar 2021 (Study Day 172) - Ongoing	Diabetes Type II
Losartan	11 Mar 2021 (Study Day 172) - Ongoing	Hypertension
Oxygen	11 Mar 2021 (Study Day 172) - Ongoing	Copd

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US331-2008 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 10 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 07 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Coronary Artery Insufficiency/ Coronary Artery Insufficiency (Involving The Left Anterior Descending And Left Circumflex Coronary Arteries)	SAE	Grade 3/ severe	Not related	15 Feb 2021 (Study Day 190) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2008, an 86-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 07 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 15 Feb 2021 (Study Day 190), 189 days after the first dose in Part A and 161 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of coronary artery insufficiency. Action taken with the IP was not applicable. The event of coronary artery insufficiency (involving the left anterior descending and left circumflex coronary arteries) was considered to be ongoing. The investigator assessed the event of coronary artery insufficiency to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-083903	Coronary artery insufficiency

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Hay fever	1958 - 1960
Drug hypersensitivity	Penicillin allergy	1960 - Ongoing
Appendectomy	Appendectomy	04 Jul 1960 (Study Day -21952) - 04 Jul 1960 (Study Day -21952)
Nephrectomy	Right nephrectomy	04 Jul 1960 (Study Day -21952) - 04 Jul 1960 (Study Day -21952)
Renal haematoma	Ruptured benign hematoma on right kidney	04 Jul 1960 (Study Day -21952) - 04 Jul 1960 (Study Day -21952)
Endometriosis	Endometriosis	1970 - 1970
Hysterectomy	Total hysterectomy	1970 - 1970
Anxiety	Anxiety	1980 - Ongoing
Drug hypersensitivity	Allergy to ace inhibitors	1980 - Ongoing
Drug hypersensitivity	Allergy to beta blockers	1980 - Ongoing
Allergy to arthropod sting	Bee sting allergy	1985 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	1990 - 2015
Hypertension	Hypertension	1990 - Ongoing
Breast cancer	Left breast cancer	Dec 1995 - 13 Mar 1996 (Study Day -8916)
Mastectomy	Left total mastectomy	13 Mar 1996 (Study Day -8916) - 13 Mar 1996 (Study Day -8916)
Lymphoedema	Left arm lymphedema	Sep 1997 - Ongoing
Intervertebral disc protrusion	Ruptured disc	2005 - 2005
Spinal laminectomy	Laminectomy	2005 - 2005
Osteoporosis	Osteoporosis bilateral hips	Jan 2012 - Jan 2012
Hip arthroplasty	Left hip replacement	Oct 2012 - Oct 2012
Insomnia	Difficulty sleeping	2015 - Ongoing
Spinal compression fracture	Back compression fracture	2015 - 2015
Hip arthroplasty	Right hip replacement	Oct 2015 - Oct 2015
Cholecystectomy	Cholecystectomy	Oct 2018 - Oct 2018
Cholelithiasis	Cholethiasis	Oct 2018 - Oct 2018
Muscle spasms	Bilateral foot cramps	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluoxetine	1980 - Ongoing	Anxiety
Diltiazem	2010 - Ongoing	Hypertension
Hydrochlorothiazide	2010 - 31 Oct 2020 (Study Day 83)	Hypertension
Metoprolol	2010 - Ongoing	Hypertension
Vitamin b complex	2014 - Ongoing	General Health Maintenance
Vitamin d nos	2014 - Ongoing	Health Maintenance
Acetylsalicylic acid	2015 - Ongoing	Difficulty Sleeping
Magnesium	2019 - Ongoing	Bilateral Foot Cramps
Clindamycin	21 Dec 2020 (Study Day 134) - 30 Dec 2020 (Study Day 143)	Dog Bite Left Shin
Diphtheria vaccine toxoid; pertussis vaccine acellular; tetanus vaccine toxoid	21 Dec 2020 (Study Day 134) - 21 Dec 2020 (Study Day 134)	Tetanus Prophylaxis
Clindamycin	31 Dec 2020 (Study Day 144) - 07 Jan 2021 (Study Day 151)	Facial Fractures X3
Hydrocodone bitartrate; paracetamol	31 Dec 2020 (Study Day 144) - 07 Jan 2021 (Study Day 151)	Facial Fractures X3
Inulin; lactobacillus rhamnosus	31 Dec 2020 (Study Day 144) - 07 Jan 2021 (Study Day 151)	Gastrointestinal Health Maintenance

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cardiac Failure Congestive	Grade 3/severe	Not related	15 Feb 2021 (Study Day 190) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US331-2093 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 14 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 22 Jan 2021 (Study Day 162)
Second Dose of Vaccine in Part B: 03 Mar 2021 (Study Day 202)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pulmonary Embolism/Pulmonary Embolus	SAE	Grade 3/ severe	Not related	08 Feb 2021 (Study Day 179) – 10 Feb 2021 (Study Day 181)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2093, a 57-year-old not Hispanic or Latino male, received the first dose of Placebo in the right arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 22 Jan 2021. The participant was unblinded on 22 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 22 Jan 2021 (Study Day 162). The second dose was administered in the left arm on 03 Mar 2021 (Study Day 202).

Event Details

On 08 Feb 2021 (Study Day 179), 178 days after the first dose in Part A/17 days after the first dose in Part B and 150 days after the second dose in Part A/23 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of pulmonary embolism. Action taken with the IP was not applicable. The event of pulmonary embolus lasted for 3 days, after which it was considered to be recovered/resolved on 10 Feb 2021 (Study Day 181). The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012489	Pulmonary embolism

Study Completion/Discontinuation

On 23 Mar 2021 (Study Day 222), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Intervertebral disc protrusion	C5/c6 cervical disc bulge	1999 - Ongoing
Diarrhoea	Occasional diarrhea	2000 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	2000 - 2014
Fungal infection	Intermittent fungal infections	2002 - Ongoing
Cough	Chronic cough related to medication	2004 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2004 - Ongoing
Restless legs syndrome	Restless leg syndrome	2010 - Ongoing
Cholecystectomy	Cholecystectomy	2014 - 2014
Cholecystitis	Cholecystitis	2014 - 2014
Deep vein thrombosis	Deep vein thrombosis	2014 - 2014
Hypogonadism	Hypogonadism	2014 - Ongoing
Pulmonary embolism	Bilateral pulmonary embolism	2014 - 2014
Anxiety	Anxiety	2015 - Ongoing
Arteriosclerosis coronary artery	Coronary atherosclerosis	2015 - Ongoing
Depression	Depression	2015 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Hypersensitivity	Environmental allergies	2015 - Ongoing
Eye naevus	Ocular nevus	2016 - Ongoing
Gastroesophageal reflux disease	Acid reflux	2016 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2016 - Ongoing
Insomnia	Difficulty sleeping	2017 - Ongoing
Actinic keratosis	Actinic keratosis	2018 - Ongoing
Erectile dysfunction	Erectile dysfunction	2018 - Ongoing
Obesity	Obesity	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loperamide	2000 - Ongoing	Occasional Diarrhea
Ramipril	2004 - Ongoing	Diabetes Mellitus
Acetylsalicylic acid	2005 - Ongoing	Cardiac Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pramipexole	2012 - Ongoing	Restless Leg Syndrome
Metformin	2014 - Ongoing	Type 2 Diabetes
Tizanidine	2015 - Ongoing	C5/C6 Cervical Disc Bulge
All other non-therapeutic products	2016 - Ongoing	Sleep Apnea
Fenofibrate	2016 - Ongoing	Hyperlipidemia
Insulin glargine	2016 - Ongoing	Type 2 Diabetes
Insulin lispro	2016 - Ongoing	Type 2 Diabetes
Omega-3-acid ethyl ester	2016 - Ongoing	Cardiovascular Prophylaxis
Omeprazole	2016 - Ongoing	Acid Reflux
Clonazepam	2017 - Ongoing	Difficulty Sleeping
Tramadol	2017 - Ongoing	C5/C6 Cervical Disc Bulge
Atorvastatin	2018 - Ongoing	Hyperlipidemia
Clindamycin	2018 - Ongoing	Cosmetic
Dapagliflozin propanediol monohydrate	2018 - Ongoing	Type 2 Diabetes
Dulaglutide	2018 - 05 Feb 2021 (Study Day 176)	Type 2 Diabetes
Lisdexamfetamine	2018 - Ongoing	Obesity
Sildenafil	2018 - 01 Sep 2020 (Study Day 19)	Erectile Dysfunction
Vortioxetine hydrobromide	2018 - Ongoing	Depression
Nystatin	2019 - Ongoing	Intermittent Fungal Infections
Propranolol	Mar 2019 - Ongoing	Difficulty Sleeping
Tacrolimus	10 Jul 2020 (Study Day -35) - 17 Jul 2020 (Study Day -28)	Intermittent Fungal Infections
Ibuprofen	19 Aug 2020 (Study Day 6) - 20 Aug 2020 (Study Day 7)	Headache
Alprostadil	01 Sep 2020 (Study Day 19) - Ongoing	Erectile Dysfunction
Tobramycin	09 Sep 2020 (Study Day 27) - 25 Sep 2020 (Study Day 43)	Left Corneal Abrasion
Influenza vaccine	21 Nov 2020 (Study Day 100) - 21 Nov 2020 (Study Day 100)	Seasonal Influenza Prophylaxis
Vitamin d nos	21 Nov 2020 (Study Day 100) - Ongoing	Health Maintenance
Atorvastatin	22 Jan 2021 (Study Day 162) - Ongoing	Hyperlipidemia
Semaglutide	06 Feb 2021 (Study Day 177) - Ongoing	Diabetes Mellitus
Glyceryl trinitrate	08 Feb 2021 (Study Day 179) - 08 Feb 2021 (Study Day 179)	Chest Pain Related To Pulmonary Embolism
Heparin	08 Feb 2021 (Study Day 179) - 09 Feb 2021 (Study Day 180)	Pulmonary Embolism
Pantoprazole	08 Feb 2021 (Study Day 179) - 09 Feb 2021 (Study Day 180)	Acid Reflux
Apixaban	09 Feb 2021 (Study Day 180) - 16 Feb 2021 (Study Day 187)	Pulmonary Embolism
Cardiac catheterization*	09 Feb 2021 (Study Day 180) - 09 Feb 2021 (Study Day 180)	Adverse Event
Omeprazole	10 Feb 2021 (Study Day 181) - Ongoing	Acid Reflux
Apixaban	17 Feb 2021 (Study Day 188) - Ongoing	Hypogonadism

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US331-2224 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 24 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 21 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 21 Jan 2021 (Study Day 151)
Second Dose of Vaccine in Part B: 18 Feb 2021 (Study Day 179)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Haemorrhage Intracranial/Intracranial Hemorrhage	SAE	Grade 3/ severe	Not related	19 Feb 2021 (Study Day 180) – 18 Mar 2021 (Study Day 207)	Recovered/ resolved
Myelodysplastic Syndrome/Myelodysplastic Syndrome	SAE	Grade 3/ severe	Not related	19 Feb 2021 (Study Day 180) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2224, a 84-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Jan 2021. The participant was unblinded on 21 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 21 Jan 2021 (Study Day 151). The second dose was administered in the left arm on 18 Feb 2021 (Study Day 179).

Event Details

On 19 Feb 2021 (Study Day 180), 179 days after the first dose in Part A/29 days after the first dose in Part B and 151 days after the second dose in Part A/1 day after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of haemorrhage intracranial. Action taken with the IP was not applicable. The event of intracranial hemorrhage lasted for 28 days, after which it was considered to be recovered/resolved on 18 Mar 2021 (Study Day 207). The investigator assessed the event of haemorrhage intracranial to be not related to the IP.

On 19 Feb 2021 (Study Day 180), 179 days after the first dose in Part A/29 days after the first dose in Part B and 151 days after the second dose in Part A/1 day after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of myelodysplastic

syndrome. Action taken with the IP was not applicable. The event of myelodysplastic syndrome was considered to be ongoing. The investigator assessed the event of myelodysplastic syndrome to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-018342	Haemorrhage intracranial
MOD-2021-018342	Myelodysplastic syndrome

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Penicillin allergy	1950 - Ongoing
Seasonal allergy	Seasonal allergies	1950 - Ongoing
Coronary artery bypass	Coronary artery bypass grafting x3 vessels	2005 - 2005
Coronary artery disease	Coronary artery disease	2005 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2005 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Hiatus hernia	Hiatal hernia	2015 - Ongoing
Osteoporosis	Osteoporosis	2015 - Ongoing
Increased tendency to bruise	Bruising easily	2017 - Ongoing
Orthostatic hypotension	Orthostatic hypotension	2017 - Ongoing
Thrombocytopenia	Thrombocytopenia	2017 - Ongoing
Constipation	Mild constipation	2019 - Ongoing
Hypothyroidism	Hypothyroidism	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	1980 - 18 Feb 2021 (Study Day 179)	Cardiac Prophylaxis
Simvastatin	2005 - Ongoing	Hyperlipidemia
Calcium carbonate; colecalciferol	2015 - Ongoing	Osteoporosis
Docusate sodium	2019 - Ongoing	Mild Constipation

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	2019 - Ongoing	Hypothyroidism
Lisinopril	Jul 2020 - 19 Feb 2021 (Study Day 180)	Hypertension
Phenylephrine	19 Feb 2021 (Study Day 180) - 22 Feb 2021 (Study Day 183)	Exacerbation Of Orthostatic Hypotension
Platelets	19 Feb 2021 (Study Day 180) - 24 Mar 2021 (Study Day 213)	Thrombocytopenia
Staples to head*	19 Feb 2021 (Study Day 180) - 19 Feb 2021 (Study Day 180)	Adverse Event
Bone marrow biopsy*	23 Feb 2021 (Study Day 184) - 23 Feb 2021 (Study Day 184)	Adverse Event
Midodrine	23 Feb 2021 (Study Day 184) - Ongoing	Orthostatic Hypotension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Orthostatic Hypotension	Grade 3/severe	Not related	19 Feb 2021 (Study Day 180) - 22 Feb 2021 (Study Day 183)
Skin Laceration	Grade 3/severe	Not related	19 Feb 2021 (Study Day 180) - Ongoing
Syncope	Grade 3/severe	Not related	19 Feb 2021 (Study Day 180) - 19 Feb 2021 (Study Day 180)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US331-2379 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 28 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 25 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Endometriosis/ Endometriosis	SAE	Grade 2/ moderate	Not related	18 Jan 2021 (Study Day 144) – Ongoing	Not recovered/ not resolved
Ovarian Cyst/Right Ovarian Cyst	SAE	Grade 3/ severe	Not related	13 Mar 2021 (Study Day 198) – 23 Mar 2021 (Study Day 208)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2379, a 27-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Jan 2021. The participant was unblinded on 04 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 18 Jan 2021 (Study Day 144), 143 days after the first dose in Part A and 115 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of endometriosis. Action taken with the IP was not applicable. The event of endometriosis was considered to be ongoing. The investigator assessed the event of endometriosis to be not related to the IP.

On 13 Mar 2021 (Study Day 198), 197 days after the first dose in Part A and 169 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of ovarian cyst. Action taken with the IP was not applicable. The event of right ovarian cyst lasted for 11 days, after which it was considered to be recovered/resolved on 23 Mar 2021 (Study Day 208). The investigator assessed the event of ovarian cyst to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-077060	Endometriosis
MOD-2021-055495	Ovarian cyst

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nasal septum deviation	Deviated nasal septum	(b) (6) 1992 - May 2016
Migraine	Migraine headaches	2005 - Ongoing
Pernicious anaemia	Pernicious anemia	2009 - Ongoing
Depression	Depression	2010 - Ongoing
Cholecystitis	Cholecystitis	2013 - Oct 2013
Cholecystectomy	Cholecystectomy	Oct 2013 - Oct 2013
Vitamin D deficiency	Vitamin d deficiency	2014 - Ongoing
Bronchiectasis	Chronic ideopathic bronchiectasis	Mar 2014 - Ongoing
Ehlers-Danlos syndrome	Ehlers-danlos syndrome type iii	2015 - Ongoing
Tachycardia	Tachycardia	2015 - Ongoing
Insomnia	Sleep difficulty	2016 - Ongoing
Nasal septal operation	Deviated septum repair	May 2016 - May 2016
Meniscus injury	Torn right meniscus	2017 - Ongoing
Seasonal allergy	Seasonal allergies	Mar 2019 - Ongoing
Ovarian cyst	Ovarian cyst (unknown side)	Jan 2020 - Jan 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cyanocobalamin	2009 - Ongoing	Pernicious Anemia
Sodium chloride	2015 - Ongoing	Chronic Ideopathic Bronchiectasis
Trazodone	2016 - Ongoing	Sleep Difficulty
Azithromycin	Jul 2016 - Ongoing	Chronic Ideopathic Bronchiectasis
Cetirizine hydrochloride	2019 - 19 Dec 2020 (Study Day 114)	Seasonal Allergies
Eletriptan	2019 - Ongoing	Migraine Headaches

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ergocalciferol	Dec 2019 - 21 Nov 2020 (Study Day 86)	Vitamin D Deficiency
Levonorgestrel	Jan 2020 - 22 Dec 2020 (Study Day 117)	Birth Control
Sertraline	Jan 2020 - Ongoing	Depression
Montelukast	Apr 2020 - 19 Dec 2020 (Study Day 114)	Seasonal Allergies
Paracetamol	28 Aug 2020 (Study Day 1) - 28 Aug 2020 (Study Day 1)	Headache
Paracetamol	01 Sep 2020 (Study Day 5) - 01 Sep 2020 (Study Day 5)	Headache
Methylprednisolone	13 Sep 2020 (Study Day 17) - 13 Sep 2020 (Study Day 17)	Neck Strain
Methylprednisolone	14 Sep 2020 (Study Day 18) - 14 Sep 2020 (Study Day 18)	Neck Strain
Ibuprofen	15 Sep 2020 (Study Day 19) - 15 Sep 2020 (Study Day 19)	Neck Strain
Amoxicillin; clavulanic acid	17 Sep 2020 (Study Day 21) - 23 Sep 2020 (Study Day 27)	Bronchiectasis Exacerbation
Paracetamol	26 Sep 2020 (Study Day 30) - 27 Sep 2020 (Study Day 31)	Headache
Influenza vaccine	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Influenza Prophylaxis
Paracetamol	27 Oct 2020 (Study Day 61) - 04 Nov 2020 (Study Day 69)	Upper Respiratory Infection
Amoxicillin; clavulanate potassium	29 Oct 2020 (Study Day 63) - 08 Nov 2020 (Study Day 73)	Exacerbation Of Bronchiectasis
Hydrocodone; paracetamol	19 Nov 2020 (Study Day 84) - 23 Nov 2020 (Study Day 88)	Torn Right Meniscus
Right meniscus repair*	19 Nov 2020 (Study Day 84) - 19 Nov 2020 (Study Day 84)	Medical History
Vitamins nos	22 Nov 2020 (Study Day 87) - Ongoing	Health Maintenance
Hydrocodone bitartrate; paracetamol	18 Jan 2021 (Study Day 144) - 22 Jan 2021 (Study Day 148)	Right Ovarian Cyst
Right ovarian cystectomy*	18 Jan 2021 (Study Day 144) - 18 Jan 2021 (Study Day 144)	Adverse Event
Doxycycline	02 Feb 2021 (Study Day 159) - 09 Feb 2021 (Study Day 166)	Chronic Idiopathic Bronchiectasis
Cefpodoxime	23 Feb 2021 (Study Day 180) - 02 Mar 2021 (Study Day 187)	Urinary Tract Infection
Ibuprofen	14 Mar 2021 (Study Day 199) - 23 Mar 2021 (Study Day 208)	Right Ovarian Cyst Pain
Oxycodone	14 Mar 2021 (Study Day 199) - 23 Mar 2021 (Study Day 208)	Right Ovarian Cyst Pain
Paracetamol	14 Mar 2021 (Study Day 199) - 23 Mar 2021 (Study Day 208)	Right Ovarian Cyst Pain
Ethinylestradiol; levonorgestrel	17 Mar 2021 (Study Day 202) - Ongoing	Birth Control
Right ovarian cystectomy*	17 Mar 2021 (Study Day 202) - 17 Mar 2021 (Study Day 202)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Ovarian Cyst	Grade 1/mild	Not related	18 Jan 2021 (Study Day 144) - Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	22 Feb 2021 (Study Day 179) - 02 Mar 2021 (Study Day 187)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US331-2434 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 29 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 11 Jan 2021 (Study Day 133)
Second Dose of Vaccine in Part B: 19 Feb 2021 (Study Day 172)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Anaemia Postoperative/ Post Operative Anemia	SAE	Grade 3/ severe	Not related	02 Feb 2021 (Study Day 155) – 03 Feb 2021 (Study Day 156)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2434, a 69-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 11 Jan 2021 (Study Day 133). The second dose was administered in the left arm on 19 Feb 2021 (Study Day 172).

Event Details

On 02 Feb 2021 (Study Day 155), 154 days after the first dose in Part A/22 days after the first dose in Part B and 126 days after the second dose in Part A/17 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of anaemia postoperative. Action taken with the IP was not applicable. The event of post operative anemia lasted for 2 days, after which it was considered to be recovered/resolved on 03 Feb 2021 (Study Day 156). The investigator assessed the event of anaemia postoperative to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-016894	Anaemia postoperative

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post menopausal	2000 - Ongoing
Osteoarthritis	Osteoarthritis left knee	2010 - Ongoing
Hypertension	Hypertension	2018 - Ongoing
Osteoporosis	Osteoporosis	2018 - Ongoing
Osteoarthritis	Osteoarthritis right hip	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2017 - Ongoing	Health Maintenance
Alendronate sodium	2018 - Ongoing	Osteoporosis
Calcium	2018 - Ongoing	Health Maintenance
Lisinopril	2018 - Ongoing	Hypertension
Colecalciferol	15 Jun 2020 (Study Day -78) - Ongoing	Health Maintenance
Naproxen	26 Jun 2020 (Study Day -67) - Ongoing	Osteoarthritis Left Knee
Paracetamol	26 Jun 2020 (Study Day -67) - Ongoing	Osteoarthritis Left Knee
Influenza vaccine	16 Oct 2020 (Study Day 46) - 16 Oct 2020 (Study Day 46)	Seasonal Influenza Vaccine
Lisinopril	20 Oct 2020 (Study Day 50) - Ongoing	Hypertension
Hydrochlorothiazide	Nov 2020 - 03 Feb 2021 (Study Day 156)	Hypertension
Amlodipine	22 Nov 2020 (Study Day 83) - Ongoing	Hypertension
Anesthetics, local	01 Feb 2021 (Study Day 154) - 01 Feb 2021 (Study Day 154)	Worsening Osteoarthritis Right Hip
Cefazolin sodium	01 Feb 2021 (Study Day 154) - 01 Feb 2021 (Study Day 154)	Perioperative Prophylaxis
Enoxaparin sodium	01 Feb 2021 (Study Day 154) - 02 Feb 2021 (Study Day 155)	Worsening Osteoarthritis Right Hip
I.v. solutions	01 Feb 2021 (Study Day 154) - 02 Feb 2021 (Study Day 155)	Worsening Osteoarthritis Right Hip
Right hip replacement*	01 Feb 2021 (Study Day 154) - 01 Feb 2021 (Study Day 154)	Adverse Event
Meloxicam	02 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 169)	Worsening Osteoarthritis Right Hip

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	02 Feb 2021 (Study Day 155) - 07 Mar 2021 (Study Day 188)	Worsening Osteoarthritis Right Hip
Oxycodone	03 Feb 2021 (Study Day 156) - 10 Feb 2021 (Study Day 163)	Post-Op Pain (Right Hip Replacement)
Acetylsalicylic acid	04 Feb 2021 (Study Day 157) - Ongoing	Deep Vein Thrombosis Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Procedural Pain	Grade 3/severe	Not related	01 Feb 2021 (Study Day 154) - 07 Mar 2021 (Study Day 188)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US331-2465 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 02 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 30 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Suicide Attempt/Suicide Attempt	SAE	Grade 3/severe	Not related	02 Mar 2021 (Study Day 182) – 02 Mar 2021 (Study Day 182)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2465, an 18-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 02 Feb 2021. The participant was unblinded on 02 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 02 Mar 2021 (Study Day 182), 181 days after the first dose in Part A and 153 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of suicide attempt. Action taken with the IP was not applicable. The event of suicide attempt lasted for 1 day, after which it was considered to be recovered/resolved on 02 Mar 2021 (Study Day 182). The investigator assessed the event of suicide attempt to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-060230	Suicide attempt

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Attention deficit hyperactivity disorder	Attention deficit disorder	2010 - Ongoing
Drug hypersensitivity	Adderall allergy	2010 - Ongoing
Alcohol use disorder	Alcohol use disorder	2016 - Ongoing
Anxiety	Anxiety	2016 - Ongoing
Depression	Depression	2016 - Ongoing
Drug abuse	Benzodiazepine abuse	2016 - Ongoing
Panic attack	Panic attacks	2016 - Ongoing
Social anxiety disorder	Social anxiety disorder	2016 - Ongoing
Substance use disorder	Cannabis use disorder	2016 - Ongoing
Suicide attempt	Suicide attempt (x4)	2016 - 2020
Asthma	Asthma	2018 - Ongoing
Bronchitis	Bronchitis	2018 - 2018
Blister	Right second finger blister	31 Aug 2020 (Study Day -2) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2018 - Ongoing	Asthma
Clonazepam	Apr 2020 - 02 Mar 2021 (Study Day 182)	Anxiety
Alprazolam	30 Sep 2020 (Study Day 29) - 02 Mar 2021 (Study Day 182)	Anxiety
Fluoxetine	02 Feb 2021 (Study Day 154) - 05 Feb 2021 (Study Day 157)	Exacerbation Of Depression
Trazodone	02 Feb 2021 (Study Day 154) - 01 Mar 2021 (Study Day 181)	Exacerbation Of Depression
Fluoxetine	06 Feb 2021 (Study Day 158) - 05 Mar 2021 (Study Day 185)	Exacerbation Of Depression
Hydroxyzine	02 Mar 2021 (Study Day 182) - Ongoing	Exacerbation Of Depression
Trazodone	02 Mar 2021 (Study Day 182) - Ongoing	Exacerbation Of Depression
Gabapentin	03 Mar 2021 (Study Day 183) - Ongoing	Exacerbation Of Depression
Fluoxetine	05 Mar 2021 (Study Day 185) - Ongoing	Exacerbation Of Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US332-2314 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Transient Ischaemic Attack/ Transient Ischemic Attack	SAE	Grade 3/ severe	Not related	05 Apr 2021 (Study Day 207) – 06 Apr 2021 (Study Day 208)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US332-2314, a 46-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was positive. The participant proceeded to Part B, the Open-Label Observational Phase, on 18 Jan 2021. The participant was unblinded on 18 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 05 Apr 2021 (Study Day 207), 206 days after the first dose in Part A and 178 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of transient ischaemic attack. Action taken with the IP was not applicable. The event of transient ischemic attack lasted for 2 days, after which it was considered to be recovered/resolved on 06 Apr 2021 (Study Day 208). The investigator assessed the event of transient ischaemic attack to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-068928	Transient ischaemic attack

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Aortic stenosis	Aortic stenosis	(b) (6) 1974 (Study Day (b) (6) - Feb 1985
Drug eruption	Codeine allergy (rash)	1975 - Ongoing
Seasonal allergy	Seasonal allergies	1975 - Ongoing
Aortic surgery	Aortic stenosis repair surgery	Feb 1985 - Feb 1985
Dextrocardia	Dextrocardia	1986 - Ongoing
Rosacea	Rosacea	2007 - Ongoing
Palpitations	Palpitation	2017 - 2017
Arteriosclerosis coronary artery	Coronary atherosclerosis	23 Aug 2018 (Study Day -750) - Ongoing
Hyperlipidaemia	Hyperlipidemia	23 Aug 2018 (Study Day -750) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol	Apr 2017 - May 2017	Palpitation
Ibuprofen	12 Sep 2020 (Study Day 2) - 12 Sep 2020 (Study Day 2)	Injection Site Pain
Influenza vaccine	12 Nov 2020 (Study Day 63) - 12 Nov 2020 (Study Day 63)	Preventative Healthcare
Minerals nos; vitamins nos	06 Dec 2020 (Study Day 87) - Ongoing	Supplement
Zinc	06 Dec 2020 (Study Day 87) - Ongoing	Immunity
Cetirizine	07 Dec 2020 (Study Day 88) - Ongoing	Allergies

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US333-2033 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 10 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 33)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Myocardial Infarction/Non-St Elevation Acute Myocardial Infarction	SAE	Grade 4	Not related	25 Feb 2021 (Study Day 200) – 05 Mar 2021 (Study Day 208)	Recovered/resolved
Coronary Artery Disease/ Worsening Of Coronary Artery Disease	SAE	Grade 4	Not related	25 Feb 2021 (Study Day 200) – 05 Mar 2021 (Study Day 208)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US333-2033, a 77-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 25 Jan 2021. The participant was unblinded on 25 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 25 Feb 2021 (Study Day 200), 199 days after the first dose in Part A and 167 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of acute myocardial infarction. Action taken with the IP was not applicable. The event of non-st elevation acute myocardial infarction lasted for 9 days, after which it was considered to be recovered/resolved on 05 Mar 2021 (Study Day 208). The investigator assessed the event of acute myocardial infarction to be not related to the IP.

On 25 Feb 2021 (Study Day 200), 199 days after the first dose in Part A and 167 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of coronary artery disease. Action taken with the IP was not applicable. The event of worsening of coronary artery disease lasted for 9 days, after which it was considered to be recovered/resolved

on 05 Mar 2021 (Study Day 208). The investigator assessed the event of coronary artery disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-026591	Acute myocardial infarction
MOD-2021-026591	Coronary artery disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Benign prostatic hyperplasia	Benign prostatic hypertrophy	2012 - Ongoing
Erectile dysfunction	Erectile dysfunction	2012 - Ongoing
Coronary artery disease	Coronary artery disease	2016 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2016 - Ongoing
Hypertension	Hypertension	2016 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2016 - Ongoing
Coronary arterial stent insertion	Cardiac stent placement	29 Sep 2016 (Study Day -1411) - 29 Sep 2016 (Study Day -1411)
Myocardial infarction	Myocardial infarction	29 Sep 2016 (Study Day -1411) - 29 Sep 2016 (Study Day -1411)
Dyspnoea	Shortness of breath intermittent	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2017 - Ongoing	Cardiac Prophylaxis
Atorvastatin	2017 - 26 Feb 2021 (Study Day 201)	Hypercholesterolemia
Clopidogrel	2017 - 30 Sep 2020 (Study Day 52)	Cardiac Prophylaxis
Losartan	2017 - 12 Dec 2020 (Study Day 125)	Hypertension
Metformin	2017 - Ongoing	Prediabetes
Metoprolol	2017 - 26 Feb 2021 (Study Day 201)	Hypertension
Sildenafil	2017 - Ongoing	Erectile Dysfunction

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	17 Nov 2020 (Study Day 100) - 17 Nov 2020 (Study Day 100)	Influenza Prophylaxis
Calcium chloride; potassium chloride; sodium lactate	12 Dec 2020 (Study Day 125) - 12 Dec 2020 (Study Day 125)	Syncope
Cefalexin	12 Dec 2020 (Study Day 125) - 19 Dec 2020 (Study Day 132)	Urinary Tract Infection
Ceftriaxone	12 Dec 2020 (Study Day 125) - 12 Dec 2020 (Study Day 125)	Urinary Tract Infection
Losartan	12 Dec 2020 (Study Day 125) - 26 Feb 2021 (Study Day 201)	Hypertension
Ciprofloxacin	20 Jan 2021 (Study Day 164) - 06 Feb 2021 (Study Day 181)	Urinary Tract Infection
Tamsulosin	20 Jan 2021 (Study Day 164) - Ongoing	Uti Prophylaxis
Atorvastatin	26 Feb 2021 (Study Day 201) - Ongoing	Worsening Of Coronary Artery Disease
Cardiac stent placement*	26 Feb 2021 (Study Day 201) - 26 Feb 2021 (Study Day 201)	Adverse Event
Chest x ray*	26 Feb 2021 (Study Day 201) - 26 Feb 2021 (Study Day 201)	Adverse Event
Echocardiogram*	26 Feb 2021 (Study Day 201) - 26 Feb 2021 (Study Day 201)	Adverse Event
Ekg*	26 Feb 2021 (Study Day 201) - 26 Feb 2021 (Study Day 201)	Adverse Event
Heparin	26 Feb 2021 (Study Day 201) - 05 Mar 2021 (Study Day 208)	Blood Clot Prophylaxis
Losartan	26 Feb 2021 (Study Day 201) - 26 Feb 2021 (Study Day 201)	Worsening Of Coronary Artery Disease
Metoprolol succinate	26 Feb 2021 (Study Day 201) - Ongoing	Worsening Of Coronary Artery Disease
Sodium chloride	26 Feb 2021 (Study Day 201) - 26 Feb 2021 (Study Day 201)	Surgical Prophylaxis
Tirofiban	26 Feb 2021 (Study Day 201) - 26 Feb 2021 (Study Day 201)	Blood Clot Prophylaxis
Coronary artery bypass graft x 2*	01 Mar 2021 (Study Day 204) - 01 Mar 2021 (Study Day 204)	Adverse Event
Norepinephrine	01 Mar 2021 (Study Day 204) - 01 Mar 2021 (Study Day 204)	Worsening Of Coronary Artery Disease
Protamine	01 Mar 2021 (Study Day 204) - 01 Mar 2021 (Study Day 204)	Hemorrhage Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anaemia	Grade 2/moderate	Not related	26 Feb 2021 (Study Day 201) - Ongoing

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pleural Effusion	Grade 2/moderate	Not related	26 Feb 2021 (Study Day 201) - Ongoing
Hiatus Hernia	Grade 1/mild	Not related	28 Feb 2021 (Study Day 203) - Ongoing
Oedema Peripheral	Grade 1/mild	Not related	01 Mar 2021 (Study Day 204) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US333-2059 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 24 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 18 Sep 2020 (Study Day 26)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acetabulum Fracture/ Right Acetabular Fracture	SAE	Grade 4	Not related	22 Apr 2021 (Study Day 242) – Ongoing	Not recovered/ not resolved
Fractured Sacrum/Closed Sacral Fracture	SAE	Grade 4	Not related	22 Apr 2021 (Study Day 242) – Ongoing	Not recovered/ not resolved
Pelvic Fracture/Multiple Pelvic Fractures	SAE	Grade 4	Not related	22 Apr 2021 (Study Day 242) – Ongoing	Not recovered/ not resolved
Rib Fracture/Right Ribs #4-8 Fractures	SAE	Grade 4	Not related	22 Apr 2021 (Study Day 242) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US333-2059, a 66-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 03 Mar 2021. The participant was unblinded on 03 Mar 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 22 Apr 2021 (Study Day 242), 241 days after the first dose in Part A and 216 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of acetabulum fracture. Action taken with the IP was not applicable. The event of right acetabular fracture was considered to be ongoing. The investigator assessed the event of acetabulum fracture to be not related to the IP.

On 22 Apr 2021 (Study Day 242), 241 days after the first dose in Part A and 216 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of fractured sacrum. Action taken with the IP was not applicable. The event of closed sacral fracture

was considered to be ongoing. The investigator assessed the event of fractured sacrum to be not related to the IP.

On 22 Apr 2021 (Study Day 242), 241 days after the first dose in Part A and 216 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of pelvic fracture. Action taken with the IP was not applicable. The event of multiple pelvic fractures was considered to be ongoing. The investigator assessed the event of pelvic fracture to be not related to the IP.

On 22 Apr 2021 (Study Day 242), 241 days after the first dose in Part A and 216 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of rib fracture. Action taken with the IP was not applicable. The event of right ribs #4-8 fractures was considered to be ongoing. The investigator assessed the event of rib fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-099268	Acetabulum fracture
MOD-2021-099268	Fractured sacrum
MOD-2021-099268	Pelvic fracture
MOD-2021-099268	Rib fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Benign neoplasm of spinal cord	Benign spinal tumor (t3-t4)	1977 - 1977
Nerve compression	Low back pinched nerve	1977 - Ongoing
Spinal laminectomy	Spinal decompressive laminectomy	1977 - 1977
Myalgia	Exercise related muscle soreness	1980 - Ongoing
Seasonal allergy	Seasonal allergies	1980 - Ongoing
Osteoporosis	Osteoporosis	1996 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	1996 - Ongoing
Drug intolerance	Venlafaxine hcl intolerance	2000 - Ongoing
Drug hypersensitivity	Allergy- sulfa drugs	2007 - Ongoing
Drug hypersensitivity	Nitrofurantoin intolerance	2007 - Ongoing
Drug hypersensitivity	Sulfamethoxazole allergy	2007 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Trimethoprim allergy	2007 - Ongoing
Anxiety	Anxiety	2010 - Ongoing
Migraine	Migraines	2010 - Ongoing
Hypercholesterolaemia	Hypoercholesterolemia	2011 - Ongoing
Postmenopause	Postmenopausal	2011 - Ongoing
Depression	Depression	2013 - Ongoing
Deafness bilateral	Bilateral hearing loss	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Naproxen sodium	1980 - Ongoing	Exercise Related Muscle Soreness
Naproxen sodium	1980 - Ongoing	Low Back Pinched Nerve
Fluticasone propionate	2000 - Ongoing	Seasonal Allergies
Escitalopram oxalate	May 2010 - Ongoing	Anxiety
Sumatriptan succinate	21 Oct 2010 (Study Day -3595) - Ongoing	Migraines
Calcium	2013 - Ongoing	Supplement
Colecalciferol	2013 - Ongoing	Supplement
Vitamins nos	2013 - Ongoing	Supplement
Krill oil	2015 - Ongoing	Supplement
Denosumab	2017 - Ongoing	Osteoporosis
Artificial tears [umbrella term]	2019 - Ongoing	Bilateral Dry Eyes
Naproxen sodium	19 Sep 2020 (Study Day 27) - 19 Sep 2020 (Study Day 27)	Headache, Muscle Aches, Joint Pain
Influenza vaccine	09 Oct 2020 (Study Day 47) - 09 Oct 2020 (Study Day 47)	Influenza Prophylaxis
Nasal cauterization*	02 Mar 2021 (Study Day 191) - 02 Mar 2021 (Study Day 191)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US334-2085 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 17 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Sep 2020 (Study Day 31)
First Dose of Vaccine in Part B: 12 Jan 2021 (Study Day 149)
Second Dose of Vaccine in Part B: 23 Feb 2021 (Study Day 191)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis/Appendicitis	SAE	Grade 4	Not related	02 Feb 2021 (Study Day 170) – 03 Feb 2021 (Study Day 171)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2085, a 51-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 12 Jan 2021 (Study Day 149). The second dose was administered in the left arm on 23 Feb 2021 (Study Day 191).

Event Details

On 02 Feb 2021 (Study Day 170), 169 days after the first dose in Part A/21 days after the first dose in Part B and 139 days after the second dose in Part A/21 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of appendicitis. The IP dose was not changed due to the appendicitis. The event of appendicitis lasted for 2 days, after which it was considered to be recovered/resolved on 03 Feb 2021 (Study Day 171). The investigator assessed the event of appendicitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-011718	Appendicitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	2005 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit disorder	2011 - Ongoing
Botulinum toxin injection	Facial botox	2014 - Ongoing
Botulinum toxin injection	Facial dysport	2015 - Ongoing
Hypothyroidism	Hypothyroidism	2015 - Ongoing
Dermal filler injection	Facial juvederm	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Citalopram hydrobromide	2010 - Ongoing	Depression
Amphetamine aspartate; amphetamine sulfate; dexamphetamine saccharate; dexamphetamine sulfate	2011 - Ongoing	Attention Deficit Disorder
Botulinum toxin type a haemagglutinin complex	2015 - Ongoing	Elective (Cosmetic)
Levothyroxine sodium	2015 - Ongoing	Hypothyroidism
Hyaluronic acid	2017 - Ongoing	Elective (Cosmetic)
Influenza vaccine	12 Oct 2020 (Study Day 57) - 12 Oct 2020 (Study Day 57)	Influenza Prophylaxis
Codeine phosphate; guaifenesin	15 Nov 2020 (Study Day 91) - 19 Nov 2020 (Study Day 95)	Viral Uri (Ae)
Ct scan*	02 Feb 2021 (Study Day 170) - 02 Feb 2021 (Study Day 170)	Diagnostic
Appendectomy*	03 Feb 2021 (Study Day 171) - 03 Feb 2021 (Study Day 171)	Adverse Event
Ketorolac	03 Feb 2021 (Study Day 171) - 07 Feb 2021 (Study Day 175)	Appendicitis Ae
Botulinum toxin type a	03 Mar 2021 (Study Day 199) - Ongoing	Elective (Cosmetic)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US334-2127 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 20 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 21 Sep 2020 (Study Day 33)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardiac Failure Congestive/Worsening Of Congestive Heart Failure	SAE	Grade 4	Not related	01 Mar 2021 (Study Day 194) – Ongoing	Recovering/ resolving
Pulmonary Embolism/ Pulmonary Embolism Right Lung	SAE	Grade 4	Not related	11 Apr 2021 (Study Day 235) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2127, a 64-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 29 Jan 2021. The participant was unblinded on 29 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 01 Mar 2021 (Study Day 194), 193 days after the first dose in Part A and 161 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of cardiac failure congestive. Action taken with the IP was not applicable. The event of worsening of congestive heart failure was considered to be ongoing. The investigator assessed the event of cardiac failure congestive to be not related to the IP.

On 11 Apr 2021 (Study Day 235), 234 days after the first dose in Part A and 202 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of pulmonary embolism. Action taken with the IP was not applicable. The event of pulmonary embolism right lung was considered to be ongoing. The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-040209	Cardiac failure congestive
MOD-2021-079725	Pulmonary embolism

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gun shot wound	Gun shot wound	1980 - 1980
Deep vein thrombosis	Deep vein thrombosis	1988 - 1988
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Hepatitis B	Hepatitis b	2006 - 2006
Anxiety	Anxiety	2010 - Ongoing
Arrhythmia	Heart arrhythmia (type unknown)	2010 - Ongoing
Depression	Depression	2015 - Ongoing
Cardiac failure congestive	Congestive heart failure	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Buspirone hydrochloride	2010 - Ongoing	Anxiety
Acetylsalicylic acid	2015 - Ongoing	Cardiac Prophylaxis
Escitalopram	2015 - Ongoing	Depression
Loratadine	2015 - Ongoing	Seasonal Allergies
Fluticasone	Jan 2020 - Ongoing	Seasonal Allergies
Acetylsalicylic acid	21 Aug 2020 (Study Day 2) - 23 Aug 2020 (Study Day 4)	Injection Site Pain
Acetylsalicylic acid	22 Sep 2020 (Study Day 34) - 22 Sep 2020 (Study Day 34)	Headache
Acetylsalicylic acid	30 Dec 2020 (Study Day 133) - 31 Dec 2020 (Study Day 134)	Viral Uri Ae
Thoracentesis*	06 Mar 2021 (Study Day 199) - 06 Mar 2021 (Study Day 199)	Adverse Event
Atorvastatin	22 Mar 2021 (Study Day 215) - Ongoing	Worsening Of Congestive Heart Failure Sae

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Carvedilol	22 Mar 2021 (Study Day 215) - Ongoing	Worsening Of Congestive Heart Failure Sae

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US334-2354 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 13 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 12 Nov 2020 (Study Day 31)
First Dose of Vaccine in Part B: 28 Jan 2021 (Study Day 108)
Second Dose of Vaccine in Part B: 26 Feb 2021 (Study Day 137)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Sepsis/Septicemia	SAE	Grade 4	Not related	18 Apr 2021 (Study Day 188) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2354, a 51-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 13 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 12 Nov 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 19 Jan 2021. The participant was unblinded on 19 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 28 Jan 2021 (Study Day 108). The second dose was administered in the left arm on 26 Feb 2021 (Study Day 137).

Event Details

On 18 Apr 2021 (Study Day 188), 187 days after the first dose in Part A/80 days after the first dose in Part B and 157 days after the second dose in Part A/51 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of sepsis. Action taken with the IP was not applicable. The event of septicemia was considered to be ongoing. The investigator assessed the event of sepsis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-099185	Sepsis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headaches	1985 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2013 - Ongoing
Hypertension	Hypertension	2013 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2013 - Ongoing
Postmenopause	Postmenopausal	2016 - Ongoing
Anxiety	Anxiety	2018 - Ongoing
Depression	Depression	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	1985 - Ongoing	Headaches
Amlodipine	2013 - Ongoing	Hypercholesterolemia
Insulin human; insulin human injection, isophane	2013 - 11 Dec 2020 (Study Day 60)	Type II Diabetes
Metformin	2013 - Ongoing	Type II Diabetes
Pravastatin	2013 - 20 Apr 2021 (Study Day 190)	Hypertension
Sitagliptin	2013 - 11 Dec 2020 (Study Day 60)	Type II Diabetes
Bupropion	2018 - Ongoing	Anxiety & Depression
Fluoxetine	2018 - Ongoing	Anxiety & Depression
Ibuprofen	14 Nov 2020 (Study Day 33) - 14 Nov 2020 (Study Day 33)	Headache Post Vaccine #2 Ar
Abdominal/pelvis ct with contrast*	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Adverse Event
Ceftriaxone sodium	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Diabetic Ketoacidosis Ae
Chest xray*	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Adverse Event
Insulin	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Diabetic Ketoacidosis Ae
Insulin human	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Diabetic Ketoacidosis Ae
Iopamidol	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Diabetic Ketoacidosis Ae

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ondansetron	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Diabetic Ketoacidosis Ae
Sodium chloride	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Diabetic Ketoacidosis Ae
Insulin aspart	13 Dec 2020 (Study Day 62) - Ongoing	Type II Diabetes Mellitus
Sitagliptin	13 Dec 2020 (Study Day 62) - Ongoing	Type II Diabetes Mellitus
Oxcarbazepine	05 Jan 2021 (Study Day 85) - Ongoing	Anxiety And Depression Exacerbation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US335-2015 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 04 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 31)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cholecystitis Acute/ Acute Cholecystitis	SAE	Grade 4	Not related	21 Mar 2021 (Study Day 230) – 28 Mar 2021 (Study Day 237)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US335-2015, a 41-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 13 Jan 2021. The participant was unblinded on 13 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 21 Mar 2021 (Study Day 230), 229 days after the first dose in Part A and 199 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of cholecystitis acute. Action taken with the IP was not applicable. The event of acute cholecystitis lasted for 8 days, after which it was considered to be recovered/resolved on 28 Mar 2021 (Study Day 237). The investigator assessed the event of cholecystitis acute to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-061249	Cholecystitis acute

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Thalassaemia minor	B-thalassemia minor	(b) (6) 1979 (Study Day (b) (6) - Ongoing
Rhinitis allergic	Allergic rhinitis	1983 - Ongoing
Intervertebral disc protrusion	L5-s1 disc herniation	Sep 2011 - Sep 2011
Spinal laminectomy	Laminectomy	Sep 2011 - Sep 2011
Cholelithiasis	Gall-bladder stones	2016 - Ongoing
Hepatic steatosis	Fatty liver	2016 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2017 - Ongoing
Anxiety	Anxiety	01 Jun 2019 (Study Day -430) - Ongoing
Dyspepsia	Heartburn	06 Jun 2020 (Study Day -59) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sertraline	01 Jun 2019 (Study Day -430) - Ongoing	Anxiety
Pantoprazole sodium sesquihydrate	06 Jun 2020 (Study Day -59) - Ongoing	Heartburn
Paracetamol	04 Sep 2020 (Study Day 32) - 04 Sep 2020 (Study Day 32)	Earache
Docusate sodium	26 Mar 2021 (Study Day 235) - 28 Mar 2021 (Study Day 237)	Abdominal Pain
Ekg*	26 Mar 2021 (Study Day 235) - 26 Mar 2021 (Study Day 235)	Diagnostic
Ketorolac tromethamine	26 Mar 2021 (Study Day 235) - 28 Mar 2021 (Study Day 237)	Acute Cholecystectomy
Oxycodone hydrochloride; paracetamol	26 Mar 2021 (Study Day 235) - 29 Mar 2021 (Study Day 238)	Abdominal Pain
Paracetamol	26 Mar 2021 (Study Day 235) - 28 Mar 2021 (Study Day 237)	Abdominal Pain
Right upper quadrant ultrasound*	26 Mar 2021 (Study Day 235) - 26 Mar 2021 (Study Day 235)	Adverse Event
Sars cov 2 (covid 19)*	26 Mar 2021 (Study Day 235) - 26 Mar 2021 (Study Day 235)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nausea	Grade 1/mild	Not related	25 Mar 2021 (Study Day 234) - 28 Mar 2021 (Study Day 237)
Hepatic Steatosis	Grade 1/mild	Not related	26 Mar 2021 (Study Day 235) - Ongoing
Leukocytosis	Grade 1/mild	Not related	26 Mar 2021 (Study Day 235) - 27 Mar 2021 (Study Day 236)
Umbilical Hernia	Grade 1/mild	Not related	26 Mar 2021 (Study Day 235) - 27 Mar 2021 (Study Day 236)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US335-2070 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 13 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 27)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Deep Vein Thrombosis/Left Popliteal Deep Vein Thrombosis	SAE	Grade 4	Not related	10 Mar 2021 (Study Day 210) – Ongoing	Not recovered/ not resolved
Sepsis/Sepsis	SAE	Grade 4	Not related	10 Mar 2021 (Study Day 210) – Ongoing	Not recovered/ not resolved
Tibia Fracture/Worsening Of Left Distal Tibia Fracture	SAE	Grade 4	Not related	10 Mar 2021 (Study Day 210) – Ongoing	Recovering/ resolving
Cellulitis/Cellulitis Of Left Leg	SAE	Grade 4	Not related	05 Apr 2021 (Study Day 236) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US335-2070, a 54-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 16 Jan 2021. The participant was unblinded on 16 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 10 Mar 2021 (Study Day 210), 209 days after the first dose in Part A and 183 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of deep vein thrombosis. Action taken with the IP was not applicable. The event of left popliteal deep vein thrombosis was considered to be ongoing. The investigator assessed the event of deep vein thrombosis to be not related to the IP.

On 10 Mar 2021 (Study Day 210), 209 days after the first dose in Part A and 183 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of sepsis. Action taken with the IP was not applicable. The event of sepsis was considered to be ongoing. The investigator assessed the event of sepsis to be not related to the IP.

On 10 Mar 2021 (Study Day 210), 209 days after the first dose in Part A and 183 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of tibia fracture. Action taken with the IP was not applicable. The event of worsening of left distal tibia fracture was considered to be ongoing. The investigator assessed the event of tibia fracture to be not related to the IP.

On 05 Apr 2021 (Study Day 236), 235 days after the first dose in Part A and 209 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of cellulitis. Action taken with the IP was not applicable. The event of cellulitis of left leg was considered to be ongoing. The investigator assessed the event of cellulitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-055683	Cellulitis
MOD-2021-055683	Deep vein thrombosis
MOD-2021-055683	Sepsis
MOD-2021-055683	Tibia fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Alcohol abuse	Alcohol abuse	Not reported
Cough	Chronic cough	Not reported
Malignant melanoma	Melanoma of the lower back	Not reported
Mastoiditis	Unspecified mastoiditis bilateral	Not reported
Otorrhoea	Purulent otorrhea of right ear	Not reported
Astigmatism	Astigmatism bilateral	1969 - Ongoing
Tobacco user	Current tobacco user	1983 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	01 Oct 2020 (Study Day 50) - Ongoing	Left Distal Tibia Fracture
Oxycodone hydrochloride; paracetamol	01 Oct 2020 (Study Day 50) - Ongoing	Left Distal Tibia Fracture
Influenza vaccine	11 Dec 2020 (Study Day 121) - 11 Dec 2020 (Study Day 121)	Flu Prevention
Covid 19 antigen bd*	10 Mar 2021 (Study Day 210) - 10 Mar 2021 (Study Day 210)	Diagnostic
Ct angiogram of pulmonary arteries with contrast*	10 Mar 2021 (Study Day 210) - 10 Mar 2021 (Study Day 210)	Adverse Event
Ecg*	10 Mar 2021 (Study Day 210) - 10 Mar 2021 (Study Day 210)	Diagnostic
Ra chest 1 view*	10 Mar 2021 (Study Day 210) - 10 Mar 2021 (Study Day 210)	Diagnostic
Us doppler lower extremity venous left.*	10 Mar 2021 (Study Day 210) - 10 Mar 2021 (Study Day 210)	Adverse Event
Cefepime hydrochloride	11 Mar 2021 (Study Day 211) - Ongoing	Cellulitis Of Right Leg
Clindamycin	11 Mar 2021 (Study Day 211) - Ongoing	Sepsis
Diazepam	11 Mar 2021 (Study Day 211) - Ongoing	Left Popliteal Deep Vein Thrombosis
Enoxaparin sodium	11 Mar 2021 (Study Day 211) - Ongoing	Left Popliteal Deep Vein Thrombosis
Ketorolac tromethamine	11 Mar 2021 (Study Day 211) - Ongoing	Left Popliteal Deep Vein Thrombosis
Ondansetron	11 Mar 2021 (Study Day 211) - Ongoing	Nausea
Oxycodone hydrochloride; paracetamol	11 Mar 2021 (Study Day 211) - Ongoing	Left Popliteal Deep Vein Thrombosis
Ra ankle portable left*	11 Mar 2021 (Study Day 211) - 11 Mar 2021 (Study Day 211)	Adverse Event
Sodium chloride; vancomycin hydrochloride	11 Mar 2021 (Study Day 211) - Ongoing	Sepsis
Vancomycin	11 Mar 2021 (Study Day 211) - 17 Mar 2021 (Study Day 217)	Sepsis
Zolpidem tartrate	11 Mar 2021 (Study Day 211) - Ongoing	Sleep
Irrigation and debridement left ankle*	13 Mar 2021 (Study Day 213) - 13 Mar 2021 (Study Day 213)	Adverse Event
Mri ankle with and without contrast left*	13 Mar 2021 (Study Day 213) - 13 Mar 2021 (Study Day 213)	Adverse Event
Removal of hardware ankle surgery*	13 Mar 2021 (Study Day 213) - 13 Mar 2021 (Study Day 213)	Adverse Event
Mri left foot with and without contrast.*	14 Mar 2021 (Study Day 214) - 14 Mar 2021 (Study Day 214)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US335-2213 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 22 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 19 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 16 Jan 2021 (Study Day 148)
Second Dose of Vaccine in Part B: 24 Feb 2021 (Study Day 187)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cerebrovascular Accident/Cerebrovascular Accident	SAE	Grade 4	Not related	29 Jan 2021 (Study Day 161) – 03 Feb 2021 (Study Day 166)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US335-2213, a 62-year-old Hispanic or Latino male, received the first dose of Placebo in the left arm on 22 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 19 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 16 Jan 2021. The participant was unblinded on 16 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 16 Jan 2021 (Study Day 148). The second dose was administered in the left arm on 24 Feb 2021 (Study Day 187).

Event Details

On 29 Jan 2021 (Study Day 161), 160 days after the first dose in Part A/13 days after the first dose in Part B and 132 days after the second dose in Part A/26 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of cerebrovascular accident. The IP dose was delayed due to the cerebrovascular accident. The event of cerebrovascular accident lasted for 6 days, after which it was considered to be recovered/resolved with sequelae on 03 Feb 2021 (Study Day 166). The investigator assessed the event of cerebrovascular accident to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014196	Cerebrovascular accident

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1995 - Ongoing
Coronary artery bypass	Coronary artery bypass	2008 - 2008
Coronary artery disease	Coronary artery disease (high risk)	2008 - 2008
Presbyopia	Presbyopia	2013 - Ongoing
Varicose vein	Varicose veins	2013 - Ongoing
Osteoarthritis	Osteoarthritis	2015 - Ongoing
Atrial fibrillation	Atrial fibrillation	2016 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2016 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	Feb 2020 - Ongoing
Pollakiuria	Urinary frequency	Feb 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide	2018 - Ongoing	Hypertension
Metoprolol	2018 - Ongoing	Hypertension
Nifedipine	2018 - Ongoing	Hypertension
Oxybutynin	Feb 2020 - Ongoing	Urinary Frequency
Ct of the brain without contrast.*	29 Jan 2021 (Study Day 161) - 29 Jan 2021 (Study Day 161)	Adverse Event
Ecg*	29 Jan 2021 (Study Day 161) - 29 Jan 2021 (Study Day 161)	Adverse Event
Rosuvastatin calcium	29 Jan 2021 (Study Day 161) - 02 Feb 2021 (Study Day 165)	Hyperlipidemia
X ray chest*	29 Jan 2021 (Study Day 161) - 29 Jan 2021 (Study Day 161)	Adverse Event
Collagenase	30 Jan 2021 (Study Day 162) - 03 Feb 2021 (Study Day 166)	Wound Of Right Foot
Mri brain without contrast*	30 Jan 2021 (Study Day 162) - 30 Jan 2021 (Study Day 162)	Adverse Event
Tamsulosin	30 Jan 2021 (Study Day 162) - 02 Feb 2021 (Study Day 165)	Benign Prostatic Hyperplasia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
X ray ankle complete right*	30 Jan 2021 (Study Day 162) - 30 Jan 2021 (Study Day 162)	Adverse Event
Enoxaparin sodium	31 Jan 2021 (Study Day 163) - 02 Feb 2021 (Study Day 165)	Cerebrovascular Accident
Hydralazine	31 Jan 2021 (Study Day 163) - 03 Feb 2021 (Study Day 166)	Worsening Of Hypertension
Ceftriaxone	01 Feb 2021 (Study Day 164) - 01 Feb 2021 (Study Day 164)	Wound Of Right Foot
Ct scan of the brain without contrast*	01 Feb 2021 (Study Day 164) - 01 Feb 2021 (Study Day 164)	Adverse Event
Potassium chloride	01 Feb 2021 (Study Day 164) - 01 Feb 2021 (Study Day 164)	Worsening Of Hypertension
Cefepime	02 Feb 2021 (Study Day 165) - 03 Feb 2021 (Study Day 166)	Wound Of Right Foot
Gentamicin	02 Feb 2021 (Study Day 165) - 03 Feb 2021 (Study Day 166)	Wound Of Right Foot
Acetylsalicylic acid	03 Feb 2021 (Study Day 166) - Ongoing	Cardiovascular Prophylaxis
Apixaban	03 Feb 2021 (Study Day 166) - Ongoing	Atrial Fibrillation
Atorvastatin	03 Feb 2021 (Study Day 166) - Ongoing	Hyperlipidemia
Clonidine	03 Feb 2021 (Study Day 166) - Ongoing	Hypertension
Hydralazine	03 Feb 2021 (Study Day 166) - 03 Feb 2021 (Study Day 166)	Worsening Of Hypertension.
Occupational therapy*	13 Feb 2021 (Study Day 176) - 13 Feb 2021 (Study Day 176)	Adverse Event
Speech therapy*	13 Feb 2021 (Study Day 176) - 13 Feb 2021 (Study Day 176)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anaemia	Grade 1/mild	Not related	29 Jan 2021 (Study Day 161) - Ongoing
Hypertension	Grade 3/severe	Not related	29 Jan 2021 (Study Day 161) - 03 Feb 2021 (Study Day 166)
Limb Injury	Grade 1/mild	Not related	30 Jan 2021 (Study Day 162) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US335-2297 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 29 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 16 Jan 2021 (Study Day 138)
Second Dose of Vaccine in Part B: 13 Feb 2021 (Study Day 166)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Limb Injury/Left Hand Trauma	SAE	Grade 4	Not related	20 Jan 2021 (Study Day 142) – 18 Feb 2021 (Study Day 171)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US335-2297, a 62-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 16 Jan 2021. The participant was unblinded on 16 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 16 Jan 2021 (Study Day 138). The second dose was administered in the left arm on 13 Feb 2021 (Study Day 166).

Event Details

On 20 Jan 2021 (Study Day 142), 141 days after the first dose in Part A/4 days after the first dose in Part B and 113 days after the second dose in Part A/24 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of limb injury. The IP dose was not changed due to the left hand trauma. The event of left hand trauma lasted for 30 days, after which it was considered to be recovered/resolved on 18 Feb 2021 (Study Day 171). The investigator assessed the event of limb injury to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-008622	Limb injury

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Surgery - tonsillectomy	Apr 1964 - Apr 1964
Tonsillitis	Tonsillitis (recurring)	Apr 1964 - Apr 1964
Myopia	Myopia	1968 - Ongoing
Food allergy	Food allergy - peach	1972 - Ongoing
Nasal injury	Nose trauma	1984 - 1984
Rhinoplasty	Surgery - rhinoplasty	Jun 1984 - Jun 1984
Hypoaesthesia	Left hand 1st digit numbness	1995 - Ongoing
Limb operation	Left hand surgery	1995 - 1995
Femoral hernia	Femoral hernia	May 2010 - May 2010
Femoral hernia repair	Surgery - femoral hernia repair	May 2010 - May 2010
Ex-tobacco user	Ex-smoker (tobacco)	Dec 2014 - 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	1998 - Ongoing	Cardiac Prophylaxis
Diphtheria vaccine toxoid; pertussis vaccine acellular 3-component; tetanus vaccine toxoid	20 Jan 2021 (Study Day 142) - 20 Jan 2021 (Study Day 142)	Left Hand Trauma
Piperacillin sodium; tazobactam sodium	20 Jan 2021 (Study Day 142) - 21 Jan 2021 (Study Day 143)	Left Hand Trauma
Sodium chloride	20 Jan 2021 (Study Day 142) - 21 Jan 2021 (Study Day 143)	Left Hand Trauma
Xray hand left lateral and oblique*	20 Jan 2021 (Study Day 142) - 20 Jan 2021 (Study Day 142)	Adverse Event
Left hand repair*	21 Jan 2021 (Study Day 143) - 21 Jan 2021 (Study Day 143)	Adverse Event
Amoxicillin trihydrate; clavulanate potassium	22 Jan 2021 (Study Day 144) - 27 Jan 2021 (Study Day 149)	Left Hand Repair
Cefalexin	22 Jan 2021 (Study Day 144) - 16 Feb 2021 (Study Day 169)	Left Hand Repair
Bacitracin; polymyxin b sulfate	30 Jan 2021 (Study Day 152) - 18 Feb 2021 (Study Day 171)	Left Hand Trauma

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US335-2349 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 03 Feb 2021 (Study Day 147)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hepatic Infection/ Unspecified Liver Infection	SAE	Grade 4	Not related	26 Feb 2021 (Study Day 170) – 24 Apr 2021 (Study Day 227)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US335-2349, a 51-year-old Hispanic or Latino male, received the first dose of Placebo in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was positive. The participant proceeded to Part B, the Open-Label Observational Phase, on 03 Feb 2021. The participant was unblinded on 03 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 03 Feb 2021 (Study Day 147). The second dose was not administered.

Event Details

On 26 Feb 2021 (Study Day 170), 169 days after the first dose in Part A/23 days after the first dose in Part B and 141 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 4 serious adverse event of hepatic infection. The IP dose was not changed due to the unspecified liver infection. The event of unspecified liver infection lasted for 58 days, after which it was considered to be recovered/resolved on 24 Apr 2021 (Study Day 227). The investigator assessed the event of hepatic infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-065707	Abdominal distension
MOD-2021-065707	Abdominal pain upper

CIOMS Number	MedDRA Preferred Term
MOD-2021-065707	Clostridium bacteriaemia
MOD-2021-065707	Liver abscess
MOD-2021-065707	Metabolic acidosis
MOD-2021-065707	Sepsis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Alcohol use	Alcohol consumption	1986 - Ongoing
Obesity	Obesity	May 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

No prior or concomitant medications or procedures were reported.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US336-2029 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 04 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 08 Jan 2021 (Study Day 158)
Second Dose of Vaccine in Part B: 03 Feb 2021 (Study Day 184)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia/Pneumonia	SAE	Grade 4	Not related	16 Feb 2021 (Study Day 197) – 04 Mar 2021 (Study Day 213)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US336-2029, a 52-year-old not Hispanic or Latino male, received the first dose of Placebo in the right arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 01 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 08 Jan 2021. The participant was unblinded on 08 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 08 Jan 2021 (Study Day 158). The second dose was administered in the right arm on 03 Feb 2021 (Study Day 184).

Event Details

On 16 Feb 2021 (Study Day 197), 196 days after the first dose in Part A/39 days after the first dose in Part B and 168 days after the second dose in Part A/13 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of pneumonia lasted for 17 days, after which it was considered to be recovered/resolved on 04 Mar 2021 (Study Day 213). The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-031994	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nasal septum deviation	Septal deviation	1994 - Ongoing
Cancer surgery	Squamous cell removal	2018 - 2018
Squamous cell carcinoma	Squamous cell carcinoma	2018 - 2018
Sleep apnoea syndrome	Possible obstructive sleep apnea	Jan 2019 - Ongoing
Rhinitis allergic	Allergic rhinitis	2020 - Ongoing
Hypertension	Hypertension	Jan 2020 - Ongoing
Asthma	Mild asthma	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	Jan 2020 - Ongoing	Hypertension
Hydrochlorothiazide; losartan	Jan 2020 - Ongoing	Hypertension
Acetylsalicylic acid	05 Aug 2020 (Study Day 2) - 05 Aug 2020 (Study Day 2)	Headache Post Injection
Salbutamol	17 Aug 2020 (Study Day 14) - Ongoing	Mild Asthma
Levocetirizine dihydrochloride	01 Sep 2020 (Study Day 29) - Ongoing	Allergic Rhinitis
Influenza vaccine	30 Oct 2020 (Study Day 88) - 30 Oct 2020 (Study Day 88)	Influenza Prevention
Dexamethasone	16 Feb 2021 (Study Day 197) - 16 Feb 2021 (Study Day 197)	Upper Respiratory Illness
Levofloxacin	16 Feb 2021 (Study Day 197) - 21 Feb 2021 (Study Day 202)	Pneumonia
Benzonatate	18 Feb 2021 (Study Day 199) - 10 Mar 2021 (Study Day 219)	Pneumonia/Upper Respiratory Illness
Fluticasone propionate; salmeterol	18 Feb 2021 (Study Day 199) - 10 Mar 2021 (Study Day 219)	Pneumonia/Upper Respiratory Illness
Prednisone	18 Feb 2021 (Study Day 199) - 04 Mar 2021 (Study Day 213)	Pneumonia/Upper Respiratory Illness
Salbutamol	18 Feb 2021 (Study Day 199) - 10 Mar 2021 (Study Day 219)	Pneumonia/Upper Respiratory Illness

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	16 Feb 2021 (Study Day 197) - 10 Mar 2021 (Study Day 219)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US336-2071 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 07 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Aortic Dissection/ Dissecting Aorta	SAE	Grade 3/ severe	Not related	05 Mar 2021 (Study Day 211) – 10 Mar 2021 (Study Day 216)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US336-2071, a 52-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 26 Feb 2021. The participant was unblinded on 26 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 05 Mar 2021 (Study Day 211), 210 days after the first dose in Part A and 182 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of aortic dissection. Action taken with the IP was not applicable. The event of dissecting aorta lasted for 6 days, after which it was considered to be recovered/resolved on 10 Mar 2021 (Study Day 216). The investigator assessed the event of aortic dissection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-043845	Aortic dissection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Congestive cardiomyopathy	Dilated cardiomyopathy	Not reported - Ongoing
Appendectomy	Appendectomy	1978 - 1978
Colonoscopy	Colonoscopy	2000 - 2000
Acute myocardial infarction	Non-stemi myocardial infarction	2015 - 2015
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Cardiac failure congestive	Systolic chf	14 Jun 2016 (Study Day -1515) - Ongoing
Chronic kidney disease	Chronic kidney disease	14 Jun 2016 (Study Day -1515) - Ongoing
Phaeochromocytoma	Pheochromocytoma	14 Jun 2016 (Study Day -1515) - Ongoing
Pulmonary hypertension	Pulmonary hypertension	14 Jun 2016 (Study Day -1515) - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	14 Jul 2016 (Study Day -1485) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2015 - Ongoing	History Of Non-Stemi Myocardial Infarct
Amlodipine	2015 - Ongoing	Hypertension
Fish oil	2015 - Ongoing	Hyperlipidemia
Lisinopril	2015 - Ongoing	Hypertension
Spironolactone	2016 - Ongoing	Systolic Congestive Heart Failure
Amoxicillin; clavulanate potassium	03 Dec 2020 (Study Day 119) - 08 Dec 2020 (Study Day 124)	Ae Upper Respiratory Infection
Colonoscopy*	03 Dec 2020 (Study Day 119) - 03 Dec 2020 (Study Day 119)	Diagnostic
Dicycloverine	03 Dec 2020 (Study Day 119) - Ongoing	Abdominal Pain
Dicycloverine hydrochloride	03 Dec 2020 (Study Day 119) - Ongoing	Gastroesophageal Reflux Disease
Salbutamol	03 Dec 2020 (Study Day 119) - 30 Dec 2020 (Study Day 146)	Shortness Of Breath
Sodium bicarbonate	03 Dec 2020 (Study Day 119) - 05 Dec 2020 (Study Day 121)	Principal Ae:dehydration

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin d nos	03 Dec 2020 (Study Day 119) - Ongoing	Nutritional Support
Pantoprazole sodium sesquihydrate	25 Jan 2021 (Study Day 172) - Ongoing	Gastroesophageal Reflux Disease
Carvedilol	05 Mar 2021 (Study Day 211) - Ongoing	Dissecting Aorta
Hydralazine	05 Mar 2021 (Study Day 211) - Ongoing	Dissecting Aorta

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US336-2116 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 12 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 18 Sep 2020 (Study Day 38)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cellulitis/Cellulitis Of Left Abdomen	SAE	Grade 4	Not related	30 Jan 2021 (Study Day 172) – 08 Feb 2021 (Study Day 181)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US336-2116, a 56-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 38). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 27 Jan 2021. The participant was unblinded on 27 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 30 Jan 2021 (Study Day 172), 171 days after the first dose in Part A and 134 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of cellulitis. Action taken with the IP was not applicable. The event of cellulitis of left abdomen lasted for 10 days, after which it was considered to be recovered/resolved on 08 Feb 2021 (Study Day 181). The investigator assessed the event of cellulitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014600	Cellulitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Drug allergy - morphine	2000 - Ongoing
Spinal fusion surgery	L4-L5 s1 fusion	2010 - 2010
Hyperlipidaemia	Hyperlipidemia	2016 - Ongoing
Coronary artery disease	Coronary artery disease	20 Dec 2016 (Study Day -1331) - Ongoing
Stent placement	Stent placement	20 Dec 2016 (Study Day -1331) - 20 Dec 2016 (Study Day -1331)
Intervertebral disc degeneration	Degenerative disc disease of l4-l5,l5-s1	2018 - 2018
Neck pain	Chronic neck pain	2018 - Ongoing
Neck surgery	Neck surgery	2018 - 2018
Abdominal hernia	Abdominal hernia	18 Oct 2019 (Study Day -299) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Dec 2016 - Ongoing	Coronary Artery Disease
Atorvastatin	Dec 2016 - Ongoing	Hyperlipidemia
Tramadol	2018 - Ongoing	Chronic Neck Pain
Paracetamol	15 Aug 2020 (Study Day 4) - 15 Aug 2020 (Study Day 4)	Headache
Azithromycin	17 Aug 2020 (Study Day 6) - 21 Aug 2020 (Study Day 10)	Pharyngitis
Meloxicam	31 Aug 2020 (Study Day 20) - 11 Sep 2020 (Study Day 31)	Lower Back Muscle Strain
Prednisone	20 Sep 2020 (Study Day 40) - 21 Sep 2020 (Study Day 41)	Worsening Of Chronic Neck Pain And Generalized Myalgias.
Ciprofloxacin	05 Jan 2021 (Study Day 147) - Ongoing	Ear Infection
Prednisone	05 Jan 2021 (Study Day 147) - Ongoing	Ear Infection
Hernia repair*	21 Jan 2021 (Study Day 163) - 21 Jan 2021 (Study Day 163)	Medical History
Sulfamethoxazole; trimethoprim	02 Feb 2021 (Study Day 175) - 07 Feb 2021 (Study Day 180)	Cellulitis Of Left Abdoomen

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US336-2125 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 13 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 15 Sep 2020 (Study Day 34)
First Dose of Vaccine in Part B: 22 Feb 2021 (Study Day 194)
Second Dose of Vaccine in Part B: 22 Mar 2021 (Study Day 222)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrioventricular Block Complete/Complete Av Block	SAE	Grade 4	Not related	17 Mar 2021 (Study Day 217) – 19 Mar 2021 (Study Day 219)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US336-2125, a 66-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 15 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 22 Feb 2021. The participant was unblinded on 22 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 22 Feb 2021 (Study Day 194). The second dose was administered in the left arm on 22 Mar 2021 (Study Day 222).

Event Details

On 17 Mar 2021 (Study Day 217), 216 days after the first dose in Part A/23 days after the first dose in Part B and 183 days after the second dose in Part A/5 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of atrioventricular block complete. The IP dose was not changed due to the complete av block. The event of complete av block lasted for 3 days, after which it was considered to be recovered/resolved on 19 Mar 2021 (Study Day 219). The investigator assessed the event of atrioventricular block complete to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-050635	Atrioventricular block complete

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2005 - Ongoing
Essential hypertension	Essential hypertension	2008 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2008 - Ongoing
Atrial flutter	Atrial flutter	2015 - 2015
Cardiac ablation	Atrial flutter ablation	2015 - 2015
Dermatitis	Dermatitis generalized	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	2005 - Ongoing	Seasonal Allergies
Hydrochlorothiazide; losartan potassium	2010 - Ongoing	Hypertension
Minocycline	2019 - Ongoing	Dermatitis
Influenza vaccine	05 Oct 2020 (Study Day 54) - 05 Oct 2020 (Study Day 54)	Prophylaxis
Fluticasone propionate	08 Nov 2020 (Study Day 88) - 08 Nov 2020 (Study Day 88)	Sars Cov-2 Positive
Dual chamber pacemaker placement*	18 Mar 2021 (Study Day 218) - 18 Mar 2021 (Study Day 218)	Adverse Event
Cefalexin	20 Mar 2021 (Study Day 220) - 27 Mar 2021 (Study Day 227)	Complete Av Heart Block/Pacemaker Placement
Hydrocodone bitartrate; paracetamol	20 Mar 2021 (Study Day 220) - Ongoing	Post-Op Pacemaker Placement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US337-2348 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 15 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 13 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 27 Jan 2021 (Study Day 135)
Second Dose of Vaccine in Part B: 23 Feb 2021 (Study Day 162)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/Myocardial Infarction	SAE	Grade 3/severe	Not related	02 Apr 2021 (Study Day 200) – 04 Apr 2021 (Study Day 202)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US337-2348, a 59-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 15 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 13 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 27 Jan 2021. The participant was unblinded on 27 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 27 Jan 2021 (Study Day 135). The second dose was administered in the left arm on 23 Feb 2021 (Study Day 162).

Event Details

On 02 Apr 2021 (Study Day 200), 199 days after the first dose in Part A/65 days after the first dose in Part B and 171 days after the second dose in Part A/38 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction lasted for 3 days, after which it was considered to be recovered/resolved on 04 Apr 2021 (Study Day 202). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-067965	Myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Coronary artery bypass	Coronary artery bypass graft	2012 - 2012
Coronary artery disease	Coronary artery disease	2012 - Ongoing
Myocardial infarction	Myocardial infarction	2012 - 2012
Hypersensitivity	Environmental allergies	2017 - Ongoing
Tendon rupture	Partial left biceps tendon rupture	2017 - 2017
Back pain	Chronic lower back pain	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	Dec 2019 - Ongoing	Chronic Lower Back Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US339-2065 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 21 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Sep 2020 (Study Day 27)
First Dose of Vaccine in Part B: 11 Jan 2021 (Study Day 144)
Second Dose of Vaccine in Part B: 05 Feb 2021 (Study Day 169)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chest Pain/Chest Pain, Unspecified	SAE	Grade 2/moderate	Not related	24 Mar 2021 (Study Day 216) – 25 Mar 2021 (Study Day 217)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US339-2065, a 70-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 11 Jan 2021 (Study Day 144). The second dose was administered in the left arm on 05 Feb 2021 (Study Day 169).

Event Details

On 24 Mar 2021 (Study Day 216), 215 days after the first dose in Part A/72 days after the first dose in Part B and 189 days after the second dose in Part A/47 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of chest pain. Action taken with the IP was not applicable. The event of chest pain, unspecified lasted for 2 days, after which it was considered to be recovered/resolved on 25 Mar 2021 (Study Day 217). The investigator assessed the event of chest pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-060172	Chest pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post-menopausal	Jan 1993 - Ongoing
Dyspareunia	Dyspareunia	Jan 2018 - Ongoing
Gastroesophageal reflux disease	Acid reflux	Aug 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	22 Aug 2020 (Study Day 2) - 27 Aug 2020 (Study Day 7)	Acid Reflux
Acetylsalicylic acid	15 Sep 2020 (Study Day 26) - 15 Sep 2020 (Study Day 26)	Injection Site Pain
Acetylsalicylic acid	20 Sep 2020 (Study Day 31) - 20 Sep 2020 (Study Day 31)	Headache
Ciprofloxacin	30 Jan 2021 (Study Day 163) - 07 Feb 2021 (Study Day 171)	Acute Diverticulitis
Metronidazole	30 Jan 2021 (Study Day 163) - 07 Feb 2021 (Study Day 171)	Acute Diverticulitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diverticulitis	Grade 2/moderate	Not related	30 Jan 2021 (Study Day 163) - 07 Feb 2021 (Study Day 171)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US339-2112 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 28 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 22 Sep 2020 (Study Day 26)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Kidney Injury/Acute Kidney Injury	SAE	Grade 2/moderate	Not related	26 Feb 2021 (Study Day 183) – 01 Mar 2021 (Study Day 186)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US339-2112, a 72-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 26 Feb 2021 (Study Day 183), 182 days after the first dose in Part A and 157 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of acute kidney injury. Action taken with the IP was not applicable. The event of acute kidney injury lasted for 4 days, after which it was considered to be recovered/resolved on 01 Mar 2021 (Study Day 186). The investigator assessed the event of acute kidney injury to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-082432	Acute kidney injury

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Herpes simplex	Herpes simplex	Mar 1951 - Ongoing
Postmenopause	Post-menopausal	May 2005 - Ongoing
Arthralgia	Knee pain	Aug 2005 - Ongoing
Hypertension	Hypertension	Jan 2010 - Ongoing
Gastroesophageal reflux disease	Acid reflux	Aug 2015 - Ongoing
Back pain	Back pain	Aug 2017 - Ongoing
Back pain	Lumbar back pain	Aug 2017 - Ongoing
Anaemia	Anemia	Jul 2018 - Ongoing
Fibromyalgia	Fibromyalgia	Jul 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Aciclovir	Mar 1951 - Ongoing	Herpes Simplex
Gabapentin	Jun 1982 - Ongoing	Neuropathy
Ibuprofen	Aug 2005 - Ongoing	Knee Pain
Benazepril	Jan 2010 - Ongoing	Hypertension
Pantoprazole	Aug 2015 - Ongoing	Acid Reflux
Methocarbamol	Aug 2017 - Ongoing	Lumbar Back Pain
Ergocalciferol	Jul 2018 - Ongoing	Anemia
Pregabalin	Aug 2019 - Ongoing	Fibromyalgia
Furosemide	Jan 2020 - Ongoing	Hypertension
Potassium chloride	Jan 2020 - Ongoing	Hypertension
Ibuprofen	29 Aug 2020 (Study Day 2) - 29 Aug 2020 (Study Day 2)	Injection Site Pain
Ibuprofen	31 Aug 2020 (Study Day 4) - 02 Sep 2020 (Study Day 6)	Pain At Injection Site, Headache
Ketorolac tromethamine	23 Sep 2020 (Study Day 27) - Ongoing	Knee Pain
Ibuprofen	24 Sep 2020 (Study Day 28) - 24 Sep 2020 (Study Day 28)	Pain At Injection Site, Headache
Metoclopramide hydrochloride	27 Dec 2020 (Study Day 122) - 30 Dec 2020 (Study Day 125)	Small Bowel Obstruction
Ondansetron	27 Dec 2020 (Study Day 122) - 30 Dec 2020 (Study Day 125)	Nausea, Secondary To Small Bowel Obstruction
Sodium chloride	26 Feb 2021 (Study Day 183) - 01 Mar 2021 (Study Day 186)	Acute Kidney Injury

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US339-2133 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Sep 2020 (Study Day 28)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Flutter/Atrial Flutter	SAE	Grade 3/ severe	Not related	09 Mar 2021 (Study Day 190) – 12 Mar 2021 (Study Day 193)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US339-2133, a 45-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 28 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 25 Jan 2021. The participant was unblinded on 25 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 09 Mar 2021 (Study Day 190), 189 days after the first dose in Part A and 162 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of atrial flutter. Action taken with the IP was not applicable. The event of atrial flutter lasted for 4 days, after which it was considered to be recovered/resolved on 12 Mar 2021 (Study Day 193). The investigator assessed the event of atrial flutter to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-050473	Atrial flutter

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	29 Sep 2020 (Study Day 29) - 30 Sep 2020 (Study Day 30)	Vaccine-Induced Fever
Apixaban	12 Mar 2021 (Study Day 193) - Ongoing	Atrial Flutter
Digoxin	12 Mar 2021 (Study Day 193) - Ongoing	Atrial Flutter
Furosemide	12 Mar 2021 (Study Day 193) - Ongoing	Atrial Flutter
Metoprolol	12 Mar 2021 (Study Day 193) - Ongoing	Atrial Flutter
Sacubitril; valsartan	12 Mar 2021 (Study Day 193) - Ongoing	Atrila Flutter

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US339-2287 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 16 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 12 Oct 2020 (Study Day 27)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Fibrillation/ Worsening Chronic Atrial Fibrillation	SAE	Grade 3/ severe	Not related	08 Feb 2021 (Study Day 146) – 09 Feb 2021 (Study Day 147)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US339-2287, a 65-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 16 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 12 Oct 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 15 Jan 2021. The participant was unblinded on 15 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 08 Feb 2021 (Study Day 146), 145 days after the first dose in Part A and 119 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of atrial fibrillation. Action taken with the IP was not applicable. The event of worsening chronic atrial fibrillation lasted for 2 days, after which it was considered to be recovered/resolved on 09 Feb 2021 (Study Day 147). The investigator assessed the event of atrial fibrillation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012512	Atrial fibrillation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Jan 1982 - Ongoing
Depression	Depression	Jan 2000 - Ongoing
Sleep apnoea syndrome	Sleep apnea	Jan 2006 - Ongoing
Atrial fibrillation	Atrial fibrillation	Jan 2007 - Ongoing
Postmenopause	Post menopausal	Jan 2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Duloxetine	Jan 2000 - Ongoing	Depression
Flecainide	Jan 2007 - Ongoing	Atrial Fibrillation
Trazodone	Jan 2019 - Ongoing	Depression
Metoprolol	Sep 2019 - Ongoing	Atrial Fibrillation
Rivaroxaban	Mar 2020 - Ongoing	Atrial Fibrillation
Paracetamol	13 Oct 2020 (Study Day 28) - 13 Oct 2020 (Study Day 28)	Headache, Pain At Injection Site
Cardiac ablation*	08 Feb 2021 (Study Day 146) - 08 Feb 2021 (Study Day 146)	Adverse Event
Sotalol	08 Feb 2021 (Study Day 146) - Ongoing	Worsening Chronic Atrial Fibrillation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US340-2082 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 29 Jul 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 26 Aug 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Balance Disorder/ Unstable Balance	SAE	Grade 2/ moderate	Not related	01 Feb 2021 (Study Day 188) – 03 Feb 2021 (Study Day 190)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2082, a 58-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 29 Jul 2020 (Study Day 1). The second dose was administered in the right arm on 26 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 28 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 01 Feb 2021 (Study Day 188), 187 days after the first dose in Part A and 159 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of balance disorder. Action taken with the IP was not applicable. The event of unstable balance lasted for 3 days, after which it was considered to be recovered/resolved on 03 Feb 2021 (Study Day 190). The investigator assessed the event of balance disorder to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010615	Balance disorder

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2005 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2006 - Ongoing
Peripheral sensory neuropathy	Bilateral neuropathy feet - sensory	2006 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2006 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Insomnia	Insomnia	2010 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2013 - Ongoing
Lumbar radiculopathy	Chronic lumbar radiculopathy	2019 - Ongoing
Anxiety	Anxiety	Dec 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	2005 - Ongoing	Gastroesophageal Reflux Disease
Gabapentin	2006 - Ongoing	Neuropathy
Insulin glargine	2006 - Ongoing	Type Ii Diabetes
Metformin	2006 - Ongoing	Type Ii Diabetes
Salbutamol sulfate	2006 - Ongoing	Chronic Obstructive Pulmonary Disorder
Lisinopril	2010 - Ongoing	Hypertension
Zolpidem	2010 - Ongoing	Insomnia
Atorvastatin	2013 - Ongoing	Hypercholesterolemia
Escitalopram	Dec 2019 - Ongoing	Anxiety
Hydroxyzine hydrochloride	Dec 2019 - Ongoing	Anxiety
Liraglutide	20 Jan 2021 (Study Day 176) - Ongoing	Type 2 Diabetes
Chest xray 1 view*	01 Feb 2021 (Study Day 188) - 01 Feb 2021 (Study Day 188)	Adverse Event
Complete blood count*	01 Feb 2021 (Study Day 188) - 01 Feb 2021 (Study Day 188)	Adverse Event
Complete metabolic profile*	01 Feb 2021 (Study Day 188) - 01 Feb 2021 (Study Day 188)	Adverse Event
Ct head without contrast*	01 Feb 2021 (Study Day 188) - 01 Feb 2021 (Study Day 188)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Troponin*	01 Feb 2021 (Study Day 188) - 01 Feb 2021 (Study Day 188)	Adverse Event
Urinalysis*	01 Feb 2021 (Study Day 188) - 01 Feb 2021 (Study Day 188)	Adverse Event
Fluticasone	02 Feb 2021 (Study Day 189) - Ongoing	Unstable Balance
Folic acid	02 Feb 2021 (Study Day 189) - Ongoing	Unstable Balance
Glucose	02 Feb 2021 (Study Day 189) - 04 Feb 2021 (Study Day 191)	Unstable Balance
Us carotid duplex bilateral*	02 Feb 2021 (Study Day 189) - 02 Feb 2021 (Study Day 189)	Adverse Event
Complete blood count*	03 Feb 2021 (Study Day 190) - 03 Feb 2021 (Study Day 190)	Adverse Event
Complete metabolic profile*	03 Feb 2021 (Study Day 190) - 03 Feb 2021 (Study Day 190)	Adverse Event
Mri brain*	03 Feb 2021 (Study Day 190) - 03 Feb 2021 (Study Day 190)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Abdominal Discomfort	Grade 1/mild	Not related	13 Feb 2021 (Study Day 200) - 15 Feb 2021 (Study Day 202)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US340-2153 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 01 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 32)
First Dose of Vaccine in Part B: 09 Mar 2021 (Study Day 221)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/SARS COVID-19	COVID-19	Grade 1/ mild	Not related	10 Jan 2021 (Study Day 163) – 28 Jan 2021 (Study Day 181)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US340-2153, a 61-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 01 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 09 Mar 2021. The participant was unblinded on 09 Mar 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 09 Mar 2021 (Study Day 221). The second dose was not administered.

Severe COVID-19 Details

On 10 Jan 2021 (Study Day 163), 162 days after the first dose in Part A/58 days before the first dose in Part B and 131 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 1/Mild non-serious adverse event of SARS COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 32, 01 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 13 Jan 2021 (Study Day 166), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
13 Jan 2021 (Study Day 166)	Body Aches	Mild
13 Jan 2021 (Study Day 166)	Chills	Mild
13 Jan 2021 (Study Day 166)	Cough	Mild
13 Jan 2021 (Study Day 166)	Headache	Mild
13 Jan 2021 (Study Day 166)	Muscle Aches (Myalgia)	Mild
13 Jan 2021 (Study Day 166)	Runny Nose (Rhinorrhea)	Mild
14 Jan 2021 (Study Day 167)	Body Aches	Mild
14 Jan 2021 (Study Day 167)	Headache	Mild
15 Jan 2021 (Study Day 168)	Fatigue	Mild
16 Jan 2021 (Study Day 169)	Body Aches	Mild
16 Jan 2021 (Study Day 169)	Cough	Mild
16 Jan 2021 (Study Day 169)	Fatigue	Mild
16 Jan 2021 (Study Day 169)	Nasal Congestion	Mild
17 Jan 2021 (Study Day 170)	Body Aches	Mild
17 Jan 2021 (Study Day 170)	Diarrhea	Mild
17 Jan 2021 (Study Day 170)	Fatigue	Mild
17 Jan 2021 (Study Day 170)	Headache	Mild
18 Jan 2021 (Study Day 171)	Body Aches	Mild
18 Jan 2021 (Study Day 171)	Cough	Mild
18 Jan 2021 (Study Day 171)	Fatigue	Mild
18 Jan 2021 (Study Day 171)	Headache	Mild
19 Jan 2021 (Study Day 172)	Body Aches	Mild
19 Jan 2021 (Study Day 172)	Cough	Mild
19 Jan 2021 (Study Day 172)	Fatigue	Mild
19 Jan 2021 (Study Day 172)	Headache	Mild
19 Jan 2021 (Study Day 172)	O2 Saturation (%)	89
20 Jan 2021 (Study Day 173)	Body Aches	Mild
20 Jan 2021 (Study Day 173)	Cough	Mild
20 Jan 2021 (Study Day 173)	Diarrhea	Mild
20 Jan 2021 (Study Day 173)	Headache	Mild
20 Jan 2021 (Study Day 173)	Nasal Congestion	Mild
21 Jan 2021 (Study Day 174)	Body Aches	Mild
21 Jan 2021 (Study Day 174)	Cough	Mild
21 Jan 2021 (Study Day 174)	Headache	Mild
21 Jan 2021 (Study Day 174)	Nasal Congestion	Mild
21 Jan 2021 (Study Day 174)	New Loss of Smell	Mild
21 Jan 2021 (Study Day 174)	New Loss of Taste	Mild
21 Jan 2021 (Study Day 174)	Shortness of Breath	Mild
22 Jan 2021 (Study Day 175)	Body Aches	Mild
22 Jan 2021 (Study Day 175)	Cough	Mild

Symptom Date	Symptom	Result
22 Jan 2021 (Study Day 175)	Headache	Mild
22 Jan 2021 (Study Day 175)	Nasal Congestion	Mild
22 Jan 2021 (Study Day 175)	New Loss of Smell	Mild
22 Jan 2021 (Study Day 175)	New Loss of Taste	Mild
22 Jan 2021 (Study Day 175)	Shortness of Breath	Mild
23 Jan 2021 (Study Day 176)	Cough	Mild
23 Jan 2021 (Study Day 176)	O2 Saturation (%)	93
23 Jan 2021 (Study Day 176)	Shortness of Breath	Mild
24 Jan 2021 (Study Day 177)	Cough	Mild
24 Jan 2021 (Study Day 177)	O2 Saturation (%)	93
24 Jan 2021 (Study Day 177)	Shortness of Breath	Mild
25 Jan 2021 (Study Day 178)	Cough	Mild
25 Jan 2021 (Study Day 178)	O2 Saturation (%)	92
25 Jan 2021 (Study Day 178)	Shortness of Breath	Mild
26 Jan 2021 (Study Day 179)	Cough	Mild
26 Jan 2021 (Study Day 179)	Shortness of Breath	Mild
27 Jan 2021 (Study Day 180)	Cough	Mild
27 Jan 2021 (Study Day 180)	Shortness of Breath	Mild
28 Jan 2021 (Study Day 181)	Cough	Mild
28 Jan 2021 (Study Day 181)	Headache	Mild
28 Jan 2021 (Study Day 181)	O2 Saturation (%)	93
28 Jan 2021 (Study Day 181)	Shortness of Breath	Mild
29 Jan 2021 (Study Day 182)	Cough	Mild
29 Jan 2021 (Study Day 182)	Headache	Mild
29 Jan 2021 (Study Day 182)	Shortness of Breath	Mild
30 Jan 2021 (Study Day 183)	Cough	Mild
30 Jan 2021 (Study Day 183)	Headache	Mild
30 Jan 2021 (Study Day 183)	Shortness of Breath	Mild

The participant had no reported indications of Severe COVID-19 infection.

Action taken with the IP was not applicable. The event of SARS COVID-19 lasted for 19 days, after which it was considered to be recovered/resolved on 28 Jan 2021 (Study Day 181). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004596	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypersensitivity	Environmental allergies	1980 - Ongoing
Osteoarthritis	Osteoarthritis: knees, hands, back	2000 - Ongoing
Knee arthroplasty	Right knee replacement	Dec 2008 - Dec 2008
Hypertension	Hypertension	2010 - Ongoing
Insomnia	Insomnia	2010 - Ongoing
Constipation	Constipation	2013 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	10 Apr 2020 (Study Day -113) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Nabumetone	2008 - Ongoing	Osteoarthritis
Benazepril	2010 - Ongoing	Hypertension
Loratadine	2010 - Ongoing	Environmental Allergies
Atorvastatin	2015 - Ongoing	Hyperlipidemia
Docusate sodium	2015 - Ongoing	Constipation
Fish oil	2015 - Ongoing	Hyperlipidemia
Vitamin b12 nos	2015 - Ongoing	Supplement
Zolpidem	2018 - Ongoing	Insomnia
Empagliflozin	10 Apr 2020 (Study Day -113) - Ongoing	Type Ii Diabetes
Metformin	10 Apr 2020 (Study Day -113) - Ongoing	Type Ii Diabetes
Paracetamol	10 Jan 2021 (Study Day 163) - Ongoing	Sars COVID-19
Acetylsalicylic acid	28 Jan 2021 (Study Day 181) - Ongoing	COVID 19
Benzonatate	28 Jan 2021 (Study Day 181) - Ongoing	COVID 19
Chest xray*	28 Jan 2021 (Study Day 181) - 28 Jan 2021 (Study Day 181)	Adverse Event
Methylprednisolone	28 Jan 2021 (Study Day 181) - Ongoing	COVID 19
Prednisone	28 Jan 2021 (Study Day 181) - Ongoing	COVID 19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US340-2204 (Part B)
Vaccination Group: Placebo in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 03 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 31 Aug 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 2/ moderate	Not related	06 Jan 2021 (Study Day 157) – 06 Feb 2021 (Study Day 188)	Recovered/ resolved
Pericarditis Infective/ Acute Infective Pericarditis	SAE	Grade 3/ severe	Not related	30 Jan 2021 (Study Day 181) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US340-2204, a 63-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 03 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 31 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 02 Mar 2021 and consented to receive 2 doses of mRNA-1273. The first dose was not administered. The second dose was not administered.

Event Details

On 30 Jan 2021 (Study Day 181), 180 days after the first dose in Part A and 152 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of pericarditis infective. Action taken with the IP was not applicable. The event of acute infective pericarditis was considered to be ongoing. The investigator assessed the event of pericarditis infective to be not related to the IP.

Severe COVID-19 Details

On 06 Jan 2021 (Study Day 157), the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 31 Aug 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 11 Jan 2021 (Study Day 162), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
06 Jan 2021 (Study Day 157)	Body Aches	Moderate
06 Jan 2021 (Study Day 157)	Chills	Mild
06 Jan 2021 (Study Day 157)	Cough	Mild
06 Jan 2021 (Study Day 157)	Difficulty Breathing	Mild
06 Jan 2021 (Study Day 157)	Fatigue	Moderate
06 Jan 2021 (Study Day 157)	Headache	Moderate
06 Jan 2021 (Study Day 157)	Muscle Aches (Myalgia)	Moderate
06 Jan 2021 (Study Day 157)	Nasal Congestion	Moderate
06 Jan 2021 (Study Day 157)	New Loss of Smell	Moderate
06 Jan 2021 (Study Day 157)	New Loss of Taste	Moderate
06 Jan 2021 (Study Day 157)	Runny Nose (Rhinorrhea)	Mild
06 Jan 2021 (Study Day 157)	Shortness of Breath	Mild
07 Jan 2021 (Study Day 158)	Body Aches	Moderate
07 Jan 2021 (Study Day 158)	Chills	Mild
07 Jan 2021 (Study Day 158)	Cough	Mild
07 Jan 2021 (Study Day 158)	Difficulty Breathing	Mild
07 Jan 2021 (Study Day 158)	Fatigue	Moderate
07 Jan 2021 (Study Day 158)	Headache	Moderate
07 Jan 2021 (Study Day 158)	Muscle Aches (Myalgia)	Moderate
07 Jan 2021 (Study Day 158)	Nasal Congestion	Moderate
07 Jan 2021 (Study Day 158)	New Loss of Smell	Moderate
07 Jan 2021 (Study Day 158)	New Loss of Taste	Moderate
07 Jan 2021 (Study Day 158)	Runny Nose (Rhinorrhea)	Mild
07 Jan 2021 (Study Day 158)	Shortness of Breath	Mild
08 Jan 2021 (Study Day 159)	Body Aches	Moderate
08 Jan 2021 (Study Day 159)	Chills	Mild
08 Jan 2021 (Study Day 159)	Cough	Mild
08 Jan 2021 (Study Day 159)	Difficulty Breathing	Mild
08 Jan 2021 (Study Day 159)	Fatigue	Moderate
08 Jan 2021 (Study Day 159)	Headache	Moderate
08 Jan 2021 (Study Day 159)	Muscle Aches (Myalgia)	Moderate
08 Jan 2021 (Study Day 159)	Nasal Congestion	Moderate
08 Jan 2021 (Study Day 159)	New Loss of Smell	Moderate
08 Jan 2021 (Study Day 159)	New Loss of Taste	Moderate
08 Jan 2021 (Study Day 159)	Runny Nose (Rhinorrhea)	Mild
08 Jan 2021 (Study Day 159)	Shortness of Breath	Mild
09 Jan 2021 (Study Day 160)	Body Aches	Moderate

Symptom Date	Symptom	Result
09 Jan 2021 (Study Day 160)	Chills	Mild
09 Jan 2021 (Study Day 160)	Cough	Mild
09 Jan 2021 (Study Day 160)	Difficulty Breathing	Mild
09 Jan 2021 (Study Day 160)	Fatigue	Moderate
09 Jan 2021 (Study Day 160)	Headache	Moderate
09 Jan 2021 (Study Day 160)	Muscle Aches (Myalgia)	Moderate
09 Jan 2021 (Study Day 160)	Nasal Congestion	Moderate
09 Jan 2021 (Study Day 160)	New Loss of Smell	Moderate
09 Jan 2021 (Study Day 160)	New Loss of Taste	Moderate
09 Jan 2021 (Study Day 160)	Runny Nose (Rhinorrhea)	Mild
09 Jan 2021 (Study Day 160)	Shortness of Breath	Mild
10 Jan 2021 (Study Day 161)	Body Aches	Moderate
10 Jan 2021 (Study Day 161)	Chills	Mild
10 Jan 2021 (Study Day 161)	Cough	Mild
10 Jan 2021 (Study Day 161)	Difficulty Breathing	Mild
10 Jan 2021 (Study Day 161)	Fatigue	Moderate
10 Jan 2021 (Study Day 161)	Headache	Moderate
10 Jan 2021 (Study Day 161)	Muscle Aches (Myalgia)	Moderate
10 Jan 2021 (Study Day 161)	Nasal Congestion	Moderate
10 Jan 2021 (Study Day 161)	New Loss of Smell	Moderate
10 Jan 2021 (Study Day 161)	New Loss of Taste	Moderate
10 Jan 2021 (Study Day 161)	Runny Nose (Rhinorrhea)	Mild
10 Jan 2021 (Study Day 161)	Shortness of Breath	Mild
11 Jan 2021 (Study Day 162)	Body Aches	Moderate
11 Jan 2021 (Study Day 162)	Chills	Mild
11 Jan 2021 (Study Day 162)	Cough	Mild
11 Jan 2021 (Study Day 162)	Difficulty Breathing	Mild
11 Jan 2021 (Study Day 162)	Fatigue	Moderate
11 Jan 2021 (Study Day 162)	Headache	Moderate
11 Jan 2021 (Study Day 162)	Muscle Aches (Myalgia)	Moderate
11 Jan 2021 (Study Day 162)	Nasal Congestion	Moderate
11 Jan 2021 (Study Day 162)	New Loss of Smell	Moderate
11 Jan 2021 (Study Day 162)	New Loss of Taste	Moderate
11 Jan 2021 (Study Day 162)	Runny Nose (Rhinorrhea)	Mild
11 Jan 2021 (Study Day 162)	Shortness of Breath	Mild
12 Jan 2021 (Study Day 163)	Chills	Mild
12 Jan 2021 (Study Day 163)	Fatigue	Mild
12 Jan 2021 (Study Day 163)	Headache	Mild
12 Jan 2021 (Study Day 163)	Muscle Aches (Myalgia)	Mild
12 Jan 2021 (Study Day 163)	Nausea	Mild
12 Jan 2021 (Study Day 163)	New Loss of Smell	Mild
12 Jan 2021 (Study Day 163)	New Loss of Taste	Mild
13 Jan 2021 (Study Day 164)	Chills	Mild

Symptom Date	Symptom	Result
13 Jan 2021 (Study Day 164)	Cough	Mild
13 Jan 2021 (Study Day 164)	Fatigue	Mild
13 Jan 2021 (Study Day 164)	Headache	Mild
13 Jan 2021 (Study Day 164)	Muscle Aches (Myalgia)	Mild
13 Jan 2021 (Study Day 164)	Nasal Congestion	Mild
13 Jan 2021 (Study Day 164)	New Loss of Smell	Mild
13 Jan 2021 (Study Day 164)	New Loss of Taste	Mild
14 Jan 2021 (Study Day 165)	Body Aches	Mild
14 Jan 2021 (Study Day 165)	Chills	Mild
14 Jan 2021 (Study Day 165)	Cough	Mild
14 Jan 2021 (Study Day 165)	Fatigue	Mild
14 Jan 2021 (Study Day 165)	Muscle Aches (Myalgia)	Mild
14 Jan 2021 (Study Day 165)	New Loss of Smell	Mild
14 Jan 2021 (Study Day 165)	New Loss of Taste	Mild
15 Jan 2021 (Study Day 166)	Chills	Mild
15 Jan 2021 (Study Day 166)	Cough	Mild
15 Jan 2021 (Study Day 166)	Fatigue	Mild
15 Jan 2021 (Study Day 166)	New Loss of Smell	Mild
15 Jan 2021 (Study Day 166)	New Loss of Taste	Mild
15 Jan 2021 (Study Day 166)	Shortness of Breath	Mild
16 Jan 2021 (Study Day 167)	Chills	Mild
16 Jan 2021 (Study Day 167)	Cough	Mild
16 Jan 2021 (Study Day 167)	Fatigue	Mild
16 Jan 2021 (Study Day 167)	New Loss of Smell	Mild
16 Jan 2021 (Study Day 167)	New Loss of Taste	Mild
16 Jan 2021 (Study Day 167)	Shortness of Breath	Mild
17 Jan 2021 (Study Day 168)	Cough	Mild
17 Jan 2021 (Study Day 168)	Fatigue	Mild
17 Jan 2021 (Study Day 168)	New Loss of Smell	Mild
17 Jan 2021 (Study Day 168)	New Loss of Taste	Mild
17 Jan 2021 (Study Day 168)	Shortness of Breath	Mild
18 Jan 2021 (Study Day 169)	Cough	Mild
18 Jan 2021 (Study Day 169)	Fatigue	Mild
18 Jan 2021 (Study Day 169)	New Loss of Smell	Mild
18 Jan 2021 (Study Day 169)	New Loss of Taste	Mild
18 Jan 2021 (Study Day 169)	O2 Saturation (%)	90
18 Jan 2021 (Study Day 169)	Shortness of Breath	Mild
19 Jan 2021 (Study Day 170)	Cough	Mild
19 Jan 2021 (Study Day 170)	Fatigue	Moderate
19 Jan 2021 (Study Day 170)	New Loss of Smell	Mild
19 Jan 2021 (Study Day 170)	New Loss of Taste	Mild
19 Jan 2021 (Study Day 170)	O2 Saturation (%)	91
19 Jan 2021 (Study Day 170)	Shortness of Breath	Moderate

Symptom Date	Symptom	Result
20 Jan 2021 (Study Day 171)	Fatigue	Mild
20 Jan 2021 (Study Day 171)	Shortness of Breath	Mild
21 Jan 2021 (Study Day 172)	Cough	Mild
21 Jan 2021 (Study Day 172)	Diarrhea	Mild
21 Jan 2021 (Study Day 172)	Fatigue	Moderate
21 Jan 2021 (Study Day 172)	New Loss of Smell	Mild
21 Jan 2021 (Study Day 172)	New Loss of Taste	Mild
21 Jan 2021 (Study Day 172)	O2 Saturation (%)	88
21 Jan 2021 (Study Day 172)	Shortness of Breath	Moderate
22 Jan 2021 (Study Day 173)	Cough	Mild
22 Jan 2021 (Study Day 173)	Fatigue	Moderate
22 Jan 2021 (Study Day 173)	New Loss of Smell	Mild
22 Jan 2021 (Study Day 173)	New Loss of Taste	Mild
22 Jan 2021 (Study Day 173)	O2 Saturation (%)	91
22 Jan 2021 (Study Day 173)	Shortness of Breath	Moderate
23 Jan 2021 (Study Day 174)	Cough	Mild
23 Jan 2021 (Study Day 174)	Fatigue	Mild
23 Jan 2021 (Study Day 174)	O2 Saturation (%)	92
23 Jan 2021 (Study Day 174)	Shortness of Breath	Mild
24 Jan 2021 (Study Day 175)	Cough	Mild
24 Jan 2021 (Study Day 175)	Fatigue	Mild
24 Jan 2021 (Study Day 175)	Shortness of Breath	Mild
25 Jan 2021 (Study Day 176)	Cough	Mild
25 Jan 2021 (Study Day 176)	Fatigue	Mild
25 Jan 2021 (Study Day 176)	Shortness of Breath	Mild
26 Jan 2021 (Study Day 177)	Cough	Mild
26 Jan 2021 (Study Day 177)	Fatigue	Mild
26 Jan 2021 (Study Day 177)	Shortness of Breath	Mild
27 Jan 2021 (Study Day 178)	Cough	Mild
27 Jan 2021 (Study Day 178)	Fatigue	Mild
27 Jan 2021 (Study Day 178)	Shortness of Breath	Mild
28 Jan 2021 (Study Day 179)	Cough	Mild
28 Jan 2021 (Study Day 179)	Fatigue	Mild
28 Jan 2021 (Study Day 179)	Shortness of Breath	Mild
29 Jan 2021 (Study Day 180)	Cough	Mild
29 Jan 2021 (Study Day 180)	Fatigue	Mild
29 Jan 2021 (Study Day 180)	Shortness of Breath	Mild
30 Jan 2021 (Study Day 181)	Fatigue	Mild
30 Jan 2021 (Study Day 181)	Shortness of Breath	Mild
30 Jan 2021 (Study Day 181)	Sore Throat	Mild
31 Jan 2021 (Study Day 182)	Fatigue	Mild
31 Jan 2021 (Study Day 182)	Shortness of Breath	Mild
31 Jan 2021 (Study Day 182)	Sore Throat	Mild

Symptom Date	Symptom	Result
01 Feb 2021 (Study Day 183)	Fatigue	Mild
01 Feb 2021 (Study Day 183)	Shortness of Breath	Mild
02 Feb 2021 (Study Day 184)	Fatigue	Mild
02 Feb 2021 (Study Day 184)	Shortness of Breath	Mild
03 Feb 2021 (Study Day 185)	Fatigue	Mild
03 Feb 2021 (Study Day 185)	Shortness of Breath	Mild
04 Feb 2021 (Study Day 186)	Shortness of Breath	Mild
05 Feb 2021 (Study Day 187)	Shortness of Breath	Mild
07 Feb 2021 (Study Day 189)	Temperature (°F)	96.2

The participant had no reported indications of Severe COVID-19 infection.

Action taken with the IP was not applicable. The event of COVID-19 lasted for 32 days, after which it was considered to be recovered/resolved on 06 Feb 2021 (Study Day 188). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004627	COVID-19
MOD-2021-009894	Pericarditis infective

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	1986 - Ongoing
Gout	Gout - left leg	1986 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	1990 - Ongoing
Hyperlipidaemia	Hyperlipidemia	1990 - Ongoing
Hypertension	Hypertension	1990 - Ongoing
Allergy to animal	Allergy to cats	2005 - Ongoing
Allergy to plants	Allergy to trees	2005 - Ongoing
Asthma	Asthma	2005 - Ongoing
Seasonal allergy	Allergy to grass	2005 - Ongoing
Neck pain	Chronic neck pain	2019 - Ongoing
Post herpetic neuralgia	Postherpetic neuralgia	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	1990 - Ongoing	Hypertension
Pravastatin	1990 - Ongoing	Hyperlipidemia
Esomeprazole magnesium	1995 - Ongoing	Gastroesophageal Reflux Disease
Acetylsalicylic acid	2000 - Ongoing	Cardiac Prophylaxis
Alprazolam	2005 - Ongoing	Anxiety
Beclometasone dipropionate	2005 - Ongoing	Asthma
Budesonide; formoterol fumarate	2005 - Ongoing	Asthma
Montelukast sodium	2005 - Ongoing	Asthma
Allopurinol	2017 - Ongoing	Gout
Cannabis sativa	2019 - Ongoing	Chronic Back Pain
Influenza vaccine	19 Sep 2020 (Study Day 48) - 19 Sep 2020 (Study Day 48)	Flu Prevention
Paracetamol	06 Jan 2021 (Study Day 157) - 30 Jan 2021 (Study Day 181)	Sars COVID 19
Clarithromycin	11 Jan 2021 (Study Day 162) - 16 Jan 2021 (Study Day 167)	Sars COVID 19
Dexamethasone	16 Jan 2021 (Study Day 167) - 01 Feb 2021 (Study Day 183)	Sars COVID19
Monoclonal antibodies	19 Jan 2021 (Study Day 170) - 19 Jan 2021 (Study Day 170)	Sars COVID 19
Apixaban	21 Jan 2021 (Study Day 172) - Ongoing	Prevent Pulmonary Embolism
Chest xray*	21 Jan 2021 (Study Day 172) - 21 Jan 2021 (Study Day 172)	Diagnostic
Prednisone	21 Jan 2021 (Study Day 172) - 25 Jan 2021 (Study Day 176)	Symptomatic COVID
Prednisone	26 Jan 2021 (Study Day 177) - 28 Jan 2021 (Study Day 179)	Symptomatic COVID
Prednisone	29 Jan 2021 (Study Day 180) - 31 Jan 2021 (Study Day 182)	Symptomatic COVID
Cardiac catheterization*	30 Jan 2021 (Study Day 181) - 30 Jan 2021 (Study Day 181)	Adverse Event
Colchicine	30 Jan 2021 (Study Day 181) - Ongoing	Acute Infective Pericarditis
Ecg*	30 Jan 2021 (Study Day 181) - 30 Jan 2021 (Study Day 181)	Adverse Event
Glyceryl trinitrate	30 Jan 2021 (Study Day 181) - 30 Jan 2021 (Study Day 181)	Acute Pericarditis
Naproxen	30 Jan 2021 (Study Day 181) - 30 Jan 2021 (Study Day 181)	Acute Pericarditis
Colchicine	01 Feb 2021 (Study Day 183) - Ongoing	Acute Pericarditis
Prednisone	01 Feb 2021 (Study Day 183) - 03 Feb 2021 (Study Day 185)	Symptomatic COVID

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	03 Feb 2021 (Study Day 185) - 06 Feb 2021 (Study Day 188)	COVID
Prednisone	04 Feb 2021 (Study Day 186) - 06 Feb 2021 (Study Day 188)	Symptomatic COVID
Prednisone	07 Feb 2021 (Study Day 189) - 09 Feb 2021 (Study Day 191)	Symptomatic COVID
Prednisone	10 Feb 2021 (Study Day 192) - 12 Feb 2021 (Study Day 194)	Symptomatic COVID
Prednisone	13 Feb 2021 (Study Day 195) - 15 Feb 2021 (Study Day 197)	Symptomatic COVID

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	06 Jan 2021 (Study Day 157) - 06 Feb 2021 (Study Day 188)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US340-2225 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 04 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 18 Jan 2021 (Study Day 168)
Second Dose of Vaccine in Part B: 09 Mar 2021 (Study Day 218)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis Perforated/ Ruptured Appendix	SAE	Grade 3/ severe	Not related	25 Jan 2021 (Study Day 175) – 16 Feb 2021 (Study Day 197)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2225, a 48-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 18 Jan 2021. The participant was unblinded on 18 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 18 Jan 2021 (Study Day 168). The second dose was administered in the left arm on 09 Mar 2021 (Study Day 218).

Event Details

On 25 Jan 2021 (Study Day 175), 174 days after the first dose in Part A/7 days after the first dose in Part B and 146 days after the second dose in Part A/43 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of appendicitis perforated. The IP dose was delayed due to the ruptured appendix. The event of ruptured appendix lasted for 23 days, after which it was considered to be recovered/resolved on 16 Feb 2021 (Study Day 197). The investigator assessed the event of appendicitis perforated to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-013304	Appendicitis perforated

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypersensitivity	Environmental allergies	1980 - Ongoing
Migraine	Migraines	1983 - Ongoing
Insomnia	Insomnia	2016 - Ongoing
Muscle spasms	Muscle spasms left arm pit	2018 - Ongoing
Endometrial ablation	Uterine ablation	Apr 2018 - Apr 2018
Female sterilisation	Bilateral tubal ligation	Apr 2018 - Apr 2018
Musculoskeletal pain	Left shoulder pain	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Codeine phosphate; paracetamol	1983 - Ongoing	Migraines
Nortriptyline	1983 - Ongoing	Migraines
Vitamins nos	2011 - Ongoing	Supplement
Melatonin	2016 - Ongoing	Insomnia
Zolpidem	2016 - Ongoing	Insomnia
Trazodone hydrochloride	2018 - Ongoing	Muscle Spasms
Botulinum toxin type a	2019 - 2019	Migraines
Magnesium	2019 - Ongoing	Supplement
Hydrocodone; paracetamol	Mar 2020 - Ongoing	Left Shoulder Pain
Influenza vaccine	28 Oct 2020 (Study Day 86) - 28 Oct 2020 (Study Day 86)	Influenza Prophylaxis
Ct scan abdomen*	25 Jan 2021 (Study Day 175) - 25 Jan 2021 (Study Day 175)	Adverse Event
Appendectomy*	08 Feb 2021 (Study Day 189) - 08 Feb 2021 (Study Day 189)	Adverse Event
C-reactive protien*	08 Feb 2021 (Study Day 189) - 08 Feb 2021 (Study Day 189)	Adverse Event
Complete blood count*	08 Feb 2021 (Study Day 189) - 08 Feb 2021 (Study Day 189)	Adverse Event
Complete metabolic profile*	08 Feb 2021 (Study Day 189) - 08 Feb 2021 (Study Day 189)	Adverse Event
Ct scan abdomen*	08 Feb 2021 (Study Day 189) - 08 Feb 2021 (Study Day 189)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lipase*	08 Feb 2021 (Study Day 189) - 08 Feb 2021 (Study Day 189)	Adverse Event
Urinalysis*	08 Feb 2021 (Study Day 189) - 08 Feb 2021 (Study Day 189)	Adverse Event
Basic metabolic profile*	10 Feb 2021 (Study Day 191) - 10 Feb 2021 (Study Day 191)	Adverse Event
C reactive protien*	10 Feb 2021 (Study Day 191) - 10 Feb 2021 (Study Day 191)	Adverse Event
Complete blood count*	10 Feb 2021 (Study Day 191) - 10 Feb 2021 (Study Day 191)	Adverse Event
Basic metabolic profile*	16 Feb 2021 (Study Day 197) - 16 Feb 2021 (Study Day 197)	Adverse Event
Complete blood count*	16 Feb 2021 (Study Day 197) - 16 Feb 2021 (Study Day 197)	Adverse Event
Ciprofloxacin	25 Feb 2021 (Study Day 206) - 08 Mar 2021 (Study Day 217)	Ruptured Appendix
Metronidazole	25 Feb 2021 (Study Day 206) - 08 Mar 2021 (Study Day 217)	Ruptured Appendix

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US340-2232 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 05 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 02 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Sars COVID 2	SAE, COVID-19	Grade 1/ mild	Not related	18 Mar 2021 (Study Day 226) – 26 Mar 2021 (Study Day 234)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2232, a 33-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 02 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 12 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 18 Mar 2021 (Study Day 226), 225 days after the first dose in Part A and 197 days after the second dose in Part A of the IP, the participant experienced a Grade 1/mild serious adverse event of covid-19. Action taken with the IP was not applicable. The event of sars COVID 2 lasted for 9 days, after which it was considered to be recovered/resolved on 26 Mar 2021 (Study Day 234). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-066925	COVID-19

Study Completion/Discontinuation

On 26 Mar 2021 (Study Day 234), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2016 - Ongoing	Dietary Supplement
Ibuprofen	03 Sep 2020 (Study Day 30) - 09 Sep 2020 (Study Day 36)	Pain At Injection Site

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US340-2288 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 08 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 32)
First Dose of Vaccine in Part B: 07 Jan 2021 (Study Day 153)
Second Dose of Vaccine in Part B: 05 Feb 2021 (Study Day 182)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abdominal Hernia/ Abdominal Hernia	SAE	Grade 3/ severe	Not related	02 Apr 2021 (Study Day 238) – 11 Apr 2021 (Study Day 247)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2288, a 42-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 08 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 07 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 07 Jan 2021 (Study Day 153). The second dose was administered in the left arm on 05 Feb 2021 (Study Day 182).

Event Details

On 02 Apr 2021 (Study Day 238), 237 days after the first dose in Part A/85 days after the first dose in Part B and 206 days after the second dose in Part A/56 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of abdominal hernia. Action taken with the IP was not applicable. The event of abdominal hernia lasted for 10 days, after which it was considered to be recovered/resolved on 11 Apr 2021 (Study Day 247). The investigator assessed the event of abdominal hernia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-084065	Abdominal hernia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	1986 - Ongoing
Asthma	Asthma	1998 - Ongoing
Obesity	Severe obesity	1998 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Hysterectomy	Complete hysterectomy	2015 - 2015
Ovarian cyst	Bilateral ovarian cysts	2015 - 2015
Vitamin D deficiency	Vitamin d deficiency	2015 - Ongoing
Constipation	Constipation	2017 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2017 - Ongoing
Dizziness	Dizziness	2018 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2018 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Clonazepam	1986 - Ongoing	Anxiety
Salbutamol	1998 - Ongoing	Asthma
Salbutamol sulfate	1998 - Ongoing	Asthma
Colecalciferol	2015 - Ongoing	Vitamin D Deficiency
Estradiol	2015 - Ongoing	Ovarian Cysts
Hydrochlorothiazide	2015 - Ongoing	Hyperension
Atorvastatin	2017 - Ongoing	Hyperlipidemia
Macrogol 3350	2017 - Ongoing	Constipation
Metformin	2018 - Ongoing	Type Ii Diabetes
Topiramate	2018 - Ongoing	Dizziness Caused From Migraines
Omeprazole	2019 - Ongoing	Gastroesophageal Reflux Disease
Umeclidinium bromide; vilanterol trifenate	2019 - Ongoing	Asthma
Amoxicillin	21 Dec 2020 (Study Day 136) - 29 Dec 2020 (Study Day 144)	Abcessed Tooth

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US340-2420 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 22 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 23 Sep 2020 (Study Day 33)
First Dose of Vaccine in Part B: 19 Jan 2021 (Study Day 151)
Second Dose of Vaccine in Part B: 16 Feb 2021 (Study Day 179)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Angina Unstable/Unstable Angina	SAE	Grade 2/moderate	Not related	19 Mar 2021 (Study Day 210) – 24 Mar 2021 (Study Day 215)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2420, a 55-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 22 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 19 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 19 Jan 2021 (Study Day 151). The second dose was administered in the left arm on 16 Feb 2021 (Study Day 179).

Event Details

On 19 Mar 2021 (Study Day 210), 209 days after the first dose in Part A/59 days after the first dose in Part B and 177 days after the second dose in Part A/31 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of angina unstable. Action taken with the IP was not applicable. The event of unstable angina lasted for 6 days, after which it was considered to be recovered/resolved on 24 Mar 2021 (Study Day 215). The investigator assessed the event of angina unstable to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-080897	Angina unstable

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2000 - Ongoing
Drug hypersensitivity	Codeine allergy	2005 - Ongoing
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Angioplasty	Angioplasty	29 Dec 2019 (Study Day -237) - 29 Dec 2019 (Study Day -237)
Arrhythmia	Cardiac dysrhythmia	29 Dec 2019 (Study Day -237) - Ongoing
Cardiac failure congestive	Congestive heart failure	29 Dec 2019 (Study Day -237) - Ongoing
Coronary artery disease	Coronary artery disease	29 Dec 2019 (Study Day -237) - Ongoing
Myocardial infarction	Myocardial infarction	29 Dec 2019 (Study Day -237) - 29 Dec 2019 (Study Day -237)
Stent placement	Stent placement	29 Dec 2019 (Study Day -237) - 29 Dec 2019 (Study Day -237)
Anxiety	Anxiety	01 Jan 2020 (Study Day -234) - Ongoing
Insomnia	Insomnia	01 Jan 2020 (Study Day -234) - Ongoing
Angioplasty	Angioplasty	28 Jan 2020 (Study Day -207) - 28 Jan 2020 (Study Day -207)
Stent placement	Stent placement	28 Jan 2020 (Study Day -207) - 28 Jan 2020 (Study Day -207)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole	2018 - Ongoing	Gastroesophageal Reflux Disease
Acetylsalicylic acid	03 Jan 2020 (Study Day -232) - Ongoing	Cardiac Dysrhythmia
Amiodarone	03 Jan 2020 (Study Day -232) - Ongoing	Cardiac Dysrhythmia
Atorvastatin	03 Jan 2020 (Study Day -232) - Ongoing	Coronary Artery Disease
Carvedilol	03 Jan 2020 (Study Day -232) - Ongoing	Coronary Artery Disease
Ticagrelor	03 Jan 2020 (Study Day -232) - Ongoing	Cardiac Dysrhythmia
Alprazolam	01 Mar 2020 (Study Day -174) - Ongoing	Anxiety
Trazodone	01 Mar 2020 (Study Day -174) - Ongoing	Insomnia
Sacubitril valsartan sodium hydrate	10 Mar 2020 (Study Day -165) - Ongoing	Congestive Heart Failure
Aptt*	23 Mar 2021 (Study Day 214) - 23 Mar 2021 (Study Day 214)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chest xray*	23 Mar 2021 (Study Day 214) - 23 Mar 2021 (Study Day 214)	Adverse Event
Complete blood count*	23 Mar 2021 (Study Day 214) - 23 Mar 2021 (Study Day 214)	Adverse Event
Complete metabolic profile*	23 Mar 2021 (Study Day 214) - 23 Mar 2021 (Study Day 214)	Adverse Event
Covid 19 test*	23 Mar 2021 (Study Day 214) - 23 Mar 2021 (Study Day 214)	Adverse Event
D-dimer*	23 Mar 2021 (Study Day 214) - 23 Mar 2021 (Study Day 214)	Adverse Event
Echo cardiogram*	23 Mar 2021 (Study Day 214) - 23 Mar 2021 (Study Day 214)	Adverse Event
Magnesium*	23 Mar 2021 (Study Day 214) - 23 Mar 2021 (Study Day 214)	Adverse Event
Protime-inr*	23 Mar 2021 (Study Day 214) - 23 Mar 2021 (Study Day 214)	Adverse Event
Stress test*	23 Mar 2021 (Study Day 214) - 23 Mar 2021 (Study Day 214)	Adverse Event
Troponin-i*	23 Mar 2021 (Study Day 214) - 23 Mar 2021 (Study Day 214)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US341-2022 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 29 Jul 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 26 Aug 2020 (Study Day 29)
First Dose of Vaccine in Part B: 06 Jan 2021 (Study Day 162)
Second Dose of Vaccine in Part B: 25 Feb 2021 (Study Day 212)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diverticulitis/Diverticulitis	SAE	Grade 4	Not related	28 Jan 2021 (Study Day 184) – 02 Feb 2021 (Study Day 189)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2022, a 50-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 29 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 26 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 06 Jan 2021 (Study Day 162). The second dose was administered in the left arm on 25 Feb 2021 (Study Day 212).

Event Details

On 28 Jan 2021 (Study Day 184), 183 days after the first dose in Part A/22 days after the first dose in Part B and 155 days after the second dose in Part A/28 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of diverticulitis. The IP dose was not changed due to the diverticulitis. The event of diverticulitis lasted for 6 days, after which it was considered to be recovered/resolved on 02 Feb 2021 (Study Day 189). The investigator assessed the event of diverticulitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010324	Diverticulitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Ligament operation	Reconstructed acl - left knee	1990 - 1990
Seasonal allergy	Allergic rhinitis - seasonal;	1990 - Ongoing
Anxiety	Anxiety	2000 - Ongoing
Depression	Depression	2000 - Ongoing
Continuous positive airway pressure	Continuous positive airway pressure	2005 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2005 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Central obesity	Abdominal obesity	2018 - Ongoing
Oedema peripheral	Peripheral edema bilateral	2018 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2018 - Ongoing
Hyperlipidaemia	Hyperlipidemia	Dec 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone propionate	1990 - Ongoing	Seasonal Allergies
Loratadine	1990 - Ongoing	Seasonal Allergies
Escitalopram oxalate	2014 - Ongoing	Anxiety, Depression
Lisinopril	2015 - Ongoing	Hypertension
Metformin	2018 - 02 Sep 2020 (Study Day 36)	Dm2
Simvastatin	Dec 2019 - Ongoing	Hyperlipidemia - Cholesterol
Furosemide	Mar 2020 - Ongoing	Peripheral Edema Swelling
Metformin hydrochloride; sitagliptin phosphate monohydrate	02 Sep 2020 (Study Day 36) - Ongoing	Diabetes Type II
Glipizide	04 Nov 2020 (Study Day 99) - Ongoing	Worsening Type 2 Diabetes
Insulin aspart	04 Nov 2020 (Study Day 99) - 30 Jan 2021 (Study Day 186)	Worsening Type 2 Diabetes
Blood culture.*	29 Jan 2021 (Study Day 185) - 29 Jan 2021 (Study Day 185)	Adverse Event
Ciprofloxacin	29 Jan 2021 (Study Day 185) - 01 Feb 2021 (Study Day 188)	Diverticulitis
Ct with contrast abdomen/pelvis*	29 Jan 2021 (Study Day 185) - 29 Jan 2021 (Study Day 185)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Heparin	29 Jan 2021 (Study Day 185) - 01 Feb 2021 (Study Day 188)	Diverticulitis
Metronidazole	29 Jan 2021 (Study Day 185) - 01 Feb 2021 (Study Day 188)	Diverticulitis
Morphine	29 Jan 2021 (Study Day 185) - 29 Jan 2021 (Study Day 185)	Diverticulitis
Ondansetron	29 Jan 2021 (Study Day 185) - 29 Jan 2021 (Study Day 185)	Diverticulitis
Paracetamol	29 Jan 2021 (Study Day 185) - 01 Feb 2021 (Study Day 188)	Diverticulitis
Amoxicillin	01 Feb 2021 (Study Day 188) - 05 Feb 2021 (Study Day 192)	Diverticulitis
Insulin aspart	01 Feb 2021 (Study Day 188) - 01 Feb 2021 (Study Day 188)	Type 2 Diabetes
Macrogol 3350	01 Feb 2021 (Study Day 188) - 01 Feb 2021 (Study Day 188)	Diverticulitis
Oxycodone	01 Feb 2021 (Study Day 188) - 05 Feb 2021 (Study Day 192)	Diverticulitis
Sennoside a+b	01 Feb 2021 (Study Day 188) - 01 Feb 2021 (Study Day 188)	Diverticulitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US341-2030 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 30 Jul 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 27 Aug 2020 (Study Day 29)
First Dose of Vaccine in Part B: 05 Jan 2021 (Study Day 160)
Second Dose of Vaccine in Part B: 02 Feb 2021 (Study Day 188)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Benign Prostatic Hyperplasia/ Worsening Bph/Urinary Retention	SAE	Grade 4	Not related	18 Apr 2021 (Study Day 263) – 22 Apr 2021 (Study Day 267)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2030, a 61-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 30 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 27 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 28 Dec 2021. The participant was unblinded on 28 Dec 2020 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 05 Jan 2021 (Study Day 160). The second dose was administered in the left arm on 02 Feb 2021 (Study Day 188).

Event Details

On 18 Apr 2021 (Study Day 263), 262 days after the first dose in Part A/103 days after the first dose in Part B and 234 days after the second dose in Part A/75 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of benign prostatic hyperplasia. Action taken with the IP was not applicable. The event of worsening bph/urinary retention lasted for 5 days, after which it was considered to be recovered/resolved on 22 Apr 2021 (Study Day 267). The investigator assessed the event of benign prostatic hyperplasia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-091381	Benign prostatic hyperplasia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1988 - Ongoing
Vasectomy	Vasectomy	1989 - 1989
Muscle spasms	Backpain / muscle spasms (2degrees) to shoulder repair	1990 - Ongoing
Shoulder operation	Subluxion repair - right shoulder	1990 - 1990
Plantar fasciitis	Plantar fasciitis	2000 - Ongoing
Meniscus operation	Left miniscus repair	2015 - 2015
Benign prostatic hyperplasia	Bph	2017 - Ongoing
Gastroesophageal reflux disease	Gerd	2019 - Ongoing
Meniscus operation	Right miniscus repair	2019 - 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	1990 - Ongoing	Back Pain / Muscle Spasm
Lisinopril	1990 - Ongoing	Htn
Tamsulosin	2017 - Ongoing	Bph
Omeprazole	2019 - Ongoing	Gerd
Famotidine	May 2020 - Ongoing	Gerd
Paracetamol	03 Aug 2020 (Study Day 5) - 03 Aug 2020 (Study Day 5)	Multiple Bee Stings Generalized But Primairly On Legs
Cyclobenzaprine	14 Sep 2020 (Study Day 47) - 15 Sep 2020 (Study Day 48)	Muscle Spasm / Back Pain
Diclofenac	28 Nov 2020 (Study Day 122) - 30 Nov 2020 (Study Day 124)	Plantar Fasciitis
Diclofenac	01 Dec 2020 (Study Day 125) - Ongoing	Plantar Fasciitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US341-2059 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 31 Jul 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Aug 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Left Ventricular Failure/ Acute Systolic Failure	SAE	Grade 4	Not related	06 Mar 2021 (Study Day 219) – 08 Mar 2021 (Study Day 221)	Recovered/resolved
Acute Myocardial Infarction/Acute Myocardial Infarction	SAE	Grade 4	Not related	06 Mar 2021 (Study Day 219) – 06 Mar 2021 (Study Day 219)	Recovered/resolved
Chest Pain/Precordial Chest Pain	SAE	Grade 4	Not related	06 Mar 2021 (Study Day 219) – 06 Mar 2021 (Study Day 219)	Recovered/resolved
Ischaemic Cardiomyopathy/ Ischemic Cardiomyopathy	SAE	Grade 4	Not related	06 Mar 2021 (Study Day 219) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2059, a 68-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 31 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 28 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 18 Jan 2021. The participant was unblinded on 18 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 06 Mar 2021 (Study Day 219), 218 days after the first dose in Part A and 190 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of acute left ventricular failure. Action taken with the IP was not applicable. The event of acute systolic failure lasted for 3 days, after which it was considered to be recovered/resolved on 08 Mar

2021 (Study Day 221). The investigator assessed the event of acute left ventricular failure to be not related to the IP.

On 06 Mar 2021 (Study Day 219), 218 days after the first dose in Part A and 190 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of acute myocardial infarction. Action taken with the IP was not applicable. The event of acute myocardial infarction lasted for 1 day, after which it was considered to be recovered/resolved on 06 Mar 2021 (Study Day 219). The investigator assessed the event of acute myocardial infarction to be not related to the IP.

On 06 Mar 2021 (Study Day 219), 218 days after the first dose in Part A and 190 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of chest pain. Action taken with the IP was not applicable. The event of precordial chest pain lasted for 1 day, after which it was considered to be recovered/resolved on 06 Mar 2021 (Study Day 219). The investigator assessed the event of chest pain to be not related to the IP.

On 06 Mar 2021 (Study Day 219), 218 days after the first dose in Part A and 190 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of ischaemic cardiomyopathy. Action taken with the IP was not applicable. The event of ischemic cardiomyopathy was considered to be ongoing. The investigator assessed the event of ischaemic cardiomyopathy to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-037772	Acute left ventricular failure
MOD-2021-037772	Acute myocardial infarction
MOD-2021-037772	Chest pain
MOD-2021-037772	Ischaemic cardiomyopathy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Lipoma	Lipoma right hip	2011 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2013 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2015 - Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing
Vascular insufficiency	Vascular insufficiency	2017 - Ongoing
Onychomycosis	Onychomycosis (b) feet	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2018 - Ongoing	Htn
Fish oil	2018 - Aug 2020	General Health
Guaifenesin	2018 - Ongoing	Seasonal Allergic Rhinitis.
Losartan	2018 - Sep 2020	Hypertension
Spironolactone	2018 - Nov 2020	Hypertension
Ciclopirox	2019 - 15 Feb 2021 (Study Day 200)	Onychomycosis - Cream For Nail Enamel Toe Fungus
Fexofenadine hydrochloride	2020 - Ongoing	Seasonal Allergies
Phytosterols nos	2020 - Ongoing	Hyperlipidemia
Paracetamol	30 Aug 2020 (Study Day 31) - 30 Aug 2020 (Study Day 31)	Headache Solicited Ae
Losartan	Sep 2020 - Ongoing	Hypertension
Atenolol	Nov 2020 - Ongoing	Hypertension
Ezetimibe	Nov 2020 - Ongoing	Hyperlipidemia
Duplex scan venous study*	11 Feb 2021 (Study Day 196) - 11 Feb 2021 (Study Day 196)	Adverse Event
Cardiac catheterization*	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Adverse Event
Chest xray*	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Adverse Event
Coronary angiography with lv*	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Adverse Event
Covid-19 swab*	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Adverse Event
Ecg*	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Adverse Event
Eptifibatide	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Ami
Fentanyl	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Ami
Glyceryl trinitrate	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Pci Procedure
Heparin	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Thrombus Prophylactic
Heparin	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Thrombus Prophylaxes

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Heparin	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Thrombus Prophylaxis
Lidocaine	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Pci Procedure
Midazolam hydrochloride	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Ami
Ondansetron	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Nausea Prophylaxis
Transthoracic echo (tte)*	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Adverse Event
Verapamil	06 Mar 2021 (Study Day 219) - 06 Mar 2021 (Study Day 219)	Pci Procedure
Acetylsalicylic acid	09 Mar 2021 (Study Day 222) - Ongoing	Heart Health
Carvedilol	09 Mar 2021 (Study Day 222) - Ongoing	Hypertension And Heart Health
Clopidogrel	09 Mar 2021 (Study Day 222) - Ongoing	Heart Health
Glycerol trinitrate	09 Mar 2021 (Study Day 222) - Ongoing	Heart Health/Chest Pain
Isosorbide mononitrate	09 Mar 2021 (Study Day 222) - Ongoing	Chest Pain Prophylaxis
Isosorbide mononitrate	09 Mar 2021 (Study Day 222) - Ongoing	Heart Health

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Vascular Insufficiency	Grade 1/mild	Related	11 Feb 2021 (Study Day 196) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US341-2200 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 11 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Depression/Severe Depression	SAE	Grade 4	Not related	06 Apr 2021 (Study Day 239) – Ongoing	Recovering/resolving
Post-Traumatic Stress Disorder/ Post Traumatic Stress Disorder	SAE	Grade 4	Not related	06 Apr 2021 (Study Day 239) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2200, a 31-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 18 Jan 2021. The participant was unblinded on 18 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 06 Apr 2021 (Study Day 239), 238 days after the first dose in Part A and 210 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of depression. Action taken with the IP was not applicable. The event of severe depression was considered to be ongoing. The investigator assessed the event of depression to be not related to the IP.

On 06 Apr 2021 (Study Day 239), 238 days after the first dose in Part A and 210 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of post-traumatic stress disorder. Action taken with the IP was not applicable. The event of post traumatic stress disorder was considered to be ongoing. The investigator assessed the event of post-traumatic stress disorder to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-077169	Depression
MOD-2021-077169	Post-traumatic stress disorder

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergic rhinitis	2015 - Ongoing
Anxiety	Anxiety	2019 - Ongoing
Depression	Depression	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Botulinum toxin type a	2018 - Ongoing	Cosmetic
Clonazepam	2018 - Ongoing	Anxiety/Depression
Bupropion hydrochloride	2019 - Ongoing	Anxiety/Depression
Duloxetine	2019 - 26 Aug 2020 (Study Day 16)	Anxiety / Depression
Duloxetine	2019 - 25 Aug 2020 (Study Day 15)	Anxiety/Depression
Ibuprofen	15 Aug 2020 (Study Day 5) - 17 Aug 2020 (Study Day 7)	Headache
Clonazepam	Sep 2020 - Ongoing	Depression/Anxiety
Influenza vaccine	14 Oct 2020 (Study Day 65) - 14 Oct 2020 (Study Day 65)	General Health
Mirtazapine	21 Oct 2020 (Study Day 72) - 01 Feb 2021 (Study Day 175)	Depression
Mirtazapine	02 Feb 2021 (Study Day 176) - 18 Mar 2021 (Study Day 220)	Depression
Mirtazapine	19 Mar 2021 (Study Day 221) - Ongoing	Worsening Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US341-2246 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 14 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cervical Vertebral Fracture/Anterior Osteophyte Avulsian Fracture C6	SAE	Grade 4	Not related	02 Mar 2021 (Study Day 201) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2246, a 70-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 02 Mar 2021 (Study Day 201), 200 days after the first dose in Part A and 172 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of cervical vertebral fracture. Action taken with the IP was not applicable. The event of anterior osteophyte avulsian fracture c6 was considered to be ongoing. The investigator assessed the event of cervical vertebral fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-036351	Cervical vertebral fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypogonadism	Hypogonadism/low testosterone	2000 - Ongoing
Insomnia	Insomnia	2010 - Ongoing
Glaucoma	Glaucoma- left eye	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2000 - Ongoing	General Health
Testosterone	2003 - Ongoing	Hypogonadism / Low Testosterone
Zolpidem tartrate	2010 - Ongoing	Insomnia
Bimatoprost	Mar 2020 - Ongoing	Glaucoma
Paracetamol	15 Aug 2020 (Study Day 2) - 15 Aug 2020 (Study Day 2)	Study Related Injection Pain
Influenza vaccine	27 Sep 2020 (Study Day 45) - 27 Sep 2020 (Study Day 45)	Influenza Propylaxis
Ct abd/pelvis w/iv contrast dual/triple phase*	02 Mar 2021 (Study Day 201) - 02 Mar 2021 (Study Day 201)	Adverse Event
Ct chest w/ iv contrast*	02 Mar 2021 (Study Day 201) - 02 Mar 2021 (Study Day 201)	Adverse Event
Ct head w/o iv contrast*	02 Mar 2021 (Study Day 201) - 02 Mar 2021 (Study Day 201)	Adverse Event
Ct trauma cta neck/cervical spine*	02 Mar 2021 (Study Day 201) - 02 Mar 2021 (Study Day 201)	Adverse Event
Docusate; senna alexandrina	02 Mar 2021 (Study Day 201) - Ongoing	Anterior Osteophyte Avulsian Fracture C6
Fentanyl	02 Mar 2021 (Study Day 201) - 02 Mar 2021 (Study Day 201)	Anterior Osteophyte Avulsian Fracture C6
Gabapentin	02 Mar 2021 (Study Day 201) - Ongoing	Cervical Spondylosis
Hydromorphone	02 Mar 2021 (Study Day 201) - 02 Mar 2021 (Study Day 201)	Anterior Osteophyte Avulsian Fracture C6
Mri cervical spine without contrast*	02 Mar 2021 (Study Day 201) - 02 Mar 2021 (Study Day 201)	Adverse Event
Paracetamol	02 Mar 2021 (Study Day 201) - Ongoing	Anterior Osteophyte Avulsian Fracture C6

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Poc us fast abdominal*	02 Mar 2021 (Study Day 201) - 02 Mar 2021 (Study Day 201)	Adverse Event
Oxycodone	03 Mar 2021 (Study Day 202) - Ongoing	Anterior Osteophyte Avulsian Fracture C6
Xr spine cervical ap and lateral*	03 Mar 2021 (Study Day 202) - 03 Mar 2021 (Study Day 202)	Adverse Event
Wear aspen collar*	04 Mar 2021 (Study Day 203) - 04 Mar 2021 (Study Day 203)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Spinal Cord Injury	Grade 4	Not related	02 Mar 2021 (Study Day 201) - Ongoing
Spinal Osteoarthritis	Grade 4	Not related	02 Mar 2021 (Study Day 201) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US341-2262 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 17 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening L Hip Oa	SAE	Grade 4	Not related	01 Apr 2021 (Study Day 228) – 21 Apr 2021 (Study Day 248)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2262, a 69-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 15 Jan 2021. The participant was unblinded on 15 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 01 Apr 2021 (Study Day 228), 227 days after the first dose in Part A and 199 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of worsening l hip oa lasted for 21 days, after which it was considered to be recovered/resolved on 21 Apr 2021 (Study Day 248). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-094040	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cataract	Cataracts.	Jan 2020 - Jan 2020
Osteoarthritis	Osteoarthritis left hip pain	Feb 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Meloxicam	Feb 2020 - Ongoing	Hip Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US341-2296 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 20 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 24 Sep 2020 (Study Day 36)
First Dose of Vaccine in Part B: 14 Jan 2021 (Study Day 148)
Second Dose of Vaccine in Part B: 11 Feb 2021 (Study Day 176)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Breast Cellulitis/Cellulitis Left Breast	SAE	Grade 4	Not related	03 Mar 2021 (Study Day 196) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2296, a 52-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 14 Jan 2021 (Study Day 148). The second dose was administered in the left arm on 11 Feb 2021 (Study Day 176).

Event Details

On 03 Mar 2021 (Study Day 196), 195 days after the first dose in Part A/48 days after the first dose in Part B and 160 days after the second dose in Part A/20 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of breast cellulitis. Action taken with the IP was not applicable. The event of cellulitis left breast was considered to be ongoing. The investigator assessed the event of breast cellulitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-041748	Breast cellulitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Allergy to animal	Cat allergy	1980 - Ongoing
Postmenopause	Postmenopausal	2010 - Ongoing
Hypertension	Hypertension	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol	2015 - Ongoing	Hypertension
Vitamins nos	2015 - Ongoing	General Health
Influenza vaccine	08 Sep 2020 (Study Day 20) - 08 Sep 2020 (Study Day 20)	General Health
Duloxetine hydrochloride	15 Sep 2020 (Study Day 27) - Ongoing	Depression
Levothyroxine sodium	15 Sep 2020 (Study Day 27) - Ongoing	Hypothyroidism
Amoxicillin; clavulanic acid	06 Mar 2021 (Study Day 199) - 08 Mar 2021 (Study Day 201)	L Breast Cellulitis
Ketorolac tromethamine	08 Mar 2021 (Study Day 201) - 08 Mar 2021 (Study Day 201)	Left Breast Cellulitis
Morphine	08 Mar 2021 (Study Day 201) - 09 Mar 2021 (Study Day 202)	Left Breast Cellulitis
Vancomycin	08 Mar 2021 (Study Day 201) - 10 Mar 2021 (Study Day 203)	L Breast Cellulitis
Vitamin d nos	08 Mar 2021 (Study Day 201) - 10 Mar 2021 (Study Day 203)	General Health
Cefepime	09 Mar 2021 (Study Day 202) - 10 Mar 2021 (Study Day 203)	Left Breast Cellulitis
Enoxaparin sodium	09 Mar 2021 (Study Day 202) - 10 Mar 2021 (Study Day 203)	Dvt Prophylaxis
Ondansetron	09 Mar 2021 (Study Day 202) - 09 Mar 2021 (Study Day 202)	Left Breast Cellulitis, Nausea
Oxycodone	09 Mar 2021 (Study Day 202) - 09 Mar 2021 (Study Day 202)	Left Breast Cellulitis
Oxycodone	09 Mar 2021 (Study Day 202) - 10 Mar 2021 (Study Day 203)	Left Breast Cellulitis
Oxycodone	10 Mar 2021 (Study Day 203) - 13 Mar 2021 (Study Day 206)	Cellulitis L Breast

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sulfamethoxazole; trimethoprim	10 Mar 2021 (Study Day 203) - 24 Mar 2021 (Study Day 217)	Cellulitis L Breast

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US341-2337 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 31 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hip Fracture/Left Hip Fracture	SAE	Grade 4	Not related	22 Feb 2021 (Study Day 176) – 23 Feb 2021 (Study Day 177)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2337, a 71-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 05 Jan 2021. The participant was unblinded on 05 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 22 Feb 2021 (Study Day 176), 175 days after the first dose in Part A and 147 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of hip fracture. Action taken with the IP was not applicable. The event of left hip fracture lasted for 2 days, after which it was considered to be recovered/resolved on 23 Feb 2021 (Study Day 177). The investigator assessed the event of hip fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-021859	Hip fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastroesophageal reflux disease	Gerd	1975 - Ongoing
Postmenopause	Post menopausal	1989 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Insomnia	Insomnia	2003 - Ongoing
Seasonal allergy	Allergic rhinitis seasonal	2010 - Ongoing
Chronic obstructive pulmonary disease	Copd	2014 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	1975 - Ongoing	Gerd
Lisinopril	2005 - Ongoing	Htn
Fluticasone propionate	2010 - Ongoing	Seasonal Allergies
Pravastatin	2010 - Ongoing	Hyperlipidemia
Formoterol fumarate; glycopyrronium bromide	2014 - Ongoing	Copd
Salbutamol	2014 - Ongoing	Copd
Fibre, dietary	2015 - Ongoing	Supplement
Vitamin d nos	2015 - Ongoing	Supplement
Trazodone	2016 - Ongoing	Insomnia
Loratadine	2018 - Ongoing	Allergic Rhinitis - Seasonal
Paracetamol	Sep 2020 - Ongoing	Solicited Injection Site Pain
Influenza vaccine	05 Nov 2020 (Study Day 67) - 05 Nov 2020 (Study Day 67)	General Health Flu Prevention
Docusate sodium; sennoside a+b	22 Feb 2021 (Study Day 176) - 16 Mar 2021 (Study Day 198)	Constipation Prophylactic
Oxycodone	22 Feb 2021 (Study Day 176) - 01 Mar 2021 (Study Day 183)	Hip Fracture Pain
Paracetamol	22 Feb 2021 (Study Day 176) - 01 Apr 2021 (Study Day 214)	Hip Fracture Pain
Chest x-ray*	23 Feb 2021 (Study Day 177) - 23 Feb 2021 (Study Day 177)	Adverse Event
Intramedullary nail fixation femur fracture*	23 Feb 2021 (Study Day 177) - 23 Feb 2021 (Study Day 177)	Adverse Event
X-ray left hip*	23 Feb 2021 (Study Day 177) - 23 Feb 2021 (Study Day 177)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Macrogol 3350	25 Feb 2021 (Study Day 179) - 16 Mar 2021 (Study Day 198)	Constipation Prophylactic
Melatonin	25 Feb 2021 (Study Day 179) - Ongoing	Insomnia
Rivaroxaban	25 Feb 2021 (Study Day 179) - 11 Mar 2021 (Study Day 193)	Dvt Prophylaxis From Surgery
Tramadol	01 Mar 2021 (Study Day 183) - 29 Mar 2021 (Study Day 211)	Hip Fracture Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US342-2101 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 25 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 22 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Ileus/Ileus	SAE	Grade 2/ moderate	Not related	13 Feb 2021 (Study Day 173) – 15 Feb 2021 (Study Day 175)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US342-2101, a 35-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 08 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 13 Feb 2021 (Study Day 173), 172 days after the first dose in Part A and 144 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of ileus. Action taken with the IP was not applicable. The event of ileus lasted for 3 days, after which it was considered to be recovered/resolved on 15 Feb 2021 (Study Day 175). The investigator assessed the event of ileus to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-016989	Ileus

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1990 - Ongoing
Anxiety	Anxiety	2011 - Ongoing
Bipolar II disorder	Bipolar disorder ii	2011 - Ongoing
Migraine	Migraines	2017 - Ongoing
Obsessive-compulsive disorder	Obsessive compulsive disorder	2018 - Ongoing
Pilonidal cyst	Pilonidal cyst	Dec 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	1990 - Ongoing	Seasonal Allergies
Lamotrigine	2011 - Ongoing	Bipolar Disorder Ii
Lorazepam	2011 - Ongoing	Anxiety
Trazodone	2015 - Ongoing	Anxiety
Propranolol	2017 - Ongoing	Anxiety
Pregabalin	2018 - Ongoing	Anxiety
Topiramate	2018 - Ongoing	Obsessive Compulsive Disorder
Sumatriptan	23 Jan 2020 (Study Day -215) - Ongoing	Migraines
Paracetamol	22 Sep 2020 (Study Day 29) - 24 Sep 2020 (Study Day 31)	Generalized Myalgias/Pain At Injection Site
Influenza vaccine	12 Oct 2020 (Study Day 49) - 12 Oct 2020 (Study Day 49)	Health Maintenance
Amoxicillin	16 Nov 2020 (Study Day 84) - 26 Nov 2020 (Study Day 94)	Streptococcal Pharyngitis
Lithium	Dec 2020 - Ongoing	Worsening Bipolar Disorder Ii
Ketamine	11 Jan 2021 (Study Day 140) - Ongoing	Worsening Bipolar Disorder Ii
Excision of pilonidal cyst*	12 Feb 2021 (Study Day 172) - 12 Feb 2021 (Study Day 172)	Medical History
Oxycodone	12 Feb 2021 (Study Day 172) - 16 Feb 2021 (Study Day 176)	Excision Of Pilonidal Cyst
Docusate; sennoside a+b	13 Feb 2021 (Study Day 173) - 14 Feb 2021 (Study Day 174)	Ileus
Magnesium hydroxide	13 Feb 2021 (Study Day 173) - 14 Feb 2021 (Study Day 174)	Ileus
Bisacodyl	14 Feb 2021 (Study Day 174) - 14 Feb 2021 (Study Day 174)	Ileus
Haloperidol	14 Feb 2021 (Study Day 174) - 15 Feb 2021 (Study Day 175)	Ileus

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ketorolac	14 Feb 2021 (Study Day 174) - 14 Feb 2021 (Study Day 174)	Ileus
Macrogol 3350	14 Feb 2021 (Study Day 174) - 15 Feb 2021 (Study Day 175)	Ileus
Magnesium citrate	14 Feb 2021 (Study Day 174) - 14 Feb 2021 (Study Day 174)	Ileus
Methocarbamol	14 Feb 2021 (Study Day 174) - 14 Feb 2021 (Study Day 174)	Ileus
Ondansetron	14 Feb 2021 (Study Day 174) - 14 Feb 2021 (Study Day 174)	Ileus
Lactulose	15 Feb 2021 (Study Day 175) - 15 Feb 2021 (Study Day 175)	Ileus

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US343-2023 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 05 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: Not Administered
First Dose of Vaccine in Part B: 16 Jan 2021 (Study Day 165)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Interstitial Lung Disease/ Idiopathic Interstitial Pneumonitis	SAE	Grade 3/ severe	Not related	28 Jan 2021 (Study Day 177) – Ongoing	Not recovered/ not resolved
Diplopia/Diplopia	SAE	Grade 3/ severe	Not related	31 Mar 2021 (Study Day 239) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2023, a 83-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 05 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 16 Jan 2021. The participant was unblinded on 16 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 16 Jan 2021 (Study Day 165). The second dose was not administered.

Event Details

On 28 Jan 2021 (Study Day 177), 176 days after the first dose in Part A/12 days after the first dose in Part B of the IP (second dose Part A not applicable/second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of interstitial lung disease. The IP dose was not changed due to the idiopathic interstitial pneumonitis. The event of idiopathic interstitial pneumonitis was considered to be ongoing. The investigator assessed the event of interstitial lung disease to be not related to the IP.

On 31 Mar 2021 (Study Day 239), 238 days after the first dose in Part A/74 days after the first dose in Part B of the IP (second dose Part A not applicable/second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of diplopia. The IP dose was not

changed due to the diplopia. The event of diplopia was considered to be ongoing. The investigator assessed the event of diplopia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009803	Interstitial lung disease
MOD-2021-068055	Diplopia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Penicillin allergy (serum sickness)	1960 - Ongoing
Depression	Mild depression	1980 - Ongoing
Hyperlipidaemia	Hyperlipidemia	1980 - Ongoing
Back pain	Chronic low back pain with intermittent flare	2000 - Ongoing
Hypothyroidism	Hypothyroidism	2005 - Ongoing
Hypertension	Hypertension (well controlled)	2010 - Ongoing
Pneumonia pneumococcal	Pneumococcal pneumonia	2010 - 2010
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Ventricular extrasystoles	Premature ventricular complex	2010 - Ongoing
Cerebrovascular accident	Stroke	2011 - 2011
Anaemia	Chronic anemia	2012 - Ongoing
Hypergammaglobulinaemia benign monoclonal	Monoclonal gammopathy of undetermined significance	2012 - Ongoing
Renal failure	Mild renal failure	2013 - Ongoing
Aortic stenosis	Aortic stenosis	Jun 2019 - Ongoing
Cardiac failure congestive	Congestive heart failure	Jun 2019 - Ongoing
Transcatheter aortic valve implantation	Tavr for aortic stenosis	Jun 2019 - Jun 2019
Coronary artery disease	Coronary heart disease	Nov 2019 - Ongoing
Constipation	Constipation	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bupropion	1980 - Ongoing	Depression
Acetylsalicylic acid	2000 - Ongoing	Chronic Low Back Pain With Intermittent Flare
Levothyroxine	2005 - Ongoing	Hypothyroidism
Atenolol	2010 - Ongoing	Premature Ventricular Complex
Fluticasone propionate	2010 - Ongoing	Seasonal Allergies
Acetylsalicylic acid	2011 - Ongoing	Stroke
Clopidogrel bisulfate	2011 - Ongoing	Stroke
Calcium	2015 - Ongoing	General Health
Vitamin d nos	2015 - Ongoing	General Health
Vitamins nos	2015 - Ongoing	General Health
Bisoprolol	2016 - Jul 2020	Heart Failure/Htn
Rosuvastatin	2018 - Ongoing	Hyperlipidemia
Docusate sodium	Jan 2020 - Ongoing	Constipation
Prednisone	20 Aug 2020 (Study Day 16) - 20 Aug 2020 (Study Day 16)	Possible Polymyalgia Rheumatica
Prednisone	21 Aug 2020 (Study Day 17) - 04 Sep 2020 (Study Day 31)	Possible Polymyalgia Rheumatica
Prednisone	11 Sep 2020 (Study Day 38) - Ongoing	Polymyalgia Rheumatica
Influenza vaccine	25 Sep 2020 (Study Day 52) - 25 Sep 2020 (Study Day 52)	Prophylaxis For Influenza
Cardiac ultrasound*	29 Jan 2021 (Study Day 178) - 29 Jan 2021 (Study Day 178)	Adverse Event
Chest xr*	29 Jan 2021 (Study Day 178) - 29 Jan 2021 (Study Day 178)	Adverse Event
Ct head*	29 Jan 2021 (Study Day 178) - 29 Jan 2021 (Study Day 178)	Adverse Event
Methylprednisolone	29 Jan 2021 (Study Day 178) - 06 Feb 2021 (Study Day 186)	Pmr
Methylprednisolone	29 Jan 2021 (Study Day 178) - 08 Feb 2021 (Study Day 188)	Pmr
Ondansetron	29 Jan 2021 (Study Day 178) - 16 Feb 2021 (Study Day 196)	Nausea
Methylprednisolone	30 Jan 2021 (Study Day 179) - 08 Feb 2021 (Study Day 188)	Pmr
Aminophylline	31 Jan 2021 (Study Day 180) - 31 Jan 2021 (Study Day 180)	Idiopathic Interstitial Pneumonitis
Myocardial perfusion spect study*	31 Jan 2021 (Study Day 180) - 31 Jan 2021 (Study Day 180)	Adverse Event
Plantago ovata	31 Jan 2021 (Study Day 180) - 16 Feb 2021 (Study Day 196)	Constipation
Lung ventilation and perfusion scan*	02 Feb 2021 (Study Day 182) - 02 Feb 2021 (Study Day 182)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxymetazoline	02 Feb 2021 (Study Day 182) - 05 Feb 2021 (Study Day 185)	Idiopathic Interstitial Pneumonitis
Ct chest*	03 Feb 2021 (Study Day 183) - 03 Feb 2021 (Study Day 183)	Adverse Event
Guaifenesin	03 Feb 2021 (Study Day 183) - 16 Feb 2021 (Study Day 196)	Cough
Heparin	03 Feb 2021 (Study Day 183) - 16 Feb 2021 (Study Day 196)	Coagulant Prophylaxis
Salbutamol	03 Feb 2021 (Study Day 183) - 16 Feb 2021 (Study Day 196)	Wheezing Associated With Idiopathic Interstitial Pneumonitis
Paracetamol	04 Feb 2021 (Study Day 184) - 16 Feb 2021 (Study Day 196)	Pain And Fever
Atovaquone	08 Feb 2021 (Study Day 188) - 11 Feb 2021 (Study Day 191)	Pjp Prophylaxis
Methylprednisolone sodium succinate	08 Feb 2021 (Study Day 188) - 11 Feb 2021 (Study Day 191)	Pmr
Prednisone	11 Feb 2021 (Study Day 191) - 15 Feb 2021 (Study Day 195)	Pmr
Prednisone	15 Feb 2021 (Study Day 195) - 03 Mar 2021 (Study Day 211)	Pmr
Abdomen ultrasound*	16 Feb 2021 (Study Day 196) - 16 Feb 2021 (Study Day 196)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US343-2094 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 11 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 31)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Haematochezia/ Hematochezia	SAE	Grade 3/ severe	Not related	30 Jan 2021 (Study Day 173) – 06 Feb 2021 (Study Day 180)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2094, a 76-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 10 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 30 Jan 2021 (Study Day 173), 172 days after the first dose in Part A and 142 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of haematochezia. Action taken with the IP was not applicable. The event of hematochezia lasted for 8 days, after which it was considered to be recovered/resolved on 06 Feb 2021 (Study Day 180). The investigator assessed the event of haematochezia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010678	Haematochezia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastroesophageal reflux disease	Esophageal reflux	1990 - Ongoing
Hypertension	Hypertension	1990 - Ongoing
Hypothyroidism	Hypothyroidism	1990 - Ongoing
Vitamin D decreased	Low vitamin d	1990 - Ongoing
Depression	Depression	2003 - Ongoing
Prostate cancer	Prostate cancer	2003 - 2003
Coronary arterial stent insertion	Coronary stent	Sep 2007 - Sep 2007
Coronary artery disease	Coronary artery disease	Sep 2007 - Ongoing
Leukaemia	History of leukemia	Nov 2011 - 2012
Meningioma	Meningioma	Nov 2011 - Ongoing
Meningioma surgery	Surgical resection for meningioma	2012 - 2012
Atrioventricular block	Heart block	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	1990 - Ongoing	Cardiovascular Prophylaxis
Irbesartan	1990 - Ongoing	Hypertension
Levothyroxine	1990 - Ongoing	Pre-Existing Hypothyroidism
Omeprazole	1990 - Ongoing	Esophageal Reflux
Escitalopram	2003 - Ongoing	Depression
Bupropion	2015 - Ongoing	Depression
Atorvastatin	Jul 2020 - Ongoing	Coronary Artery Disease
Paracetamol	10 Sep 2020 (Study Day 31) - 12 Sep 2020 (Study Day 33)	Soreness At Injection Site
Mri brain*	28 Oct 2020 (Study Day 79) - 28 Oct 2020 (Study Day 79)	Adverse Event
Bisacodyl	23 Nov 2020 (Study Day 105) - Ongoing	Constipation
Ceftriaxone	23 Nov 2020 (Study Day 105) - 24 Nov 2020 (Study Day 106)	Bacteremia
Craniectomy*	23 Nov 2020 (Study Day 105) - 23 Nov 2020 (Study Day 105)	Medical History
Cranioplasty*	23 Nov 2020 (Study Day 105) - 23 Nov 2020 (Study Day 105)	Medical History
Docusate sodium	23 Nov 2020 (Study Day 105) - Ongoing	Constipation
Esomeprazole	24 Nov 2020 (Study Day 106) - Ongoing	Gastric Reflux

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Furosemide	24 Nov 2020 (Study Day 106) - 24 Nov 2020 (Study Day 106)	Fluid Retention Treatment
Paracetamol	24 Nov 2020 (Study Day 106) - Ongoing	Pain After Cranioplasty And Craniectomy
Atropine	25 Nov 2020 (Study Day 107) - Ongoing	Bradycardia
Paracetamol	25 Nov 2020 (Study Day 107) - Ongoing	Pain After Cranioplasty And Craniectomy
Escitalopram oxalate	27 Nov 2020 (Study Day 109) - Ongoing	Anxiety From Surgery
Furosemide	27 Nov 2020 (Study Day 109) - 27 Nov 2020 (Study Day 109)	Fluid Retention Treatment
Hydromorphone hydrochloride	01 Dec 2020 (Study Day 113) - Ongoing	Severe Pain After Cranioplasty And Craniectomy
Hydralazine	03 Dec 2020 (Study Day 115) - Ongoing	High Blood Pressure
Dexamethasone	04 Dec 2020 (Study Day 116) - Ongoing	Inflammation (General)
Heparin	04 Dec 2020 (Study Day 116) - 04 Dec 2020 (Study Day 116)	Anticoagulant
Vancomycin	06 Dec 2020 (Study Day 118) - 04 Jan 2021 (Study Day 147)	Bacteremia
Cefradine	07 Dec 2020 (Study Day 119) - Ongoing	Bacterial Infection Prevention
Heparin	11 Dec 2020 (Study Day 123) - Ongoing	Anticoagulant
Furosemide	15 Dec 2020 (Study Day 127) - 15 Dec 2020 (Study Day 127)	Fluid Retention Treatment
Furosemide	20 Dec 2020 (Study Day 132) - 20 Dec 2020 (Study Day 132)	Fluid Retention Treatment
Bisacodyl	23 Dec 2020 (Study Day 135) - Ongoing	Constipation
Famotidine	23 Dec 2020 (Study Day 135) - Ongoing	Antacid
Heparin	23 Dec 2020 (Study Day 135) - Ongoing	Coagulant Prophylaxis
Ipratropium bromide; salbutamol sulfate	23 Dec 2020 (Study Day 135) - Ongoing	Shortness Of Breath
Ct scan head*	29 Dec 2020 (Study Day 141) - 29 Dec 2020 (Study Day 141)	Adverse Event
Ceftriaxone	02 Jan 2021 (Study Day 145) - 03 Feb 2021 (Study Day 177)	Bacteremia
Hydrocortisone	04 Jan 2021 (Study Day 147) - 11 Jan 2021 (Study Day 154)	Adrenal Insufficiency
Hydrocortisone	05 Jan 2021 (Study Day 148) - 05 Jan 2021 (Study Day 148)	Adrenal Insufficiency
Hydrocortisone	06 Jan 2021 (Study Day 149) - 12 Jan 2021 (Study Day 155)	Adrenal Insufficiency
Ct abdomen and pelvis*	02 Feb 2021 (Study Day 176) - 02 Feb 2021 (Study Day 176)	Adverse Event
Macrogol 3350	02 Feb 2021 (Study Day 176) - Ongoing	Constipation
Flexible sigmoidoscopy*	03 Feb 2021 (Study Day 177) - 03 Feb 2021 (Study Day 177)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US343-2120 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 12 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 28)
First Dose of Vaccine in Part B: 19 Jan 2021 (Study Day 161)
Second Dose of Vaccine in Part B: 26 Feb 2021 (Study Day 199)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Small Intestinal Obstruction/ Sbo (Small Bowel Obstruction)	SAE	Grade 3/ severe	Not related	30 Jan 2021 (Study Day 172) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2120, a 46-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 19 Jan 2021. The participant was unblinded on 19 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 19 Jan 2021 (Study Day 161). The second dose was administered in the left arm on 26 Feb 2021 (Study Day 199).

Event Details

On 30 Jan 2021 (Study Day 172), 171 days after the first dose in Part A/11 days after the first dose in Part B and 144 days after the second dose in Part A/27 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of small intestinal obstruction. The IP dose was not changed due to the sbo (small bowel obstruction). The event of sbo (small bowel obstruction) was considered to be ongoing. The investigator assessed the event of small intestinal obstruction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010616	Small intestinal obstruction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraines	1990 - Ongoing
Drug hypersensitivity	Allergy to levofloxacin	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium	2010 - Ongoing	General Health
Vitamins nos	2010 - Ongoing	General Health
Paracetamol	13 Aug 2020 (Study Day 2) - 13 Aug 2020 (Study Day 2)	Headache (Reactogenicity)
Paracetamol	09 Sep 2020 (Study Day 29) - 09 Sep 2020 (Study Day 29)	Headache
Ibuprofen	25 Dec 2020 (Study Day 136) - 20 Feb 2021 (Study Day 193)	Fractured Arm
Paracetamol	25 Dec 2020 (Study Day 136) - 20 Feb 2021 (Study Day 193)	Fractured Arm
Left distal radius surgery - putting plate in*	31 Dec 2020 (Study Day 142) - 31 Dec 2020 (Study Day 142)	Adverse Event
Analgesics	31 Jan 2021 (Study Day 173) - 02 Feb 2021 (Study Day 175)	Small Bowel Obstruction
Ct with contrast of abdomen and pelvis*	31 Jan 2021 (Study Day 173) - 31 Jan 2021 (Study Day 173)	Adverse Event
Ondansetron	31 Jan 2021 (Study Day 173) - 02 Feb 2021 (Study Day 175)	Small Bowel Obstruction
X ray chest*	31 Jan 2021 (Study Day 173) - 31 Jan 2021 (Study Day 173)	Adverse Event
X-ray small bowel*	01 Feb 2021 (Study Day 174) - 01 Feb 2021 (Study Day 174)	Adverse Event
Mammogram*	20 Feb 2021 (Study Day 193) - 20 Feb 2021 (Study Day 193)	Other, General Health

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US343-2240 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 22 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 25 Sep 2020 (Study Day 35)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arthritis Bacterial/L Shoulder Septic Arthritis	SAE	Grade 3/ severe	Not related	08 Mar 2021 (Study Day 199) – 19 Apr 2021 (Study Day 241)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2240, a 69-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 22 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 25 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 08 Mar 2021 (Study Day 199), 198 days after the first dose in Part A and 164 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of arthritis bacterial. Action taken with the IP was not applicable. The event of 1 shoulder septic arthritis lasted for 43 days, after which it was considered to be recovered/resolved on 19 Apr 2021 (Study Day 241). The investigator assessed the event of arthritis bacterial to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-047165	Arthritis bacterial

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastroesophageal reflux disease	Gerd	1990 - Ongoing
Dysplastic naevus	Dysplastic nevi	2000 - Ongoing
Blood cholesterol increased	High cholesterol	2005 - Ongoing
Erectile dysfunction	Erectile dysfunction	2005 - Ongoing
Prostate cancer	Prostate cancer	2005 - 2005
Prostatectomy	Prostatectomy	2005 - 2005
Joint dislocation	L shoulder dislocation	Apr 2019 - Apr 2019
Rotator cuff syndrome	L shoulder rotator cuff tear	Apr 2019 - Ongoing
Upper limb fracture	Left shoulder fracture	Apr 2019 - Apr 2019
Basal cell carcinoma	Basal cell cancer skin	Aug 2020 - Ongoing
Cervical spinal stenosis	C-spine stenosis	Aug 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2005 - Ongoing	High Cholesterol
Omeprazole	2010 - Ongoing	Gerd
Vitamin d nos	2015 - Ongoing	General Health
Tadalafil	May 2020 - Ongoing	Erectile Dysfunction
Basal cell carcinoma removal surgery*	28 Aug 2020 (Study Day 7) - 28 Aug 2020 (Study Day 7)	Medical History
Influenza vaccine	01 Sep 2020 (Study Day 11) - 01 Sep 2020 (Study Day 11)	Prophylaxis
Electromyography*	12 Sep 2020 (Study Day 22) - 12 Sep 2020 (Study Day 22)	Diagnostic
Amoxicillin	23 Sep 2020 (Study Day 33) - 29 Sep 2020 (Study Day 39)	Dental Procedure
Dental implants*	23 Sep 2020 (Study Day 33) - 23 Sep 2020 (Study Day 33)	Other, Reconstructive
Ibuprofen	23 Sep 2020 (Study Day 33) - 30 Sep 2020 (Study Day 40)	Dental Procedure
Clindamycin	30 Sep 2020 (Study Day 40) - 06 Oct 2020 (Study Day 46)	Dental Implant
Ceftriaxone	08 Mar 2021 (Study Day 199) - 20 Apr 2021 (Study Day 242)	L Shoulder Septic Arthritis
Removal of hardware in l shoulder*	08 Mar 2021 (Study Day 199) - 08 Mar 2021 (Study Day 199)	Adverse Event
Vancomycin	08 Mar 2021 (Study Day 199) - 19 Mar 2021 (Study Day 210)	L Shoulder Septic Arthritis
Vancomycin	19 Mar 2021 (Study Day 210) - 16 Apr 2021 (Study Day 238)	L Shoulder Septic Arthritis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US343-2380 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 01 Oct 2020 (Study Day 31)
First Dose of Vaccine in Part B: 31 Dec 2020 (Study Day 122)
Second Dose of Vaccine in Part B: 09 Feb 2021 (Study Day 162)
Reason for Narrative: SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	SAE, COVID-19	Grade 3/ severe	Not related	08 Jan 2021 (Study Day 130) – 01 Feb 2021 (Study Day 154)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US343-2380, a 68-year-old not Hispanic or Latino female, received the first dose of Placebo in the right arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 01 Oct 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 31 Dec 2020. The participant was unblinded on 31 Dec 2020 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 31 Dec 2020 (Study Day 122). The second dose was administered in the left arm on 09 Feb 2021 (Study Day 162).

Severe COVID-19 Details

On 08 Jan 2021 (Study Day 130), 129 days after the first dose in Part A/8 days after the first dose in Part B and 99 days after the second dose in Part A/32 days before the second dose in Part B of the IP, the participant experienced a Grade 3/Severe serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 01 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 31 Dec 2020 (Study Day 122), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
08 Jan 2021 (Study Day 130)	Body Aches	Mild
08 Jan 2021 (Study Day 130)	Chills	Mild
08 Jan 2021 (Study Day 130)	Cough	Mild
08 Jan 2021 (Study Day 130)	Fatigue	Moderate
08 Jan 2021 (Study Day 130)	Shortness of Breath	Mild
09 Jan 2021 (Study Day 131)	Chills	Mild
09 Jan 2021 (Study Day 131)	Cough	Mild
09 Jan 2021 (Study Day 131)	Fatigue	Moderate
09 Jan 2021 (Study Day 131)	Muscle Aches (Myalgia)	Mild
09 Jan 2021 (Study Day 131)	O2 Saturation (%)	93
09 Jan 2021 (Study Day 131)	Shortness of Breath	Mild
10 Jan 2021 (Study Day 132)	Chills	Mild
10 Jan 2021 (Study Day 132)	Cough	Mild
10 Jan 2021 (Study Day 132)	Fatigue	Moderate
10 Jan 2021 (Study Day 132)	Muscle Aches (Myalgia)	Mild
10 Jan 2021 (Study Day 132)	Shortness of Breath	Mild
11 Jan 2021 (Study Day 133)	Chills	Mild
11 Jan 2021 (Study Day 133)	Cough	Mild
11 Jan 2021 (Study Day 133)	Diarrhea	Mild
11 Jan 2021 (Study Day 133)	Fatigue	Moderate
11 Jan 2021 (Study Day 133)	Headache	Mild
11 Jan 2021 (Study Day 133)	Muscle Aches (Myalgia)	Mild
11 Jan 2021 (Study Day 133)	Nausea	Moderate
11 Jan 2021 (Study Day 133)	Shortness of Breath	Mild
11 Jan 2021 (Study Day 133)	Vomiting	Mild
12 Jan 2021 (Study Day 134)	Body Aches	Mild
12 Jan 2021 (Study Day 134)	Chills	Mild
12 Jan 2021 (Study Day 134)	Cough	Moderate
12 Jan 2021 (Study Day 134)	Diarrhea	Mild
12 Jan 2021 (Study Day 134)	Fatigue	Moderate
12 Jan 2021 (Study Day 134)	Nausea	Moderate
12 Jan 2021 (Study Day 134)	O2 Saturation (%)	92
12 Jan 2021 (Study Day 134)	Shortness of Breath	Mild
12 Jan 2021 (Study Day 134)	Vomiting	Mild
13 Jan 2021 (Study Day 135)	Body Aches	Moderate
13 Jan 2021 (Study Day 135)	Cough	Moderate
13 Jan 2021 (Study Day 135)	Diarrhea	Moderate
13 Jan 2021 (Study Day 135)	Difficulty Breathing	Moderate
13 Jan 2021 (Study Day 135)	Fatigue	Moderate
13 Jan 2021 (Study Day 135)	Muscle Aches (Myalgia)	Moderate

Symptom Date	Symptom	Result
13 Jan 2021 (Study Day 135)	Nausea	Moderate
13 Jan 2021 (Study Day 135)	New Loss of Smell	Moderate
13 Jan 2021 (Study Day 135)	New Loss of Taste	Moderate
13 Jan 2021 (Study Day 135)	O2 Saturation (%)	90
13 Jan 2021 (Study Day 135)	Shortness of Breath	Moderate
14 Jan 2021 (Study Day 136)	Body Aches	Mild
14 Jan 2021 (Study Day 136)	Cough	Moderate
14 Jan 2021 (Study Day 136)	Diarrhea	Mild
14 Jan 2021 (Study Day 136)	Difficulty Breathing	Mild
14 Jan 2021 (Study Day 136)	Fatigue	Moderate
14 Jan 2021 (Study Day 136)	Muscle Aches (Myalgia)	Mild
14 Jan 2021 (Study Day 136)	Nausea	Mild
14 Jan 2021 (Study Day 136)	New Loss of Smell	Moderate
14 Jan 2021 (Study Day 136)	New Loss of Taste	Moderate
14 Jan 2021 (Study Day 136)	O2 Saturation (%)	92
14 Jan 2021 (Study Day 136)	Shortness of Breath	Moderate
16 Jan 2021 (Study Day 138)	Cough	Mild
18 Jan 2021 (Study Day 140)	Cough	Mild
18 Jan 2021 (Study Day 140)	Fatigue	Moderate
18 Jan 2021 (Study Day 140)	New Loss of Smell	Moderate
18 Jan 2021 (Study Day 140)	New Loss of Taste	Moderate
18 Jan 2021 (Study Day 140)	Shortness of Breath	Mild
19 Jan 2021 (Study Day 141)	Fatigue	Mild
19 Jan 2021 (Study Day 141)	New Loss of Smell	Severe
19 Jan 2021 (Study Day 141)	New Loss of Taste	Severe
20 Jan 2021 (Study Day 142)	Cough	Mild
20 Jan 2021 (Study Day 142)	Fatigue	Mild
20 Jan 2021 (Study Day 142)	New Loss of Smell	Severe
20 Jan 2021 (Study Day 142)	New Loss of Taste	Severe
21 Jan 2021 (Study Day 143)	Fatigue	Mild
21 Jan 2021 (Study Day 143)	New Loss of Smell	Moderate
21 Jan 2021 (Study Day 143)	New Loss of Taste	Moderate
23 Jan 2021 (Study Day 145)	New Loss of Smell	Severe
23 Jan 2021 (Study Day 145)	New Loss of Taste	Severe
25 Jan 2021 (Study Day 147)	New Loss of Smell	Severe
25 Jan 2021 (Study Day 147)	New Loss of Taste	Severe
26 Jan 2021 (Study Day 148)	New Loss of Smell	Severe
26 Jan 2021 (Study Day 148)	New Loss of Taste	Severe
27 Jan 2021 (Study Day 149)	Fatigue	Mild
27 Jan 2021 (Study Day 149)	New Loss of Smell	Mild
27 Jan 2021 (Study Day 149)	New Loss of Taste	Mild
28 Jan 2021 (Study Day 150)	New Loss of Smell	Mild
28 Jan 2021 (Study Day 150)	New Loss of Taste	Mild

Symptom Date	Symptom	Result
29 Jan 2021 (Study Day 151)	New Loss of Smell	Mild
29 Jan 2021 (Study Day 151)	New Loss of Taste	Mild
30 Jan 2021 (Study Day 152)	Fatigue	Mild
30 Jan 2021 (Study Day 152)	New Loss of Smell	Mild
30 Jan 2021 (Study Day 152)	New Loss of Taste	Mild
31 Jan 2021 (Study Day 153)	Fatigue	Mild
01 Feb 2021 (Study Day 154)	Fatigue	Mild
02 Feb 2021 (Study Day 155)	New Loss of Smell	Moderate
02 Feb 2021 (Study Day 155)	New Loss of Taste	Moderate
03 Feb 2021 (Study Day 156)	Fatigue	Mild
03 Feb 2021 (Study Day 156)	New Loss of Smell	Mild
03 Feb 2021 (Study Day 156)	New Loss of Taste	Mild
04 Feb 2021 (Study Day 157)	Fatigue	Mild
04 Feb 2021 (Study Day 157)	Nasal Congestion	Mild
04 Feb 2021 (Study Day 157)	New Loss of Smell	Mild
05 Feb 2021 (Study Day 158)	New Loss of Smell	Mild
05 Feb 2021 (Study Day 158)	New Loss of Taste	Mild
06 Feb 2021 (Study Day 159)	New Loss of Smell	Moderate
06 Feb 2021 (Study Day 159)	New Loss of Taste	Moderate
09 Feb 2021 (Study Day 162)	New Loss of Smell	Mild
09 Feb 2021 (Study Day 162)	New Loss of Taste	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
09 Jan 2021 (Study Day 131)	Oxygen Saturation	90%
09 Jan 2021 - 15 Jan 2021 (Study Day 131-137)	Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 25 days, after which it was considered to be recovered/resolved on 01 Feb 2021 (Study Day 154). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002882	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Breast cancer	L breast cancer	2001 - 2002
Headache	Headaches	2001 - Ongoing
Postmenopause	Post-menopausal	2001 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2015 - Ongoing
Ovarian cancer	L ovarian cancer	Feb 2017 - Feb 2017
Abdominal hernia repair	Ventral hernia repair	Oct 2019 - Oct 2019
Atrial fibrillation	Atrial fibrillation	Oct 2019 - Ongoing
Cholecystitis	Cholecystitis	Jul 2020 - 23 Jul 2020 (Study Day -40)
Cholelithiasis	Stones in gall bladder	Jul 2020 - Jul 2020
Cholecystectomy	Cholecystectomy	23 Jul 2020 (Study Day -40) - 23 Jul 2020 (Study Day -40)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ondansetron	2001 - Ongoing	Headaches
Amlodipine	2006 - Ongoing	Hypertension
Lisinopril	2006 - Ongoing	Hypertension
Metoprolol	2010 - Ongoing	Hypertension
Potassium	2010 - Ongoing	General Health
Atorvastatin	2015 - Ongoing	High Cholesterol
Unspecified herbal and traditional medicine	2016 - Ongoing	General Health
Rivaroxaban	Oct 2019 - Ongoing	Atrial Fibrillation
Botox*	17 Sep 2020 (Study Day 17) - 17 Sep 2020 (Study Day 17)	Other, Cosmetic
Influenza vaccine	26 Oct 2020 (Study Day 56) - 26 Oct 2020 (Study Day 56)	Prophylaxis
Benzonatate	09 Jan 2021 (Study Day 131) - 10 Feb 2021 (Study Day 163)	COVID-19 Infection
Dexamethasone	09 Jan 2021 (Study Day 131) - 09 Jan 2021 (Study Day 131)	COVID 19
Guaifenesin	09 Jan 2021 (Study Day 131) - 10 Feb 2021 (Study Day 163)	COVID-19 Infection
Paracetamol	09 Jan 2021 (Study Day 131) - 12 Jan 2021 (Study Day 134)	COVID-19 Infection
Remdesivir	09 Jan 2021 (Study Day 131) - 11 Jan 2021 (Study Day 133)	COVID-19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Docusate sodium	11 Jan 2021 (Study Day 133) - 12 Jan 2021 (Study Day 134)	COVID-19 Infection Constipation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US343-2497 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 14 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Oct 2020 (Study Day 31)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Breast Cancer/Breast Cancer (L Breast)	SAE	Grade 3/ severe	Not related	12 Apr 2021 (Study Day 211) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2497, a 67-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 14 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 14 Oct 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 25 Jan 2021. The participant was unblinded on 25 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 12 Apr 2021 (Study Day 211), 210 days after the first dose in Part A and 180 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of breast cancer. Action taken with the IP was not applicable. The event of breast cancer (1 breast) was considered to be ongoing. The investigator assessed the event of breast cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-082439	Breast cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Muscle spasms	Chronic leg cramps	1980 - Ongoing
Depression	Depression	1990 - Ongoing
Postmenopause	Post-menopausal	2005 - Ongoing
Skin abrasion	Non-pruritic excoriation (left wrist)	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram oxalate	2010 - Ongoing	Depression
Hydrocortisone	2018 - Ongoing	Non-Pruritic Excoriation (Left Wrist)
Vitamin b12 nos	2019 - Ongoing	General Health
Magnesium	25 Sep 2020 (Study Day 12) - Ongoing	Leg Cramps
Ibuprofen	15 Oct 2020 (Study Day 32) - 15 Oct 2020 (Study Day 32)	Fever
Influenza vaccine	05 Nov 2020 (Study Day 53) - 05 Nov 2020 (Study Day 53)	Influenza Prophylaxis
Mammogram*	18 Mar 2021 (Study Day 186) - 18 Mar 2021 (Study Day 186)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US343-2617 (Part B)
Vaccination Group: Placebo in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 20 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 02 Dec 2020 (Study Day 44)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug Dependence/ Opioid Detox For Drug Addiction	SAE	Grade 3/ severe	Not related	10 Jan 2021 (Study Day 83) – 03 Feb 2021 (Study Day 107)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2617, a 33-year-old Hispanic or Latino male, received the first dose of Placebo in the left arm on 20 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 02 Dec 2020 (Study Day 44). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 31 Dec 2020. The participant was unblinded on 31 Dec 2020 and consented to receive 2 doses of mRNA-1273. The first dose was not administered. The second dose was not administered.

Event Details

On 10 Jan 2021 (Study Day 83), 82 days after the first dose in Part A and 39 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of drug dependence. Action taken with the IP was not applicable. The event of opioid detox for drug addiction lasted for 25 days, after which it was considered to be recovered/resolved on 03 Feb 2021 (Study Day 107). The investigator assessed the event of drug dependence to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-011140	Drug dependence

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	1995 - Ongoing
Drug dependence	Drug addiction	2004 - Jun 2020
Diabetes mellitus	Diabetes	2015 - Ongoing
Musculoskeletal pain	Left shoulder pain	Nov 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin hydrochloride	2016 - Ongoing	Dm2
Buprenorphine; naloxone	Feb 2020 - Ongoing	Drug Addiction
Vitamins, other combinations	Oct 2020 - Ongoing	Prophylaxis
Bupropion	10 Nov 2020 (Study Day 22) - Ongoing	Depression
Gabapentin	10 Nov 2020 (Study Day 22) - Ongoing	Left Shoulder Pain
Salbutamol sulfate	12 Nov 2020 (Study Day 24) - Ongoing	Difficulty Breathing
Ibuprofen	24 Dec 2020 (Study Day 66) - 24 Dec 2020 (Study Day 66)	Gastroenteritis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US344-2087 (Part B)
Vaccination Group: mRNA-1273 in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 25 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: Not Administered
First Dose of Vaccine in Part B: 25 Jan 2021 (Study Day 154)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Thyroid Cancer/Thyroid Cancer	SAE	Grade 3/severe	Not related	22 Apr 2021 (Study Day 241) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US344-2087, a 43-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 25 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Jan 2021. The participant was unblinded on 21 Jan 2021 and consented to receive the second dose of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 25 Jan 2021 (Study Day 154). The second dose was not administered.

Event Details

On 22 Apr 2021 (Study Day 241), 240 days after the first dose in Part A/87 days after the first dose in Part B of the IP (second dose Part A not applicable/second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of thyroid cancer. Action taken with the IP was not applicable. The event of thyroid cancer was considered to be ongoing. The investigator assessed the event of thyroid cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-101966	Thyroid cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraines	1995 - Ongoing
Rhinitis allergic	Allergic rhinitis	1995 - Ongoing
Anaemia	Anemia	2002 - Ongoing
Drug hypersensitivity	Morphine allergy	2002 - Ongoing
Thyroid cyst	Cyst in thyroid benign	2002 - 2002
Thyroidectomy	Thyroid removal	2002 - 2002
Food allergy	Peanut butter allergy	2015 - Ongoing
Food allergy	Tomato allergy	2015 - Ongoing
Insomnia	Insomnia	2015 - Ongoing
Hypertension	Hypertension	2016 - Ongoing
Hyperthyroidism	Hyperthyroidism	2017 - 2017
Anxiety	Anxiety	2018 - Ongoing
Depression	Mild depression	2018 - Ongoing
Drug hypersensitivity	Pen allergy	2018 - Ongoing
Dyspepsia	Heartburn	2018 - Ongoing
Gastroesophageal reflux disease	Gerd	2018 - Ongoing
Hypothyroidism	Hypothyroidism	2018 - Ongoing
Uterine leiomyoma	Uterine fibroids	2018 - 2018
Myomectomy	Myomectomy	Feb 2018 - Feb 2018
Blood potassium decreased	Low potassium	2019 - Ongoing
Polycystic ovaries	Polycystic ovary syndrome	2019 - Ongoing
Drug hypersensitivity	Amlodipine allergy	Mar 2020 - Ongoing
Panic attack	Panic attacks	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Azilsartan kamedoxomil	2019 - Ongoing	Hypertension
Montelukast sodium	2019 - Ongoing	Allergies
Potassium	2019 - Ongoing	Low Potassium
Semaglutide	2019 - Ongoing	Pcos
Vortioxetine hydrobromide	2019 - Ongoing	Anxiety
Chlortalidone	Jan 2020 - Ongoing	Hypertension
Fexofenadine hydrochloride	Feb 2020 - Ongoing	Allergies
Mirtazapine	Aug 2020 - Ongoing	Anxiety And Sleep Aid

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	31 Aug 2020 (Study Day 7) - 23 Oct 2020 (Study Day 60)	Joint Aches
Methocarbamol	28 Sep 2020 (Study Day 35) - 23 Oct 2020 (Study Day 60)	Intermittent Lower Back Pain
Influenza vaccine	12 Oct 2020 (Study Day 49) - 12 Oct 2020 (Study Day 49)	Influenza
Doxycycline	19 Oct 2020 (Study Day 56) - 26 Oct 2020 (Study Day 63)	Sinus Infection
Vortioxetine hydrobromide	20 Nov 2020 (Study Day 88) - Ongoing	Anxiety
Dulaglutide	Dec 2020 - Ongoing	Polycystic Ovary Syndrome (Pcos)
Cefdinir	30 Dec 2020 (Study Day 128) - 08 Jan 2021 (Study Day 137)	Sinus Infection
Bacitracin; neomycin sulfate; polymyxin b sulfate	16 Mar 2021 (Study Day 204) - 18 Apr 2021 (Study Day 237)	Left Arm Infection
Hydrocortisone	16 Mar 2021 (Study Day 204) - 18 Apr 2021 (Study Day 237)	Left Arm Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Skin Infection	Grade 2/moderate	Not related	06 Mar 2021 (Study Day 194) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US346-2097 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 10 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Sep 2020 (Study Day 36)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Prostate Cancer/Prostate Cancer	SAE	Grade 3/ severe	Not related	28 Feb 2021 (Study Day 203) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US346-2097, a 64-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 28 Feb 2021 (Study Day 203), 202 days after the first dose in Part A and 167 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of prostate cancer. Action taken with the IP was not applicable. The event of prostate cancer was considered to be ongoing. The investigator assessed the event of prostate cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-063070	Prostate cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Penicillin allergy	1962 - Ongoing
Rhinitis perennial	Perennial allergic rhinitis	1964 - Ongoing
Seasonal allergy	Seasonal allergic rhinitis	1964 - Ongoing
Asthma	Asthma	1965 - Ongoing
Strabismus	Bilateral strabismus	1965 - Ongoing
Strabismus correction	Right eye strabismus repair	1965 - 1965
Arthralgia	Bilateral knee pain	1987 - Ongoing
Joint arthroplasty	Left knee reconstruction surgery	1987 - 1987
Ligament rupture	Left anterior cruciate ligament tear	1987 - 1987
Meniscus injury	Left medial meniscus tear	1987 - 1987
Headache	Occasional headaches	1989 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2009 - Ongoing
Synovial cyst	Left knee ganglion cyst	2009 - 2009
Hypertension	Hypertension	Feb 2009 - Ongoing
Neck pain	Occasional neck pain	2010 - Ongoing
Prostatic specific antigen increased	Elevated psa	Feb 2010 - Ongoing
Cyst	Right knee benign cyst	2011 - 2011
Cyst removal	Right knee cyst removal	2011 - 2011
Back pain	Occasional back pain	2012 - Ongoing
Drug hypersensitivity	Cortisone injection allergy	Apr 2015 - Ongoing
Knee arthroplasty	Left knee replacement	Jan 2016 - Jan 2016

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	1990 - Ongoing	Occasional Headaches
Paracetamol	1990 - Ongoing	Occasional Headaches
Salbutamol	1990 - Ongoing	Asthma
Budesonide; formoterol fumarate	Feb 2020 - Ongoing	Asthma
Ibuprofen	15 Sep 2020 (Study Day 37) - 15 Sep 2020 (Study Day 37)	Post-Dose Fever
Ibuprofen	17 Sep 2020 (Study Day 39) - 17 Sep 2020 (Study Day 39)	Post-Dose Muscle Aches

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US346-2364 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 27 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 24 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 18 Jan 2021 (Study Day 145)
Second Dose of Vaccine in Part B: 24 Feb 2021 (Study Day 182)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nephrolithiasis/Kidney Stones	SAE	Grade 4	Not related	06 Feb 2021 (Study Day 164) – 08 Feb 2021 (Study Day 166)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US346-2364, a 66-year-old not Hispanic or Latino female, received the first dose of Placebo in the right arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 24 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 18 Jan 2021. The participant was unblinded on 18 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 18 Jan 2021 (Study Day 145). The second dose was administered in the right arm on 24 Feb 2021 (Study Day 182).

Event Details

On 06 Feb 2021 (Study Day 164), 163 days after the first dose in Part A/19 days after the first dose in Part B and 135 days after the second dose in Part A/18 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of nephrolithiasis. The IP dose was not changed due to the kidney stones. The event of kidney stones lasted for 3 days, after which it was considered to be recovered/resolved on 08 Feb 2021 (Study Day 166). The investigator assessed the event of nephrolithiasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-022082	Nephrolithiasis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nephrolithiasis	Occasional kidney stones left kidney	1975 - Ongoing
Ovarian cyst	Ovarian cyst both ovaries	1975 - 2004
Drug hypersensitivity	Allergy to morphine	1978 - Ongoing
Drug hypersensitivity	Allergy to sulfa	1985 - Ongoing
Anxiety	Anxiety	2004 - Ongoing
Hysterectomy	Total hysterectomy	2004 - 2004
Urinary tract infection	Urinary tract infections	2010 - 2011

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sumatriptan	2004 - 2004	Migraines
Ibuprofen	29 Aug 2020 (Study Day 3) - 03 Sep 2020 (Study Day 8)	Injection Side Pain In Right Deltoid
Influenza vaccine	04 Nov 2020 (Study Day 70) - 04 Nov 2020 (Study Day 70)	Influenza Prophylaxis
Lithotripsy procedure*	08 Feb 2021 (Study Day 166) - 08 Feb 2021 (Study Day 166)	Adverse Event
Oxycodone	09 Feb 2021 (Study Day 167) - 10 Feb 2021 (Study Day 168)	Kidney Stones

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US347-2020 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 07 Oct 2020 (Study Day 30)
First Dose of Vaccine in Part B: 04 Feb 2021 (Study Day 150)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Parotitis/Parotitis	AE leading to withdrawal from study vaccine	Grade 3/ severe	Related	15 Feb 2021 (Study Day 161) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US347-2020, a 55-year-old not Hispanic or Latino female, received the first dose of Placebo in the right arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 07 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Feb 2021. The participant was unblinded on 04 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 04 Feb 2021 (Study Day 150). The second dose was not administered.

Event Details

On 15 Feb 2021 (Study Day 161), 160 days after the first dose in Part A/11 days after the first dose in Part B and 131 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 3/severe non-serious adverse event of parotitis. The IP dose was withdrawn due to the parotitis. The event of parotitis was considered to be ongoing. The investigator assessed the event of parotitis to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Carotid artery dissection	Dissected r carotid	Nov 2006 - Oct 2007
Basal cell carcinoma	Basal cell carcinoma (skin)	2010 - Ongoing
Affective disorder	Mood disorder	2017 - Ongoing
Hepatitis C virus test positive	Hep c+	Jan 2017 - Feb 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram oxalate	2017 - Ongoing	Mood Disorder
Magnesium citrate	28 Aug 2020 (Study Day -11) - Ongoing	Nutritional Support
Magnesium glycinate	28 Aug 2020 (Study Day -11) - Ongoing	Nutritional Support
Influenza vaccine	10 Nov 2020 (Study Day 64) - 10 Nov 2020 (Study Day 64)	Influenza Prophylaxis
Paracetamol	03 Dec 2020 (Study Day 87) - 18 Dec 2020 (Study Day 102)	COVID-19
Escitalopram oxalate	02 Jan 2021 (Study Day 117) - Ongoing	Mood Disorder
Cough and cold preparations	19 Jan 2021 (Study Day 134) - 19 Jan 2021 (Study Day 134)	Sore Throat
Cough and cold preparations	04 Feb 2021 (Study Day 150) - 04 Feb 2021 (Study Day 150)	Malaise
Naproxen	04 Feb 2021 (Study Day 150) - 06 Feb 2021 (Study Day 152)	Fever
Paracetamol	04 Feb 2021 (Study Day 150) - 06 Feb 2021 (Study Day 152)	Fever
Paracetamol	25 Feb 2021 (Study Day 171) - 25 Feb 2021 (Study Day 171)	Parotitis
Prednisone	25 Feb 2021 (Study Day 171) - 03 Mar 2021 (Study Day 177)	Parotitis
Meloxicam	16 Mar 2021 (Study Day 190) - Ongoing	Parotitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Parotitis	Grade 3/severe	Related	15 Feb 2021 (Study Day 161) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US348-2005 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 10 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 31)
First Dose of Vaccine in Part B: 04 Feb 2021 (Study Day 179)
Second Dose of Vaccine in Part B: 12 Mar 2021 (Study Day 215)
Reason for Narrative: Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 3/ severe	Not related	26 Dec 2020 (Study Day 139) – 23 Jan 2021 (Study Day 167)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US348-2005, a 57-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 04 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 04 Feb 2021 (Study Day 179). The second dose was administered in the left arm on 12 Mar 2021 (Study Day 215).

Severe COVID-19 Details

On 26 Dec 2020 (Study Day 139), 138 days after the first dose in Part A/40 days before the first dose in Part B and 108 days after the second dose in Part A/76 days before the second dose in Part B of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 31, 09 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 08 Jan 2021 (Study Day 152), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
26 Dec 2020 (Study Day 139)	Headache	Mild
27 Dec 2020 (Study Day 140)	Runny Nose (Rhinorrhea)	Mild
28 Dec 2020 (Study Day 141)	Runny Nose (Rhinorrhea)	Mild
29 Dec 2020 (Study Day 142)	Runny Nose (Rhinorrhea)	Mild
29 Dec 2020 (Study Day 142)	Temperature (°F)	100.4
09 Jan 2021 (Study Day 153)	O2 Saturation (%)	92
15 Jan 2021 (Study Day 159)	O2 Saturation (%)	93
18 Jan 2021 (Study Day 162)	Headache	Mild
20 Jan 2021 (Study Day 164)	Headache	Mild
21 Jan 2021 (Study Day 165)	Headache	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
09 Jan 2021 (Study Day 153)	Oxygen Saturation	92%
09 Jan 2021 - 15 Jan 2021 (Study Day 153-159)	Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 29 days, after which it was considered to be recovered/resolved on 23 Jan 2021 (Study Day 167). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005780	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrointestinal ulcer	Upper gi ulcer	Not reported - Ongoing
Glaucoma	Bilateral glaucoma	Not reported - Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Nasal septum deviation	Deviated sinus septum	Not reported - 1995
Type 2 diabetes mellitus	Diabetes mellitus type 2	Not reported - Ongoing
Sinus operation	Sinus surgery	01 Jan 1995 (Study Day -9353) - 01 Jan 1995 (Study Day -9353)
Gastric bypass	Gastric bypass	01 Jan 2009 (Study Day -4239) - 01 Jan 2009 (Study Day -4239)
Menopause	Menopause	01 Jun 2015 (Study Day -1897) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	Not reported - Ongoing	High Cholesterol
Bimatoprost; brimonidine; timolol	Not reported - Ongoing	Bilateral Glaucoma
Fluticasone	Not reported - Ongoing	Unknown
Glipizide	Not reported - 08 Apr 2021 (Study Day 242)	Diabetes
Losartan	Not reported - Ongoing	High Blood Pressure
Omeprazole	Not reported - Ongoing	Ulcer
Oxymetazoline hydrochloride	Not reported - Ongoing	Unknown
Acetylsalicylic acid	2016 - Ongoing	Unknown
Metformin	2016 - 13 Jan 2021 (Study Day 157)	Diabetes
Hydrochlorothiazide; triamterene	Jan 2020 - Jan 2021	High Blood Pressure
Vitamins nos	May 2020 - Ongoing	Unk
Colecalciferol	Aug 2020 - Ongoing	Nutritional Supplement
Pioglitazone	Aug 2020 - Ongoing	Diabetes
Influenza vaccine	Oct 2020 - Oct 2020	Preventative
Biotin	01 Oct 2020 (Study Day 53) - Ongoing	Nutritional Supplement
Ascorbic acid; herbal nos; levoglutamide; lysine; magnesium; manganese; retinol; riboflavin; selenium; tocopherol; zinc	27 Dec 2020 (Study Day 140) - 27 Dec 2020 (Study Day 140)	Immune Support
Dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	27 Dec 2020 (Study Day 140) - 30 Dec 2020 (Study Day 143)	COVID-19
Homatropine methylbromide; hydrocodone bitartrate	27 Dec 2020 (Study Day 140) - 30 Dec 2020 (Study Day 143)	Runny Nose
Oxymetazoline hydrochloride	27 Dec 2020 (Study Day 140) - 30 Dec 2020 (Study Day 143)	Runny Nose
Amlodipine	Jan 2021 - Ongoing	High Blood Pressure
Semaglutide	13 Jan 2021 (Study Day 157) - Ongoing	Diabetes

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US348-2240 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 29 Sep 2020 (Study Day 26)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pain In Extremity/ Left Arm Pain	SAE	Grade 3/ severe	Not related	07 Jan 2021 (Study Day 126) – 15 Feb 2021 (Study Day 165)	Recovered/resolved
Acute Kidney Injury/Acute Kidney Injury	SAE	Grade 3/ severe	Not related	19 Jan 2021 (Study Day 138) – 23 Jan 2021 (Study Day 142)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US348-2240, a 75-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 07 Jan 2021. The participant was unblinded on 07 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 07 Jan 2021 (Study Day 126), 125 days after the first dose in Part A and 100 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of pain in extremity. Action taken with the IP was not applicable. The event of left arm pain lasted for 40 days, after which it was considered to be recovered/resolved on 15 Feb 2021 (Study Day 165). The investigator assessed the event of pain in extremity to be not related to the IP.

On 19 Jan 2021 (Study Day 138), 137 days after the first dose in Part A and 112 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of acute kidney injury. Action taken with the IP was not applicable. The event of acute kidney injury lasted for 5 days, after which it was considered to be recovered/resolved on 23 Jan 2021 (Study Day 142). The investigator assessed the event of acute kidney injury to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005504	Pain in extremity
MOD-2021-005504	Acute kidney injury

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Sulfa allergy	1948 - Ongoing
Seasonal allergy	Seasonal allergies	1960 - Ongoing
Diabetes mellitus	Diabetes	1989 - Ongoing
Herpes zoster	Shingles	2004 - Ongoing
Osteoarthritis	Osteoarthritis in both hands	2010 - Ongoing
Urinary retention	Urinary retention	2010 - Ongoing
Hypertension	Hypertension	2012 - Ongoing
Erectile dysfunction	Erectile dysfunction	2015 - Ongoing
Gastroesophageal reflux disease	Gerd	2015 - Ongoing
Hypothyroidism	Hypothyroidism	2016 - Ongoing
Hyponatraemia	Chronic hyponatremia	14 Feb 2020 (Study Day -203) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Meloxicam	Not reported - Ongoing	Arthritis Muscle Soreness
Insulin glargine	2000 - Ongoing	Diabetes
Insulin lispro	2000 - Ongoing	Diabetes
Vitamins nos	2000 - Ongoing	Health Promotion
Fexofenadine	2010 - Ongoing	Seasonal Allergies
Glucosamine	2010 - Ongoing	Health Promotion
Meloxicam	2010 - Ongoing	Arthritis
Tamsulosin	2010 - Ongoing	Urinary Retention
Losartan	2015 - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole	2015 - Ongoing	Gerd
Sildenafil	2015 - Ongoing	Erectile Dysfunction
Levothyroxine	2016 - Ongoing	Hypothyroidism
Mupirocin	2017 - Ongoing	Skin Infection
Paracetamol	2019 - Ongoing	Arthritis
Famotidine	Feb 2020 - Ongoing	Gerd
Influenza vaccine	14 Oct 2020 (Study Day 41) - 14 Oct 2020 (Study Day 41)	Vaccination
Paracetamol	07 Jan 2021 (Study Day 126) - 15 Feb 2021 (Study Day 165)	Left Arm And Shoulder Pain
Amlodipine	19 Jan 2021 (Study Day 138) - Ongoing	Hypertension
Sodium chloride	19 Jan 2021 (Study Day 138) - 22 Jan 2021 (Study Day 141)	Acute Kidney Injury
Mri*	22 Jan 2021 (Study Day 141) - 22 Jan 2021 (Study Day 141)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Musculoskeletal Pain	Grade 2/moderate	Not related	11 Jan 2021 (Study Day 130) - 15 Feb 2021 (Study Day 165)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US348-2302 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 19 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Nov 2020 (Study Day 29)
First Dose of Vaccine in Part B: 19 Feb 2021 (Study Day 124)
Second Dose of Vaccine in Part B: 16 Mar 2021 (Study Day 149)
Reason for Narrative: Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 3/ severe	Not related	11 Jan 2021 (Study Day 85) – 27 Jan 2021 (Study Day 101)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US348-2302, a 73-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 19 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 16 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 19 Feb 2021 (Study Day 124). The second dose was administered in the left arm on 16 Mar 2021 (Study Day 149).

Severe COVID-19 Details

On 11 Jan 2021 (Study Day 85), 84 days after the first dose in Part A/39 days before the first dose in Part B and 56 days after the second dose in Part A/64 days before the second dose in Part B of the IP, the participant experienced a Grade 3/Severe serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 16 Nov 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 14 Jan 2021 (Study Day 88), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
11 Jan 2021 (Study Day 85)	Fatigue	Mild
11 Jan 2021 (Study Day 85)	Temperature (°F)	100.4
12 Jan 2021 (Study Day 86)	Fatigue	Mild
12 Jan 2021 (Study Day 86)	Temperature (°F)	100.4
13 Jan 2021 (Study Day 87)	Fatigue	Mild
13 Jan 2021 (Study Day 87)	Temperature (°F)	100.4
14 Jan 2021 (Study Day 88)	Fatigue	Mild
15 Jan 2021 (Study Day 89)	Temperature (°F)	100.4
17 Jan 2021 (Study Day 91)	Chills	Mild
17 Jan 2021 (Study Day 91)	Cough	Mild
17 Jan 2021 (Study Day 91)	Fatigue	Mild
18 Jan 2021 (Study Day 92)	Chills	Mild
18 Jan 2021 (Study Day 92)	Cough	Mild
18 Jan 2021 (Study Day 92)	Fatigue	Mild
19 Jan 2021 (Study Day 93)	Chills	Mild
19 Jan 2021 (Study Day 93)	Cough	Mild
19 Jan 2021 (Study Day 93)	Fatigue	Mild
20 Jan 2021 (Study Day 94)	Chills	Mild
20 Jan 2021 (Study Day 94)	Cough	Mild
20 Jan 2021 (Study Day 94)	Fatigue	Mild
20 Jan 2021 (Study Day 94)	O2 Saturation (%)	91
20 Jan 2021 (Study Day 94)	Temperature (°F)	102.1
21 Jan 2021 (Study Day 95)	Diarrhea	Mild
21 Jan 2021 (Study Day 95)	Fatigue	Mild
21 Jan 2021 (Study Day 95)	O2 Saturation (%)	86
22 Jan 2021 (Study Day 96)	O2 Saturation (%)	93
24 Jan 2021 (Study Day 98)	O2 Saturation (%)	90
25 Jan 2021 (Study Day 99)	O2 Saturation (%)	93
26 Jan 2021 (Study Day 100)	Diarrhea	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
20 Jan 2021 (Study Day 94)	Oxygen Saturation	86%
20 Jan 2021 - 25 Jan 2021 (Study Day 94-99)	Oxygen Saturation of SpO2 <= 93% on room air at sea level	Yes
21 Jan 2021 - 21 Jan 2021 (Study Day 95-95)	Acute Renal Dysfunction	Yes
21 Jan 2021 - 21 Jan 2021 (Study Day 95-95)	Clinical Evidence of Pneumonia	Yes
21 Jan 2021 - 21 Jan 2021 (Study Day 95-95)	Radiographical Evidence of Pneumonia	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 17 days, after which it was considered to be recovered/resolved on 27 Jan 2021 (Study Day 101). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-006694	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1996 - Ongoing
Arthritis	Arthritis in right knee	2012 - Ongoing
Chronic kidney disease	Chronic kidney disease stage 3	2014 - Ongoing
Cataract	Cataract	2017 - Ongoing
Glaucoma	Glaucoma	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2014 - Ongoing	Hypertension
Metoprolol	2014 - Ongoing	Hypertension
Diclofenac	2016 - Ongoing	Arthritis In Knee
Dorzolamide; timolol	2017 - Ongoing	Glaucoma
Latanoprost	2017 - Ongoing	Glaucoma
Azithromycin	21 Jan 2021 (Study Day 95) - 25 Jan 2021 (Study Day 99)	COVID 19
Ceftriaxone	21 Jan 2021 (Study Day 95) - 24 Jan 2021 (Study Day 98)	COVID 19 Related Pneumonia
Dexamethasone	21 Jan 2021 (Study Day 95) - 21 Jan 2021 (Study Day 95)	COVID 19
Paracetamol	21 Jan 2021 (Study Day 95) - 25 Jan 2021 (Study Day 99)	Fever
Supplemental oxygen*	21 Jan 2021 (Study Day 95) - 21 Jan 2021 (Study Day 95)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
X-ray chest*	21 Jan 2021 (Study Day 95) - 21 Jan 2021 (Study Day 95)	Diagnostic
Ascorbic acid	22 Jan 2021 (Study Day 96) - 30 Jan 2021 (Study Day 104)	COVID 19
Convalescent plasma infusion*	22 Jan 2021 (Study Day 96) - 22 Jan 2021 (Study Day 96)	Adverse Event
Dexamethasone	22 Jan 2021 (Study Day 96) - 01 Feb 2021 (Study Day 106)	COVID 19
Enoxaparin	22 Jan 2021 (Study Day 96) - 25 Jan 2021 (Study Day 99)	Vte Prophylaxis
Famotidine	22 Jan 2021 (Study Day 96) - 24 Jan 2021 (Study Day 98)	Peptic Ulcer Disease Prophylaxis
Lung perfusion scan*	22 Jan 2021 (Study Day 96) - 22 Jan 2021 (Study Day 96)	Diagnostic
Remdesivir	22 Jan 2021 (Study Day 96) - 25 Jan 2021 (Study Day 99)	COVID 19
Zinc sulfate	22 Jan 2021 (Study Day 96) - 30 Jan 2021 (Study Day 104)	COVID 19
Enoxaparin	01 Feb 2021 (Study Day 106) - 03 Feb 2021 (Study Day 108)	Vte Prophylaxis
Insulin lispro	01 Feb 2021 (Study Day 106) - 03 Feb 2021 (Study Day 108)	Hyperglycemia From Newly Diagnosed Diabetes Type II
Sodium chloride	02 Feb 2021 (Study Day 107) - 03 Feb 2021 (Study Day 108)	Hyponatremia
Metformin	03 Feb 2021 (Study Day 108) - Ongoing	Hyperglycemia From Newly Diagnosed Diabetes Type II
Omeprazole	04 Feb 2021 (Study Day 109) - Ongoing	Gerd Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US349-2078 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 05 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 02 Oct 2020 (Study Day 28)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pleural Effusion/ Right Lung Pleural Effusion	SAE	Grade 4	Not related	24 Apr 2021 (Study Day 232) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2078, a 93-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 05 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 15 Jan 2021. The participant was unblinded on 15 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 24 Apr 2021 (Study Day 232), 231 days after the first dose in Part A and 204 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of pleural effusion. Action taken with the IP was not applicable. The event of right lung pleural effusion was considered to be ongoing. The investigator assessed the event of pleural effusion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-099377	Pneumothorax

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1932 - 1932
Tonsillitis	Tonsillitis	1932 - 1932
Cardiac arrest	S/p cardiac arrest with resuscitation	1973 - 1973
Prostate cancer	Prostate cancer	1998 - 1998
Prostatectomy	Prostatectomy	1998 - 1998
Coronary artery bypass	Coronary artery bypass graft	2003 - 2003
Coronary artery disease	Coronary artery disease	2003 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2003 - Ongoing
Oedema peripheral	Right lower extremity edema	2003 - Ongoing
Nephrectomy	Left nephrectomy for kidney cancer	2013 - 2013
Atrial fibrillation	Atrial fibrillation	2015 - Ongoing
Cardiac failure congestive	Congestive heart failure	2015 - Ongoing
Cerebrovascular accident	S/p cva	2015 - 2015
Cerebrovascular accident	S/p cva	2017 - 2017
Depression	Depression	2017 - Ongoing
Skin neoplasm excision	S/p resection of basal cell cancer	2018 - 2018
Cerebrovascular accident	S/p cva with residual right lower extremity weakness and ataxia	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2003 - Ongoing	Hyperlipidemia
Metoprolol	2016 - 17 Nov 2020 (Study Day 74)	Atrial Fibrillation
Sertraline	2017 - Ongoing	Depression
Apixaban	2018 - 10 Nov 2020 (Study Day 67)	S/P History Of Multiple Cva's
Furosemide	2018 - Ongoing	Congestive Heart Failure
Acetylsalicylic acid	2019 - 10 Nov 2020 (Study Day 67)	Coronary Artery Disease
3 units of prbc infusion*	10 Nov 2020 (Study Day 67) - 10 Nov 2020 (Study Day 67)	Adverse Event
Colonoscopy*	11 Nov 2020 (Study Day 68) - 11 Nov 2020 (Study Day 68)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ct right lower extremity*	11 Nov 2020 (Study Day 68) - 11 Nov 2020 (Study Day 68)	Adverse Event
Iron	11 Nov 2020 (Study Day 68) - Ongoing	Low Hemoglobin
Arterial angiogram with embolization*	13 Nov 2020 (Study Day 70) - 13 Nov 2020 (Study Day 70)	Adverse Event
Apixaban	16 Nov 2020 (Study Day 73) - Ongoing	Cerebrovascular Disease And Atrial Fibrillation
Metoprolol	18 Nov 2020 (Study Day 75) - 01 Mar 2021 (Study Day 178)	Atrial Fibrillation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US349-2107 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 07 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Coronary Artery Disease/ Worsening Of Existing Coronary Artery Disease	SAE	Grade 4	Not related	08 Jan 2021 (Study Day 122) – 11 Jan 2021 (Study Day 125)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2107, a 75-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 08 Jan 2021. The participant was unblinded on 08 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 08 Jan 2021 (Study Day 122), 121 days after the first dose in Part A and 93 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of coronary artery disease. Action taken with the IP was not applicable. The event of worsening of existing coronary artery disease lasted for 4 days, after which it was considered to be recovered/resolved with sequelae on 11 Jan 2021 (Study Day 125). The investigator assessed the event of coronary artery disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002623	Coronary artery disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Hypertrichosis	Facial hair	Not reported - Ongoing
Hypothyroidism	Hypothyroidism	Not reported - Ongoing
Osteoarthritis	Osteoarthritis of right knee, right hip, lumbar spine	Not reported - Ongoing
Postmenopause	Post-menopausal	Not reported - Ongoing
Retinal detachment	Detached retina	Not reported - Ongoing
Type 1 diabetes mellitus	Type 1 diabetes	1970 - Ongoing
Carotid artery disease	Carotid artery disease	2005 - Ongoing
Anxiety	Anxiety	2010 - Ongoing
Spinal fusion surgery	Lumbar spinal fusion	2015 - 2015
Spinal stenosis	Spinal stenosis	2015 - 2015

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	2000 - Ongoing	Hypothyroidism
Atorvastatin	2005 - Ongoing	Hyperlipidemia/R Carotid Artery Blockage
Alprazolam	2010 - Ongoing	Anxiety
Eflornithine hydrochloride	2010 - Ongoing	Facial Hair
Insulin glargine	2010 - Ongoing	Diabetes
Losartan	2010 - Ongoing	Hypertension
Hydrocodone	30 Jan 2020 (Study Day -223) - Ongoing	S/P Cabg (Due To Worsening Cad)
Influenza vaccine	26 Oct 2020 (Study Day 48) - 26 Oct 2020 (Study Day 48)	Vaccination
Angiogram*	08 Jan 2021 (Study Day 122) - 08 Jan 2021 (Study Day 122)	Medical History
Cabg*	11 Jan 2021 (Study Day 125) - 11 Jan 2021 (Study Day 125)	Adverse Event
Colecalciferol	30 Jan 2021 (Study Day 144) - Ongoing	Supplement
Furosemide	30 Jan 2021 (Study Day 144) - Ongoing	Cad
Metoprolol	30 Jan 2021 (Study Day 144) - Ongoing	Worsening Cad
Vitamins nos	30 Jan 2021 (Study Day 144) - Ongoing	Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	05 Feb 2021 (Study Day 150) - Ongoing	Fever

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pyrexia	Grade 2/moderate	Not related	05 Feb 2021 (Study Day 150) - 06 Feb 2021 (Study Day 151)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US349-2273 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 30 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis/Appendicitis	SAE	Grade 4	Not related	30 Jan 2021 (Study Day 123) – 05 Feb 2021 (Study Day 129)	Recovered/resolved
Streptococcal Infection/ Streptococcal Anginosus Blood Stream Infection	SAE	Grade 4	Not related	30 Jan 2021 (Study Day 123) – 05 Feb 2021 (Study Day 129)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2273, a 65-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 30 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 28 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 19 Jan 2021. The participant was unblinded on 19 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 30 Jan 2021 (Study Day 123), 122 days after the first dose in Part A and 94 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of appendicitis. Action taken with the IP was not applicable. The event of appendicitis lasted for 7 days, after which it was considered to be recovered/resolved on 05 Feb 2021 (Study Day 129). The investigator assessed the event of appendicitis to be not related to the IP.

On 30 Jan 2021 (Study Day 123), 122 days after the first dose in Part A and 94 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of streptococcal infection. Action taken with the IP was not applicable. The event of streptococcal anginosus blood stream infection lasted for 7 days, after which it was considered to be recovered/resolved on 05 Feb 2021 (Study Day 129). The investigator assessed the event of streptococcal infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-011705	Appendicitis
MOD-2021-011705	Streptococcal bacteraemia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Coronary artery disease	Coronary artery disease	Not reported
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Intervertebral disc protrusion	Lumbar spine bulging disc	Not reported - Ongoing
Pituitary tumour benign	Benign pituitary gland tumor	Not reported - 1978
Nephrolithiasis	Kidney stones	1989 - Ongoing
Arthritis	Arthritis of the right knee	2010 - Ongoing
Pollakiuria	Urinary frequency of unknown origin	2014 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2017 - Ongoing
Myocardial infarction	Myocardial infarction	Mar 2019 - Mar 2019
Hypertension	Hypertension	Aug 2020 - Ongoing
Rotator cuff syndrome	Left shoulder rotator tear	12 Aug 2020 (Study Day -49) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2019 - Ongoing	Health Maintenance
Cyclobenzaprine	2020 - Ongoing	Pain From Left Shoulder Rotator Tear
Diclofenac	2020 - Ongoing	Pain From Arthritis To Right Knee
Lisinopril	2020 - Ongoing	Hypertension
Pneumococcal vaccine polysacch 23v	01 Sep 2020 (Study Day -29) - 01 Sep 2020 (Study Day -29)	Preventative Care
Varicella zoster vaccine rge (cho)	01 Sep 2020 (Study Day -29) - 01 Sep 2020 (Study Day -29)	Preventative Care
Amoxicillin	09 Oct 2020 (Study Day 10) - 09 Oct 2020 (Study Day 10)	Prior To Dental Work

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tamsulosin	14 Nov 2020 (Study Day 46) - Ongoing	Benign Prostatic Hyperplasia
Influenza vaccine	23 Nov 2020 (Study Day 55) - 23 Nov 2020 (Study Day 55)	Prevent Influenza
Varicella zoster vaccine	23 Nov 2020 (Study Day 55) - 23 Nov 2020 (Study Day 55)	Prevent Shingles
Tamsulosin hydrochloride	25 Nov 2020 (Study Day 57) - Ongoing	Urinary Frequecnny Of Unknown Origin
Acs rule out with troponin negative x3*	30 Dec 2020 (Study Day 92) - 30 Dec 2020 (Study Day 92)	Adverse Event
Chest x-ray 1 view*	30 Dec 2020 (Study Day 92) - 30 Dec 2020 (Study Day 92)	Adverse Event
Ekg*	30 Dec 2020 (Study Day 92) - 30 Dec 2020 (Study Day 92)	Adverse Event
Exercise stress echo*	30 Dec 2020 (Study Day 92) - 30 Dec 2020 (Study Day 92)	Adverse Event
Metoprolol succinate	31 Dec 2020 (Study Day 93) - Ongoing	Premature Ventricular Contractions - In Relation To Chest Pressure Ae
Angiogram with stent placement*	18 Jan 2021 (Study Day 111) - 18 Jan 2021 (Study Day 111)	Medical History
Clopidogrel bisulfate	18 Jan 2021 (Study Day 111) - Ongoing	Post-Procedure Stent
Rosuvastatin calcium	18 Jan 2021 (Study Day 111) - Ongoing	Hyperlipidemia
Blood cultures*	30 Jan 2021 (Study Day 123) - 30 Jan 2021 (Study Day 123)	Adverse Event
Appendectomy*	01 Feb 2021 (Study Day 125) - 01 Feb 2021 (Study Day 125)	Adverse Event
Piperacillin; tazobactam	01 Feb 2021 (Study Day 125) - 05 Feb 2021 (Study Day 129)	Streptococcal Anginosus Blood Stream Infection
Amoxicillin; clavulanic acid	05 Feb 2021 (Study Day 129) - 13 Feb 2021 (Study Day 137)	Post-Appendectomy Antibiotic Coverage
Docusate sodium	05 Feb 2021 (Study Day 129) - Ongoing	Stool Softener
Paracetamol	05 Feb 2021 (Study Day 129) - Ongoing	Post-Operative Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US350-2125 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 07 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Transient Global Amnesia/Transient Global Amnesia	SAE	Grade 3/ severe	Not related	09 Apr 2021 (Study Day 213) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US350-2125, a 49-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 09 Apr 2021 (Study Day 213), 212 days after the first dose in Part A and 184 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of transient global amnesia. Action taken with the IP was not applicable. The event of transient global amnesia was considered to be ongoing. The investigator assessed the event of transient global amnesia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-084197	Transient global amnesia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Pain	General aches	2000 - Ongoing
Transient global amnesia	Transient global amnesia	2015 - 2015

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2000 - Ongoing	General Aches
Paracetamol	2000 - Ongoing	General Aches
Vitamins nos	2001 - Ongoing	General Wellness
Levonorgestrel	2016 - Ongoing	Pregnancy Prevention
Ibuprofen	08 Oct 2020 (Study Day 30) - 08 Oct 2020 (Study Day 30)	Headache, Myalgia Per Diary
Naproxen	08 Oct 2020 (Study Day 30) - 08 Oct 2020 (Study Day 30)	Headache, Myalgia Per Diary
Paracetamol	08 Oct 2020 (Study Day 30) - 08 Oct 2020 (Study Day 30)	Headache, Myalgia Per Diary
Influenza vaccine	29 Oct 2020 (Study Day 51) - 29 Oct 2020 (Study Day 51)	Flu Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US351-2082 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 14 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 22 Jan 2021 (Study Day 162)
Second Dose of Vaccine in Part B: 03 Mar 2021 (Study Day 202)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Urinary Retention/Acute Urinary Retention	SAE	Grade 4	Not related	26 Jan 2021 (Study Day 166) – 07 Mar 2021 (Study Day 206)	Recovered/ resolved with sequelae
Haematuria/Hematuria	SAE	Grade 2/ moderate	Not related	27 Jan 2021 (Study Day 167) – 08 Mar 2021 (Study Day 207)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US351-2082, a 68-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 22 Jan 2021. The participant was unblinded on 22 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 22 Jan 2021 (Study Day 162). The second dose was administered in the left arm on 03 Mar 2021 (Study Day 202).

Event Details

On 26 Jan 2021 (Study Day 166), 165 days after the first dose in Part A/4 days after the first dose in Part B and 137 days after the second dose in Part A/36 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of urinary retention. The IP dose was not changed due to the acute urinary retention. The event of acute urinary retention lasted for 41 days, after which it was considered to be recovered/resolved with sequelae on 07 Mar 2021 (Study Day 206). The investigator assessed the event of urinary retention to be not related to the IP.

On 27 Jan 2021 (Study Day 167), 166 days after the first dose in Part A/5 days after the first dose in Part B and 138 days after the second dose in Part A/35 days before the second dose in Part B of

the IP, the participant experienced a Grade 2/moderate serious adverse event of haematuria. The IP dose was not changed due to the hematuria. The event of hematuria lasted for 41 days, after which it was considered to be recovered/resolved on 08 Mar 2021 (Study Day 207). The investigator assessed the event of haematuria to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012980	Urinary retention
MOD-2021-012980	Haematuria

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Finger repair operation	Surgical repair of left middle finger	1966 - 1966
Hand fracture	Fractured left middle finger	1966 - 1966
Concussion	Concussion	1972 - 1972
Deafness bilateral	Hearing loss bilateral	1980 - Ongoing
Facial bones fracture	Nasal fracture	1980 - 1980
Hypercholesterolaemia	Hypercholesterolemia	1991 - Ongoing
Presbyopia	Presbyopia	1993 - Ongoing
Onychomycosis	Onychomycosis	2000 - Ongoing
Rash	Intermittent rash in ear canals	2000 - Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Sinusitis	Recurrent subacute sinusitis	2000 - Ongoing
Upper-airway cough syndrome	Post nasal drip	2000 - Ongoing
Rosacea	Roasacea	2006 - Ongoing
Constipation	Constipation	2007 - Ongoing
Erectile dysfunction	Erectile dysfunction	2007 - Ongoing
Prostate cancer	Prostate cancer	2007 - 2007
Prostatectomy	Prostatectomy	2007 - 2007
Radiation proctitis	Radiation proctitis with intermittent bleeding	2007 - 2007
Hypertension	Hypertension	2008 - Ongoing
Coronary arterial stent insertion	Cardiac stents inserted x3	Jul 2008 - Jul 2008
Coronary artery disease	Coronary artery disease	Jul 2008 - Ongoing
Myocardial infarction	Myocardial infarction	Jul 2008 - Jul 2008
Basal cell carcinoma	Basal cell carcinoma on back	Jun 2009 - Jun 2009

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Back pain	2010 - Ongoing
Muscle spasms	Back muscle spasms	2010 - Ongoing
Colon adenoma	Tubular adenoma of the transverse colon	Feb 2011 - Feb 2011
Neuropathy peripheral	Transient left peroneal nerve neuropathy	Aug 2013 - Aug 2013
Vitamin B12 deficiency	Vitamin b12 deficiency	2014 - Ongoing
Coronary arterial stent insertion	Cardiac stents inserted x3	2015 - 2015
Myocardial infarction	Myocardial infarction	2015 - 2015
Sleep apnoea syndrome	Sleep apnea	2019 - Ongoing
Catheterisation cardiac	Heart catheterization	Dec 2019 - Dec 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrocortisone	2000 - Ongoing	Rash In Ear Canals
Metronidazole	2006 - Ongoing	Rosacea
Docusate calcium	2007 - Ongoing	Constipation
Acetylsalicylic acid	2008 - 03 Feb 2021 (Study Day 174)	Cardioprotective
Atorvastatin	2008 - Ongoing	Hypercholesterolemia
Lisinopril	2008 - 27 Nov 2020 (Study Day 106)	Hypertension
Pantoprazole	2008 - Ongoing	Preventative Due To Aspirin Use
Fexofenadine	2010 - Ongoing	Seasonal Allergies
Paracetamol	2010 - Ongoing	Back Pain
Prasugrel hydrochloride	2015 - 03 Feb 2021 (Study Day 174)	Coronary Artery Disease
Diclofenac	2017 - Ongoing	Back Pain
Vitamin b12 nos	2018 - Ongoing	Vitamin B12 Deficiency
Azelastine hydrochloride	2019 - Ongoing	Seasonal Allergies
Fluocinolone acetonide	2019 - Ongoing	Rash In Ear Canals
Fluticasone	2019 - Ongoing	Seasonal Allergies
Tadalafil	2019 - Ongoing	Erectile Dysfunction
Methylprednisolone	19 Oct 2020 (Study Day 67) - 19 Oct 2020 (Study Day 67)	Exercise Worsened Back Muscle Spasms
Methocarbamol	20 Oct 2020 (Study Day 68) - Ongoing	Back Muscle Spasms
Erythromycin	30 Oct 2020 (Study Day 78) - 11 Nov 2020 (Study Day 90)	Right Hordeolum
Amoxicillin; clavulanic acid	04 Nov 2020 (Study Day 83) - 11 Nov 2020 (Study Day 90)	Bilateral Hordeolum
Carmellose sodium	04 Nov 2020 (Study Day 83) - 11 Nov 2020 (Study Day 90)	Bilateral Hordeolum
Erythromycin	04 Nov 2020 (Study Day 83) - 11 Nov 2020 (Study Day 90)	Left Hordeolum
Lisinopril	28 Nov 2020 (Study Day 107) - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Varicella zoster vaccine	10 Dec 2020 (Study Day 119) - 10 Dec 2020 (Study Day 119)	Shingles Prophylaxis
Indwelling catheterization*	26 Jan 2021 (Study Day 166) - 26 Jan 2021 (Study Day 166)	Adverse Event
Sulfamethoxazole; trimethoprim	26 Jan 2021 (Study Day 166) - 02 Feb 2021 (Study Day 173)	Acute Urinary Retention
Continuous bladder lavage*	02 Feb 2021 (Study Day 173) - 02 Feb 2021 (Study Day 173)	Adverse Event
Phenazopyridine hydrochloride	02 Feb 2021 (Study Day 173) - Ongoing	Acute Urinary Retention
Acetylsalicylic acid	04 Feb 2021 (Study Day 175) - Ongoing	Cardioprotective
Indwelling catheterization*	04 Feb 2021 (Study Day 175) - 04 Feb 2021 (Study Day 175)	Adverse Event
Nitrofurantoin	18 Feb 2021 (Study Day 189) - 24 Feb 2021 (Study Day 195)	Escherichia Coli Infection
Paracetamol	03 Mar 2021 (Study Day 202) - 03 Mar 2021 (Study Day 202)	Injection Reaction Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nephrolithiasis	Grade 1/mild	Not related	16 Feb 2021 (Study Day 187) - Ongoing
Escherichia Infection	Grade 2/moderate	Not related	18 Feb 2021 (Study Day 189) - Ongoing
Urinary Retention	Grade 2/moderate	Not applicable	08 Mar 2021 (Study Day 207) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US351-2248 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 20 Jan 2021 (Study Day 133)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arthritis Bacterial/Left Elbow Septic Arthritis	SAE, AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	24 Feb 2021 (Study Day 168) – 12 Apr 2021 (Study Day 215)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US351-2248, a 76-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 20 Jan 2021. The participant was unblinded on 20 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 20 Jan 2021 (Study Day 133). The second dose was not administered.

Event Details

On 24 Feb 2021 (Study Day 168), 167 days after the first dose in Part A/35 days after the first dose in Part B and 139 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of arthritis bacterial. The IP dose was withdrawn due to the left elbow septic arthritis. The event of left elbow septic arthritis lasted for 48 days, after which it was considered to be recovered/resolved with sequelae on 12 Apr 2021 (Study Day 215). The investigator assessed the event of arthritis bacterial to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-041522	Arthritis bacterial

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Amblyopia	Amblyopia	(b) (6) 1943 (Study Day (b) (6) - Ongoing
Headache	Headaches	1945 - 1960
Migraine	Migraines	1945 - 1960
Seasonal allergy	Seasonal allergies	1950 - Ongoing
Tobacco user	Smoker	1963 - 1993
Vasectomy	Vasectomy	1972 - 1972
Hyperkeratosis	Keratosis on bilateral arms, legs, head and scalp	1990 - Ongoing
Cataract	Cataracts	1993 - Ongoing
Presbyopia	Presbyopia	1993 - Ongoing
Fracture treatment	Repair of broken right arm	1996 - 1996
Fracture treatment	Repair of broken right leg	1996 - 1996
Lower limb fracture	Broken right leg	1996 - 1996
Upper limb fracture	Broken right arm	1996 - 1996
Overweight	Overweight	1998 - Ongoing
Back pain	Back pain	2000 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2003 - Ongoing
Catheterisation cardiac	Heart cauterization	2006 - 2006
Hypercholesterolaemia	Hypercholesterolemia	2006 - Ongoing
Osteoarthritis	Osteoarthritis of ankle	2006 - Ongoing
Osteoarthritis	Osteoarthritis of right fingers	2006 - Ongoing
Pain	General aches and pains	2006 - Ongoing
Coronary artery disease	Coronary artery disease	2008 - Ongoing
Erectile dysfunction	Erectile dysfunction	2008 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2008 - Ongoing
Libido decreased	Low libido	2008 - Ongoing
Prostatomegaly	Enlarged prostate	2008 - Ongoing
Glucose tolerance impaired	Pre-diabetes	2012 - Ongoing
Anaemia	Anemia	2016 - Ongoing
Large intestine polyp	Benign colon polyps	2016 - 2016

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Diabetic neuropathy	Diabetic neuropathy bilateral hands	2017 - Ongoing
Inguinal hernia repair	Left inguinal hernia repair	2017 - 2017
Atrial fibrillation	Atrial fibrillation	Apr 2018 - Ongoing
Inguinal hernia	Left inguinal hernia	Aug 2018 - Sep 2018
Inguinal hernia repair	Left inguinal hernia repair	Sep 2018 - Sep 2018
Meniscus injury	Left meniscus tear	2019 - Ongoing
Cardiac ablation	Cardiac ablation	Apr 2019 - Apr 2019
Joint effusion	Right lateral meniscus effusion	08 Aug 2020 (Study Day -33) - 08 Aug 2020 (Study Day -33)
Patella fracture	Right patella fracture	08 Aug 2020 (Study Day -33) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2006 - Ongoing	General Aches And Pains
Atorvastatin	Jan 2006 - Ongoing	Hypercholesterolemia
Omeprazole	Jan 2008 - Ongoing	Gastroesophageal Reflux Disease
Acetylsalicylic acid	Jan 2009 - Ongoing	Coronary Artery Disease
Tamsulosin hydrochloride	Jan 2014 - Ongoing	Benign Prostatic Hyperplasia
Vitamin b12 nos	Jan 2017 - Ongoing	Supplement
Apixaban	Apr 2018 - Ongoing	Atrial Fibrillation
Other ophthalmologicals	Apr 2018 - Ongoing	Supplement
Salbutamol	May 2018 - Ongoing	Chronic Obstructive Pulmonary Disease
Ibuprofen	16 Jul 2019 (Study Day -422) - Ongoing	Left Meniscus Tear
Budesonide; formoterol fumarate	Aug 2020 - Ongoing	Chronic Obstructive Pulmonary Disease
Losartan	17 Sep 2020 (Study Day 8) - Ongoing	Hypertension
Lidocaine	05 Oct 2020 (Study Day 26) - 05 Oct 2020 (Study Day 26)	Right Hip Trochanteric Bursitis
Triamcinolone acetonide	05 Oct 2020 (Study Day 26) - 05 Oct 2020 (Study Day 26)	Right Hip Trochanteric Bursitis
Dextromethorphan hydrobromide; guaifenesin	01 Feb 2021 (Study Day 145) - 14 Feb 2021 (Study Day 158)	COVID Like-Illness
Cryotherapy*	03 Feb 2021 (Study Day 147) - 03 Feb 2021 (Study Day 147)	Adverse Event
Cefalexin	24 Feb 2021 (Study Day 168) - 03 Mar 2021 (Study Day 175)	Left Elbow Septic Arthritis
Vancomycin	25 Feb 2021 (Study Day 169) - 25 Feb 2021 (Study Day 169)	Left Elbow Septic Arthritis
Linezolid	26 Feb 2021 (Study Day 170) - 05 Mar 2021 (Study Day 177)	Left Elbow Septic Arthritis
Pyridoxine hydrochloride	03 Mar 2021 (Study Day 175) - Ongoing	Dietary Supplement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Suspected COVID-19	Grade 1/mild	Not related	23 Jan 2021 (Study Day 136) - 14 Feb 2021 (Study Day 158)
Actinic Keratosis	Grade 2/moderate	Not related	03 Feb 2021 (Study Day 147) - 03 Feb 2021 (Study Day 147)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US352-2082 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 11 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Respiratory Tract Congestion/Chest Congestion	SAE	Grade 2/ moderate	Not related	01 Mar 2021 (Study Day 203) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2082, a 62-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 28 Jan 2021. The participant was unblinded on 28 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 01 Mar 2021 (Study Day 203), 202 days after the first dose in Part A and 174 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of respiratory tract congestion. Action taken with the IP was not applicable. The event of chest congestion was considered to be ongoing. The investigator assessed the event of respiratory tract congestion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-033754	Respiratory tract congestion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Coronary artery disease	Coronary artery disease	Not reported - Ongoing
Essential hypertension	Primary hypertension	Not reported - Ongoing
Gastroesophageal reflux disease	Gerd	Not reported - Ongoing
Implantable defibrillator insertion	Icd implant	Not reported - Ongoing
Iron deficiency anaemia	Iron deficiency anemia	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Not reported - Ongoing	Cad
Atorvastatin	Not reported - Ongoing	Cad
Carvedilol	Not reported - Ongoing	Cad
Ferrous sulfate	Not reported - Ongoing	Iron Deficiency Anemia
Furosemide	Not reported - Ongoing	Cad
Lisinopril	Not reported - 01 Mar 2021 (Study Day 203)	Hypertension
Pantoprazole	Not reported - Ongoing	Gerd
Rivaroxaban	Not reported - Dec 2020	Cad
Vitamins nos	Not reported - Ongoing	Dietary Supplement
Apixaban	Dec 2020 - Ongoing	Cad
Nuclear stress test*	10 Feb 2021 (Study Day 184) - 10 Feb 2021 (Study Day 184)	Adverse Event
Chest x-ray*	01 Mar 2021 (Study Day 203) - 01 Mar 2021 (Study Day 203)	Adverse Event
Empagliflozin	01 Mar 2021 (Study Day 203) - Ongoing	Cad
Sacubitril; valsartan	05 Mar 2021 (Study Day 207) - Ongoing	Cad
Bloodwork- lactate and aspartate aminotransferase*	10 Mar 2021 (Study Day 212) - 10 Mar 2021 (Study Day 212)	Medical History
Bloodwork- ptt, protime, pt, nt pro bnp, magnesium, cbc w/ diff, bmp, whole blood glucose*	11 Mar 2021 (Study Day 213) - 11 Mar 2021 (Study Day 213)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Angina Pectoris	Grade 2/moderate	Not related	03 Feb 2021 (Study Day 177) - 04 Feb 2021 (Study Day 178)
Heart Rate Irregular	Grade 2/moderate	Not related	03 Feb 2021 (Study Day 177) - 04 Feb 2021 (Study Day 178)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US352-2112 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 13 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dyspnoea Exertional/ Exertional Dyspnea	SAE	Grade 2/ moderate	Not related	13 Apr 2021 (Study Day 244) – 19 Apr 2021 (Study Day 250)	Recovered/ resolved with sequelae
Cardiac Failure Congestive/New Diagnosis Of Congestive Heart Failure	SAE	Grade 2/ moderate	Not related	15 Apr 2021 (Study Day 246) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2112, a 71-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 13 Jan 2021. The participant was unblinded on 13 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 13 Apr 2021 (Study Day 244), 243 days after the first dose in Part A and 215 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of dyspnoea exertional. Action taken with the IP was not applicable. The event of exertional dyspnea lasted for 7 days, after which it was considered to be recovered/resolved with sequelae on 19 Apr 2021 (Study Day 250). The investigator assessed the event of dyspnoea exertional to be not related to the IP.

On 15 Apr 2021 (Study Day 246), 245 days after the first dose in Part A and 217 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of cardiac failure congestive. Action taken with the IP was not applicable. The event of new

diagnosis of congestive heart failure was considered to be ongoing. The investigator assessed the event of cardiac failure congestive to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-081037	Dyspnoea exertional
MOD-2021-081037	Cardiac failure congestive

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	Not reported - Ongoing
Cataract	Cataracts	Not reported - 05 Jul 2017 (Study Day - 1135)
Hypercholesterolaemia	Hypercholestermia	Not reported - Ongoing
Hypothyroidism	Hypothyroidism	Not reported - Ongoing
Osteoarthritis	Osteoarthritis of back, hips, wrist, and shoulders	Not reported - Ongoing
Postmenopause	Post menopause	Not reported - Ongoing
Pulmonary embolism	S/p pulmonary emboli	Not reported - Ongoing
Spinal stenosis	Spinal stenosis	Not reported - Ongoing
Type 2 diabetes mellitus	Niddm ii	Not reported - Ongoing
Vena cava filter insertion	Ivc filter	Not reported

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Not reported - Ongoing	S/P Pulmonary Emboli
Budesonide; formoterol fumarate	Not reported - 15 Dec 2020 (Study Day 125)	Asthma
Diclofenac	Not reported - Ongoing	Osteoarthritis
Epinephrine	Not reported - Ongoing	Asthma
Levothyroxine sodium	Not reported - Ongoing	Hypothyroidism
Metformin hydrochloride; sitagliptin	Not reported - Ongoing	Niddm Ii
Rosuvastatin calcium	Not reported - Ongoing	Hypercholestermia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sertraline	Not reported - Ongoing	Depression
Fluticasone; vilanterol	16 Dec 2020 (Study Day 126) - Ongoing	Asthma
Steroid injection bilateral shoulders*	07 Jan 2021 (Study Day 148) - 07 Jan 2021 (Study Day 148)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US352-2128 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 14 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 03 Feb 2021 (Study Day 174)
Second Dose of Vaccine in Part B: 03 Mar 2021 (Study Day 202)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Fibrillation/Recurrent Paroxysmal Atrial Fibrillation Status Post Multiple Failed Ablations And Medical/Direct Cardioversions	SAE	Grade 3/ severe	Not related	01 Apr 2021 (Study Day 231) – Ongoing	Unknown

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2128, a 70-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 05 Jan 2021. The participant was unblinded on 05 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 03 Feb 2021 (Study Day 174). The second dose was administered in the right arm on 03 Mar 2021 (Study Day 202).

Event Details

On 01 Apr 2021 (Study Day 231), 230 days after the first dose in Part A/57 days after the first dose in Part B and 202 days after the second dose in Part A/29 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of atrial fibrillation. Action taken with the IP was not applicable. The outcome of the event was unknown. The investigator assessed the event of atrial fibrillation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-065802	Atrial fibrillation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Atrial fibrillation	Afib	Not reported - Ongoing
Cardiac failure congestive	Chf	Not reported - Ongoing
Cardiomyopathy	Cardiomyopathy	Not reported - Ongoing
Cerebrovascular accident	Past of stroke	Not reported
Chronic kidney disease	Ckd stage 3	Not reported - Ongoing
Coronary artery disease	Cad	Not reported - Ongoing
Diabetic autonomic neuropathy	Diabetic autonomic neuropathy associated with type 2 diabetes mellitus- generalized peripheral pain and numbness	Not reported - Ongoing
Gout	Gout (flairs in left knee and right elbow)	Not reported - Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Hyperparathyroidism	Hyperparathyroidism	Not reported - Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	Not reported - Ongoing	Hyperlipidemia
Diltiazem	Not reported - Ongoing	Afib
Furosemide	Not reported - 26 Sep 2020 (Study Day 44)	Chf
Gabapentin	Not reported - 14 Oct 2020 (Study Day 62)	Neuropathy
Metformin	Not reported - Ongoing	Type Two Diabetes
Metoprolol	Not reported - 26 Sep 2017 (Study Day -1053)	Hypertension / Afib
Warfarin	Not reported - 11 Oct 2020 (Study Day 59)	Afib
Potassium chloride	24 Apr 2020 (Study Day -112) - 07 Apr 2021 (Study Day 237)	Chronic Systolic Heart Failure
Cardioversion*	29 Aug 2020 (Study Day 16) - 29 Aug 2020 (Study Day 16)	Medical History
Digoxin	25 Sep 2020 (Study Day 43) - 25 Sep 2020 (Study Day 43)	Atrial Flutter With Rvr
Metoprolol	26 Sep 2020 (Study Day 44) - Ongoing	Hypertension/Afib
Furosemide	27 Sep 2020 (Study Day 45) - 07 Apr 2021 (Study Day 237)	Chf

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Digoxin	28 Sep 2020 (Study Day 46) - 12 Oct 2020 (Study Day 60)	Atrial Fibrillation
Cardiac profile (blood draw)*	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Adverse Event
Ct chest*	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Adverse Event
Electrophysiology study*	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Adverse Event
Emergency department ultrasound cardiac*	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Adverse Event
Piperacillin sodium; tazobactam sodium	08 Oct 2020 (Study Day 56) - 11 Oct 2020 (Study Day 59)	Multifocal Pneumonia In Both Lungs
Protine with inr (blood draw)*	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Adverse Event
Vancomycin	08 Oct 2020 (Study Day 56) - 09 Oct 2020 (Study Day 57)	Multifocal Pneumonia In Both Lungs
Xray chest portable 1 view*	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Adverse Event
Blood culture*	09 Oct 2020 (Study Day 57) - 09 Oct 2020 (Study Day 57)	Adverse Event
Heated high flow nasal cannula*	09 Oct 2020 (Study Day 57) - 09 Oct 2020 (Study Day 57)	Adverse Event
Sputum culture*	09 Oct 2020 (Study Day 57) - 09 Oct 2020 (Study Day 57)	Adverse Event
Vancomycin	09 Oct 2020 (Study Day 57) - 11 Oct 2020 (Study Day 59)	Multifocal Pneumonia In Both Lungs
Anakinra	10 Oct 2020 (Study Day 58) - 12 Oct 2020 (Study Day 60)	Gout Flair
Levofloxacin	11 Oct 2020 (Study Day 59) - 14 Oct 2020 (Study Day 62)	Multifocal Pneumonia In Both Lungs
Metronidazole	11 Oct 2020 (Study Day 59) - 14 Oct 2020 (Study Day 62)	Multifocal Pneumonia In Both Lungs
Ekg 12 lead*	12 Oct 2020 (Study Day 60) - 12 Oct 2020 (Study Day 60)	Adverse Event
Elective ablation in heart for afib*	12 Oct 2020 (Study Day 60) - 12 Oct 2020 (Study Day 60)	Medical History
Prednisone	12 Oct 2020 (Study Day 60) - Ongoing	Gout / Gout Flair
Apixaban	13 Oct 2020 (Study Day 61) - 16 Oct 2020 (Study Day 64)	Atrial Fibrillation
Apixaban	18 Oct 2020 (Study Day 66) - Ongoing	A-Fib

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US352-2173 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 18 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 15 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Borderline Mucinous Tumour Of Ovary/Stage 1a Mucinous Borderline Tumor Of The Ovary With Intraepithelial Carcinoma	SAE	Grade 4	Not related	19 Feb 2021 (Study Day 186) – 16 Mar 2021 (Study Day 211)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2173, a 42-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 18 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 15 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 31 Dec 2020. The participant was unblinded on 31 Dec 2020 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 19 Feb 2021 (Study Day 186), 185 days after the first dose in Part A and 157 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of borderline mucinous tumour of ovary. Action taken with the IP was not applicable. The event of stage 1a mucinous borderline tumor of the ovary with intraepithelial carcinoma lasted for 26 days, after which it was considered to be recovered/resolved on 16 Mar 2021 (Study Day 211). The investigator assessed the event of borderline mucinous tumour of ovary to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-017315	Borderline mucinous tumour of ovary

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Mild asthma	Not reported - Ongoing
Gastroesophageal reflux disease	Acid reflux	Not reported - Ongoing
Glucose tolerance impaired	Pre-diabetic	Not reported - Ongoing
Obesity	Obesity bmi > 40	Not reported - Ongoing
Polycystic ovaries	Pcos	Not reported - Ongoing
Salpingo-oophorectomy	Salpingoophorectomy	Not reported

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	Not reported - Ongoing	Pre-Diabetic
Omeprazole	Not reported - 26 Jan 2021 (Study Day 162)	Acid Reflux
Salbutamol	Not reported - Ongoing	Mild Asthma
Influenza vaccine	09 Nov 2020 (Study Day 84) - 09 Nov 2020 (Study Day 84)	Prevention Of Influenza
Omeprazole	10 Nov 2020 (Study Day 85) - 20 Nov 2020 (Study Day 95)	Lower Right Stomach Pain
Omeprazole	26 Jan 2021 (Study Day 162) - Ongoing	Acid Reflux
Ct scan, abdomen/pelvis*	21 Feb 2021 (Study Day 188) - 21 Feb 2021 (Study Day 188)	Adverse Event
Hydrocodone bitartrate; paracetamol	21 Feb 2021 (Study Day 188) - Ongoing	Pelvic Pain Related To Pelvic Mass Believed To Be A Cystic Ovarian Neoplasm
Ibuprofen	21 Feb 2021 (Study Day 188) - Ongoing	Pain Related To Pelvic Mass
Iopamidol	21 Feb 2021 (Study Day 188) - 21 Feb 2021 (Study Day 188)	Ct Scan Related To Pain From Pelvic Mass
Ketorolac	21 Feb 2021 (Study Day 188) - 21 Feb 2021 (Study Day 188)	Pelvic Pain Related To Pelvic Mass
Lab work*	21 Feb 2021 (Study Day 188) - 21 Feb 2021 (Study Day 188)	Adverse Event
Morphine	21 Feb 2021 (Study Day 188) - 21 Feb 2021 (Study Day 188)	Pelvic Mass
Paracetamol	21 Feb 2021 (Study Day 188) - 21 Feb 2021 (Study Day 188)	Pain Related To Pelvic Mass

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Exploration laparotomy, removal of pelvic mass, left ureterolysis, total abdominal hysterectomy, right salpingectomy, right ureterolysis, right oophoropexy*	16 Mar 2021 (Study Day 211) - 16 Mar 2021 (Study Day 211)	Adverse Event
Enoxaparin sodium	18 Mar 2021 (Study Day 213) - Ongoing	Post Surgical Dvt Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypoaesthesia	Grade 1/mild	Not related	16 Mar 2021 (Study Day 211) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US352-2274 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 26 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 23 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 19 Jan 2021 (Study Day 147)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Coronary Artery Disease/ Coronary Artery Disease	SAE	Grade 4	Not related	10 Feb 2021 (Study Day 169) – Ongoing	Not recovered/ not resolved
Dyspnoea/New Onset Shortness Of Breath	SAE	Grade 3/ severe	Not related	17 Feb 2021 (Study Day 176) – Ongoing	Recovering/ resolving
Deep Vein Thrombosis/ Bilateral Deep Vein Thrombosis	SAE	Grade 4	Not related	10 Mar 2021 (Study Day 197) – Ongoing	Recovering/ resolving
Pleural Effusion/Pleural Effusion	SAE	Grade 3/ severe	Not related	10 Mar 2021 (Study Day 197) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2274, a 72-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 19 Jan 2021. The participant was unblinded on 19 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 19 Jan 2021 (Study Day 147). The second dose was not administered.

Event Details

On 10 Feb 2021 (Study Day 169), 168 days after the first dose in Part A/22 days after the first dose in Part B and 140 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 4 serious adverse event of coronary artery disease. The IP dose was delayed due to the coronary artery disease. The event of coronary artery disease was considered to be ongoing. The investigator assessed the event of coronary artery disease to be not related to the IP.

On 17 Feb 2021 (Study Day 176), 175 days after the first dose in Part A/29 days after the first dose in Part B and 147 days after the second dose in Part A of the IP (second dose Part B not applicable),

the participant experienced a Grade 3/severe serious adverse event of dyspnoea. The IP dose was delayed due to the new onset shortness of breath. The event of new onset shortness of breath was considered to be ongoing. The investigator assessed the event of dyspnoea to be not related to the IP.

On 10 Mar 2021 (Study Day 197), 196 days after the first dose in Part A/50 days after the first dose in Part B and 168 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 4 serious adverse event of deep vein thrombosis. The IP dose was delayed due to the bilateral deep vein thrombosis. The event of bilateral deep vein thrombosis was considered to be ongoing. The investigator assessed the event of deep vein thrombosis to be not related to the IP.

On 10 Mar 2021 (Study Day 197), 196 days after the first dose in Part A/50 days after the first dose in Part B and 168 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of pleural effusion. The IP dose was delayed due to the pleural effusion. The event of pleural effusion was considered to be ongoing. The investigator assessed the event of pleural effusion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-031848	Coronary artery disease
MOD-2021-031848	Dyspnoea
MOD-2021-031848	Deep vein thrombosis
MOD-2021-031848	Pleural effusion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cardiac murmur	Heart murmur	Not reported - Ongoing
Chest pain	History of exertional chest pain	Not reported - Ongoing
Depression	Anxiety, depression	Not reported - Ongoing
Gastroesophageal reflux disease	Gerd	Not reported - Ongoing
Hypertension	Hypertension	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
8-tetrahydrocannabinol	Not reported - Ongoing	Anxiety
Losartan	Not reported - 19 Feb 2021 (Study Day 178)	Hypertension
Mirtazapine	Not reported - Ongoing	Anxiety And Depression
Omeprazole	Not reported - Ongoing	Gerd
Coronary artery bypass and aortic valve replacement*	19 Feb 2021 (Study Day 178) - 19 Feb 2021 (Study Day 178)	Adverse Event
Thoracentesis*	10 Mar 2021 (Study Day 197) - 10 Mar 2021 (Study Day 197)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US352-2299 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 24 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 21 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Incarcerated Hernia/ Ventral Hernia With Incarcerated Small Bowel	SAE	Grade 3/ severe	Not related	23 Mar 2021 (Study Day 212) – 25 Mar 2021 (Study Day 214)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2299, a 58-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 15 Jan 2021. The participant was unblinded on 15 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 23 Mar 2021 (Study Day 212), 211 days after the first dose in Part A and 183 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of incarcerated hernia. Action taken with the IP was not applicable. The event of ventral hernia with incarcerated small bowel lasted for 3 days, after which it was considered to be recovered/resolved on 25 Mar 2021 (Study Day 214). The investigator assessed the event of incarcerated hernia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-065739	Abdominal hernia
MOD-2021-065739	Small intestinal obstruction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma - mild allergy mediated	Not reported - Ongoing
Hypothyroidism	Underactive thyroid	Not reported - Ongoing
Lymphatic disorder	Lymphatic system damage	Not reported - Ongoing
Obesity	Obesity bmi > 40	Not reported - Ongoing
Peripheral swelling	Bilateral lower extremity swelling	Not reported - Ongoing
Rosacea	Rosacea	Not reported - Ongoing
Seasonal allergy	Allergies- seasonal	Not reported - Ongoing
Postmenopause	Post menopause	Dec 2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Doxycycline	Not reported - Ongoing	Roscae
Levothyroxine	Not reported - Ongoing	Underactive Thyroid
Salbutamol	Not reported - Ongoing	Asthma
Paracetamol	24 Aug 2020 (Study Day 1) - 24 Aug 2020 (Study Day 1)	Headache
Paracetamol	21 Sep 2020 (Study Day 29) - 21 Sep 2020 (Study Day 29)	Headache
Paracetamol	29 Sep 2020 (Study Day 37) - Oct 2020	Pain Due To Swelling In Lower Bilateral Extremities
Influenza vaccine inact split 4v	09 Oct 2020 (Study Day 47) - 09 Oct 2020 (Study Day 47)	Prevention Of Influenza
Amlodipine	20 Nov 2020 (Study Day 89) - 15 Feb 2021 (Study Day 176)	Hypertension
Losartan potassium	10 Dec 2020 (Study Day 109) - 11 Jan 2021 (Study Day 141)	Hypertension
Losartan	12 Jan 2021 (Study Day 142) - Ongoing	Hypertension
Amlodipine	15 Feb 2021 (Study Day 176) - Ongoing	Hypertension
2019 ncoronavirus, pcr (covid-19) test*	24 Mar 2021 (Study Day 213) - 24 Mar 2021 (Study Day 213)	Diagnostic
Bupivacaine	24 Mar 2021 (Study Day 213) - 24 Mar 2021 (Study Day 213)	Ventral Hernia Surgery

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cefazolin	24 Mar 2021 (Study Day 213) - 24 Mar 2021 (Study Day 213)	Pre Surgical Prophylaxis
Citric acid; sodium citrate	24 Mar 2021 (Study Day 213) - 24 Mar 2021 (Study Day 213)	Nauseas From Ventral Hernia
Ct abdomen/pelvis without iv contrast*	24 Mar 2021 (Study Day 213) - 24 Mar 2021 (Study Day 213)	Diagnostic
Famotidine	24 Mar 2021 (Study Day 213) - 24 Mar 2021 (Study Day 213)	Nausea From Ventral Hernia
Hydrocodone; paracetamol	24 Mar 2021 (Study Day 213) - 25 Mar 2021 (Study Day 214)	Post Surgical Pain
Hydromorphone hydrochloride	24 Mar 2021 (Study Day 213) - 25 Mar 2021 (Study Day 214)	Post Surgical Pain
Methocarbamol	24 Mar 2021 (Study Day 213) - 24 Mar 2021 (Study Day 213)	Post Surgical Pain
Midazolam	24 Mar 2021 (Study Day 213) - 25 Mar 2021 (Study Day 214)	Sedation For Ventral Hernia Surgery
Morphine	24 Mar 2021 (Study Day 213) - 24 Mar 2021 (Study Day 213)	Ventral Hernia Pain
Ondansetron	24 Mar 2021 (Study Day 213) - 24 Mar 2021 (Study Day 213)	Nausea Related To Ventral Hernia
Open ventral hernia repair with reduction of strangulated small bowel*	24 Mar 2021 (Study Day 213) - 24 Mar 2021 (Study Day 213)	Adverse Event
Peritoneal fluid (surgical) culture and gram stain*	24 Mar 2021 (Study Day 213) - 24 Mar 2021 (Study Day 213)	Diagnostic
Pre-op bloodwork (cbc with differential, bmp, liver profile, lipase, abo/rh type and antibody screen, pt/inr/ptt)*	24 Mar 2021 (Study Day 213) - 24 Mar 2021 (Study Day 213)	Adverse Event
Surgical specimen exam (pathology)*	24 Mar 2021 (Study Day 213) - 24 Mar 2021 (Study Day 213)	Diagnostic
Enoxaparin	25 Mar 2021 (Study Day 214) - 26 Mar 2021 (Study Day 215)	Dvt Prophylaxis
Nystatin	25 Mar 2021 (Study Day 214) - 26 Mar 2021 (Study Day 215)	Antifungal Prophylaxis Of Groin Region
Paracetamol	25 Mar 2021 (Study Day 214) - 26 Mar 2021 (Study Day 215)	Post Surgical Pain
Macrofol	26 Mar 2021 (Study Day 215) - 29 Mar 2021 (Study Day 218)	Ventral Hernia Surgery
Tramadol	26 Mar 2021 (Study Day 215) - Ongoing	Post Surgical Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US352-2666 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 12 Oct 2020 (Study Day 32)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Coronary Artery Disease/Worsening Of Coronary Artery Disease	SAE	Grade 4	Not related	16 Mar 2021 (Study Day 187) – 26 Mar 2021 (Study Day 197)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2666, a 76-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 12 Oct 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 18 Jan 2021. The participant was unblinded on 18 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 16 Mar 2021 (Study Day 187), 186 days after the first dose in Part A and 155 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of coronary artery disease. Action taken with the IP was not applicable. The event of worsening of coronary artery disease lasted for 11 days, after which it was considered to be recovered/resolved on 26 Mar 2021 (Study Day 197). The investigator assessed the event of coronary artery disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-057121	Coronary artery disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	Not reported - Ongoing
Atrial fibrillation	Afib	Not reported - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	Not reported - Ongoing
Coronary artery disease	Coronary artery disease	Not reported - Ongoing
Depression	Depression	Not reported - Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Apixaban	Not reported - Ongoing	A Fib
Atorvastatin	Not reported - 06 Apr 2021 (Study Day 208)	Hyperlipidemia
Escitalopram oxalate	Not reported - Ongoing	Depression
Finasteride	Not reported - Ongoing	Bph
Insulin	Not reported - Ongoing	Diabetes
Lisinopril	Not reported - Ongoing	Hypertension
Tamsulosin hydrochloride	Not reported - Ongoing	Bph
Ibuprofen	13 Sep 2020 (Study Day 3) - 13 Sep 2020 (Study Day 3)	Pain At Site Of Injection
Paracetamol	13 Oct 2020 (Study Day 33) - 13 Oct 2020 (Study Day 33)	Headache, Body Aches
Metformin	18 Jan 2021 (Study Day 130) - Ongoing	Diabetes Type 2
Bismuth subsalicylate	08 Feb 2021 (Study Day 151) - 08 Feb 2021 (Study Day 151)	Diarrhea
Chemical cardiac stress test*	08 Feb 2021 (Study Day 151) - 08 Feb 2021 (Study Day 151)	Medical History
Acetylsalicylic acid	12 Mar 2021 (Study Day 183) - Ongoing	Cardio Protective
Coronary angiography*	12 Mar 2021 (Study Day 183) - 12 Mar 2021 (Study Day 183)	Adverse Event
Heparin	12 Mar 2021 (Study Day 183) - 15 Mar 2021 (Study Day 186)	Blood Clots Prophylaxis/Coronary Artery Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin glargine	12 Mar 2021 (Study Day 183) - 14 Mar 2021 (Study Day 185)	Diabetes
Insulin lispro	12 Mar 2021 (Study Day 183) - 13 Mar 2021 (Study Day 184)	Diabetes
Glucose; glyceryl trinitrate	13 Mar 2021 (Study Day 184) - 14 Mar 2021 (Study Day 185)	Worsening Coronary Artery Disease
Insulin glargine	13 Mar 2021 (Study Day 184) - 15 Mar 2021 (Study Day 186)	Diabetes
Lisinopril	13 Mar 2021 (Study Day 184) - 15 Mar 2021 (Study Day 186)	Hypertension
Allopurinol	15 Mar 2021 (Study Day 186) - 16 Mar 2021 (Study Day 187)	Unknown Why Received Two Doses
Docusate sodium	15 Mar 2021 (Study Day 186) - 26 Mar 2021 (Study Day 197)	Constipation Prophylaxis
Insulin lispro	15 Mar 2021 (Study Day 186) - 15 Mar 2021 (Study Day 186)	Diabetes
Mupirocin	15 Mar 2021 (Study Day 186) - 17 Mar 2021 (Study Day 188)	Pre And Post Op Prophylaxis For Infection
Sennoside a+b	15 Mar 2021 (Study Day 186) - 26 Mar 2021 (Study Day 197)	Constipation Prophylaxis
Coronary artery bypass grafting x3 (lima to lad, svg to om, svg to pda)*	16 Mar 2021 (Study Day 187) - 16 Mar 2021 (Study Day 187)	Medical History
Endoscopic vein harvesting of the left greater saphenous vein*	16 Mar 2021 (Study Day 187) - 16 Mar 2021 (Study Day 187)	Medical History
Epinephrine	16 Mar 2021 (Study Day 187) - 17 Mar 2021 (Study Day 188)	Coronary Artery Disease
Excision of left atrial appendage*	16 Mar 2021 (Study Day 187) - 16 Mar 2021 (Study Day 187)	Medical History
Famotidine	16 Mar 2021 (Study Day 187) - 26 Mar 2021 (Study Day 197)	Prevents Ulcers
Hydromorphone hydrochloride	16 Mar 2021 (Study Day 187) - 18 Mar 2021 (Study Day 189)	Post Surgical Pain
Lidocaine	16 Mar 2021 (Study Day 187) - 16 Mar 2021 (Study Day 187)	Iv Start Pain
Metoprolol tartrate	16 Mar 2021 (Study Day 187) - 18 Mar 2021 (Study Day 189)	Hypertension
Norepinephrine bitartrate	16 Mar 2021 (Study Day 187) - 17 Mar 2021 (Study Day 188)	Worsening Coronary Artery Disease
Open reduction rigid internal sternal fixation (sternalock planting system)*	16 Mar 2021 (Study Day 187) - 16 Mar 2021 (Study Day 187)	Medical History
Potassium chloride	16 Mar 2021 (Study Day 187) - 16 Mar 2021 (Study Day 187)	Electrolyte Disturbance
Propofol	16 Mar 2021 (Study Day 187) - 16 Mar 2021 (Study Day 187)	Procedural Sedation
Albumin human	17 Mar 2021 (Study Day 188) - 17 Mar 2021 (Study Day 188)	Post Surgical
Ceftriaxone	17 Mar 2021 (Study Day 188) - 18 Mar 2021 (Study Day 189)	Surgical Infections Prophylaxis
Heparin	17 Mar 2021 (Study Day 188) - 26 Mar 2021 (Study Day 197)	Blood Clots Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin human	17 Mar 2021 (Study Day 188) - 17 Mar 2021 (Study Day 188)	Diabetes
Macrogol 3350	17 Mar 2021 (Study Day 188) - 20 Mar 2021 (Study Day 191)	Constipation Prophylaxis
Magnesium sulfate	17 Mar 2021 (Study Day 188) - 17 Mar 2021 (Study Day 188)	Electrolyte Disturbance
Paracetamol	17 Mar 2021 (Study Day 188) - 18 Mar 2021 (Study Day 189)	Surgery Pain
Sodium bicarbonate	17 Mar 2021 (Study Day 188) - 17 Mar 2021 (Study Day 188)	Electrolyte Disturbance
Solutions affecting the electrolyte balance	17 Mar 2021 (Study Day 188) - 17 Mar 2021 (Study Day 188)	Electrolyte Replacement
Insulin glargine	18 Mar 2021 (Study Day 189) - 19 Mar 2021 (Study Day 190)	Diabetes
Paracetamol	18 Mar 2021 (Study Day 189) - 25 Mar 2021 (Study Day 196)	Surgery Pain
Furosemide	19 Mar 2021 (Study Day 190) - 23 Mar 2021 (Study Day 194)	Pleural Effusion
Hydrocodone bitartrate; paracetamol	19 Mar 2021 (Study Day 190) - 22 Mar 2021 (Study Day 193)	Post Surgical Pain
Magnesium oxide	19 Mar 2021 (Study Day 190) - 19 Mar 2021 (Study Day 190)	Vitamin
Metoprolol tartrate	19 Mar 2021 (Study Day 190) - 19 Mar 2021 (Study Day 190)	Hypertension
Potassium chloride	19 Mar 2021 (Study Day 190) - 21 Mar 2021 (Study Day 192)	Electrolyte Disturbance
Potassium phosphate monobasic	19 Mar 2021 (Study Day 190) - 19 Mar 2021 (Study Day 190)	Electrolyte Disturbance
Magnesium	20 Mar 2021 (Study Day 191) - 21 Mar 2021 (Study Day 192)	Electrolyte Disturbance
Insulin lispro	22 Mar 2021 (Study Day 193) - 24 Mar 2021 (Study Day 195)	Diabetes
Sulfamethoxazole; trimethoprim	22 Mar 2021 (Study Day 193) - 23 Mar 2021 (Study Day 194)	Prophylactic Treatment Of Possible Uti (Culture Negative)
Thoracentesis (left pleural effusion)*	22 Mar 2021 (Study Day 193) - 22 Mar 2021 (Study Day 193)	Adverse Event
Insulin lispro	23 Mar 2021 (Study Day 194) - 25 Mar 2021 (Study Day 196)	Diabetes
Melatonin	23 Mar 2021 (Study Day 194) - 25 Mar 2021 (Study Day 196)	Sleep In Hospital
Insulin glargine	24 Mar 2021 (Study Day 195) - 26 Mar 2021 (Study Day 197)	Diabetes
Insulin lispro	24 Mar 2021 (Study Day 195) - 26 Mar 2021 (Study Day 197)	Diabetes
Lidocaine	24 Mar 2021 (Study Day 195) - 26 Mar 2021 (Study Day 197)	Post Surgical Pain
Tramadol	24 Mar 2021 (Study Day 195) - 26 Mar 2021 (Study Day 197)	Post Surgical Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol tartrate	25 Mar 2021 (Study Day 196) - 26 Mar 2021 (Study Day 197)	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Not related	06 Feb 2021 (Study Day 149) - 19 Feb 2021 (Study Day 162)
Nausea	Grade 1/mild	Not related	07 Feb 2021 (Study Day 150) - 08 Feb 2021 (Study Day 151)
Cardiac Stress Test Abnormal	Grade 2/moderate	Not related	08 Feb 2021 (Study Day 151) - 08 Feb 2021 (Study Day 151)
Diarrhoea	Grade 2/moderate	Not related	08 Feb 2021 (Study Day 151) - 09 Feb 2021 (Study Day 152)
Pain	Grade 1/mild	Not related	08 Feb 2021 (Study Day 151) - 10 Feb 2021 (Study Day 153)
Vomiting	Grade 1/mild	Not related	08 Feb 2021 (Study Day 151) - 09 Feb 2021 (Study Day 152)
Electrolyte Imbalance	Grade 2/moderate	Not related	16 Mar 2021 (Study Day 187) - 17 Mar 2021 (Study Day 188)
Pleural Effusion	Grade 3/severe	Not related	22 Mar 2021 (Study Day 193) - 24 Mar 2021 (Study Day 195)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US352-2696 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 16 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 11 Jan 2021 (Study Day 118)
Second Dose of Vaccine in Part B: 22 Feb 2021 (Study Day 160)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Deep Vein Thrombosis/Right Lower Extremity Dvt	SAE	Grade 3/ severe	Not related	04 Feb 2021 (Study Day 142) – 09 Mar 2021 (Study Day 175)	Recovered/ resolved
Staphylococcal Sepsis/Sepsis Secondary To Methicillin Susceptible Staphylococcus Aureus	SAE	Grade 3/ severe	Not related	04 Feb 2021 (Study Day 142) – 08 Mar 2021 (Study Day 174)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2696, a 59-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 16 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 14 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 11 Jan 2021 (Study Day 118). The second dose was administered in the left arm on 22 Feb 2021 (Study Day 160).

Event Details

On 04 Feb 2021 (Study Day 142), 141 days after the first dose in Part A/24 days after the first dose in Part B and 113 days after the second dose in Part A/18 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of deep vein thrombosis. The IP dose was delayed due to the right lower extremity dvt. The event of right lower extremity dvt lasted for 34 days, after which it was considered to be recovered/resolved on 09 Mar 2021 (Study Day 175). The investigator assessed the event of deep vein thrombosis to be not related to the IP.

On 04 Feb 2021 (Study Day 142), 141 days after the first dose in Part A/24 days after the first dose in Part B and 113 days after the second dose in Part A/18 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of staphylococcal sepsis. The IP dose was delayed due to the sepsis secondary to methicillin susceptible staphylococcus aureus. The event of sepsis secondary to methicillin susceptible staphylococcus aureus lasted for 33 days, after which it was considered to be recovered/resolved on 08 Mar 2021 (Study Day 174). The investigator assessed the event of staphylococcal sepsis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-011588	Deep vein thrombosis
MOD-2021-011588	Staphylococcal sepsis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Arthritis	Knee arthritis	Not reported - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	Not reported - Ongoing
Diabetic neuropathy	Diabetic neuropathy of bilateral feet	Not reported - Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Hypertriglyceridaemia	Hypertriglyceridemia	Not reported - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	Not reported - Ongoing
Migraine	Migraine headaches	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Sleep apnoea syndrome	Sleep apnea	Not reported - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes mellitus	Not reported - Ongoing
Diabetic foot	Diabetic ulcer of toe of right foot associated with type 2 diabetes mellitus	31 Dec 2019 (Study Day -260) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Not reported - Ongoing	Cardiovascular Health

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	Not reported - Ongoing	Hyperlipidemia
Cyclobenzaprine	Not reported - Ongoing	Muscle Spasms
Dichloralphenazone; isometheptene; paracetamol	Not reported - 12 Jan 2021 (Study Day 119)	Migraine Pain
Dulaglutide	Not reported - Ongoing	Type 2 Diabetes Mellitus
Duloxetine	Not reported - Ongoing	Diabetic Neuropathy Pain Of Bilateral Feet
Fenofibrate	Not reported - Ongoing	Hyperlipidemia
Flunisolide	Not reported - Ongoing	Seasonal Allergies
Lisinopril	Not reported - Ongoing	Hypertension
Metformin	Not reported - Ongoing	Type 2 Diabetes Mellitus
Pregabalin	Not reported - Ongoing	Neuropathy Of Feet
Tamsulosin	Not reported - Ongoing	Benign Prostatic Hyperplasia
Paracetamol	18 Sep 2020 (Study Day 3) - 19 Sep 2020 (Study Day 4)	Arthritic Knee Pain
Influenza vaccine rha 3v (baculovirus)	29 Oct 2020 (Study Day 44) - 29 Oct 2020 (Study Day 44)	Influenza Prevention
Right big toe diabetic ulcer surgery (stravix graft)*	01 Dec 2020 (Study Day 77) - 01 Dec 2020 (Study Day 77)	Medical History
2 view chest x-ray*	05 Feb 2021 (Study Day 143) - 05 Feb 2021 (Study Day 143)	Adverse Event
Bilateral lower extremity venous duplex*	05 Feb 2021 (Study Day 143) - 05 Feb 2021 (Study Day 143)	Adverse Event
Ct chest iv contrast*	05 Feb 2021 (Study Day 143) - 05 Feb 2021 (Study Day 143)	Adverse Event
Ct soft tissue neck with contrast*	05 Feb 2021 (Study Day 143) - 05 Feb 2021 (Study Day 143)	Adverse Event
Heparin	05 Feb 2021 (Study Day 143) - 10 Feb 2021 (Study Day 148)	Right Lower Dvt
Piperacillin sodium; tazobactam sodium	05 Feb 2021 (Study Day 143) - 06 Feb 2021 (Study Day 144)	Sepsis
Vancomycin	05 Feb 2021 (Study Day 143) - 05 Feb 2021 (Study Day 143)	Sepsis
Vancomycin	05 Feb 2021 (Study Day 143) - 06 Feb 2021 (Study Day 144)	Sepsis
Cefazolin	06 Feb 2021 (Study Day 144) - 02 Mar 2021 (Study Day 168)	Sepsis
Echocardiogram*	10 Feb 2021 (Study Day 148) - 10 Feb 2021 (Study Day 148)	Adverse Event
Cefazolin sodium	11 Feb 2021 (Study Day 149) - 02 Mar 2021 (Study Day 168)	Bacteremia/Sepsis
Warfarin	11 Feb 2021 (Study Day 149) - Ongoing	Dvt
Doxycycline	02 Mar 2021 (Study Day 168) - 08 Mar 2021 (Study Day 174)	Post Mrsa Infection/Sepsis
Lower extremity venous duplex*	09 Mar 2021 (Study Day 175) - 09 Mar 2021 (Study Day 175)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US352-2709 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 18 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 23 Oct 2020 (Study Day 36)
First Dose of Vaccine in Part B: 27 Jan 2021 (Study Day 132)
Second Dose of Vaccine in Part B: 24 Feb 2021 (Study Day 160)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis/Appendicitis	SAE	Grade 3/ severe	Not related	08 Feb 2021 (Study Day 144) – 11 Feb 2021 (Study Day 147)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2709, a 25-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 18 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 23 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 27 Jan 2021. The participant was unblinded on 27 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 27 Jan 2021 (Study Day 132). The second dose was administered in the left arm on 24 Feb 2021 (Study Day 160).

Event Details

On 08 Feb 2021 (Study Day 144), 143 days after the first dose in Part A/12 days after the first dose in Part B and 108 days after the second dose in Part A/16 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of appendicitis. The IP dose was not changed due to the appendicitis. The event of appendicitis lasted for 4 days, after which it was considered to be recovered/resolved on 11 Feb 2021 (Study Day 147). The investigator assessed the event of appendicitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-015604	Appendicitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	09 Feb 2021 (Study Day 145) - 09 Feb 2021 (Study Day 145)	Appendicitis
Ondansetron	09 Feb 2021 (Study Day 145) - 09 Feb 2021 (Study Day 145)	Appendicitis
Laparoscopic appendectomy*	10 Feb 2021 (Study Day 146) - 10 Feb 2021 (Study Day 146)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US353-2170 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 27 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: Not Administered
First Dose of Vaccine in Part B: 02 Feb 2021 (Study Day 160)
Second Dose of Vaccine in Part B: 10 Mar 2021 (Study Day 196)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Wound Infection/Wound Infection Left Buttock	SAE	Grade 4	Not related	17 Feb 2021 (Study Day 175) – 09 Mar 2021 (Study Day 195)	Recovered/resolved
Sepsis/Sepsis	SAE	Grade 4	Not related	19 Feb 2021 (Study Day 177) – 24 Feb 2021 (Study Day 182)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US353-2170, a 66-year-old not Hispanic or Latino female, received the first dose of Placebo in the right arm on 27 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 02 Feb 2021. The participant was unblinded on 02 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 02 Feb 2021 (Study Day 160). The second dose was administered in the right arm on 10 Mar 2021 (Study Day 196).

Event Details

On 17 Feb 2021 (Study Day 175), 174 days after the first dose in Part A/15 days after the first dose in Part B and second dose Part A not applicable/21 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of wound infection. The IP dose was not changed due to the wound infection left buttock. The event of wound infection left buttock lasted for 21 days, after which it was considered to be recovered/resolved on 09 Mar 2021 (Study Day 195). The investigator assessed the event of wound infection to be not related to the IP.

On 19 Feb 2021 (Study Day 177), 176 days after the first dose in Part A/17 days after the first dose in Part B and second dose Part A not applicable/19 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of sepsis. Action taken with the IP was not applicable. The event of sepsis lasted for 6 days, after which it was considered to be

recovered/resolved on 24 Feb 2021 (Study Day 182). The investigator assessed the event of sepsis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-018778	Wound infection
MOD-2021-018778	Sepsis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myalgia	Generalized muscle aches	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Encephalitis viral	Viral encephalitis	1975 - Ongoing
Hypothyroidism	Hypothyroidism	1985 - Ongoing
Gastroesophageal reflux disease	Gerd	1995 - Ongoing
Cataract operation	Bilateral cataract surgery	2002 - 2002
Menopause	Menopause	2008 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Osteoarthritis	Basillar thrumb osteoarthritis	2016 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2016 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2017 - Ongoing
Plantar fasciitis	Plantar fasciitis	2018 - Ongoing
Limb operation	Thumb surgery	25 Nov 2019 (Study Day -276) - 25 Nov 2019 (Study Day -276)
Vitamin D decreased	Low vitamin d level	18 Feb 2020 (Study Day -191) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	Not reported - Ongoing	Generalized Muscle Aches
Levothyroxine	1985 - Ongoing	Hypothyroidism
Vitamins nos	1985 - Sep 2020	General Health
Lisinopril	2015 - 30 Sep 2020 (Study Day 35)	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	2016 - Ongoing	Type II Diabetes
Insulin glargine	16 Feb 2020 (Study Day -193) - 12 Oct 2020 (Study Day 47)	Type II Diabetes
Vitamin D	18 Feb 2020 (Study Day -191) - Ongoing	General Health
Paracetamol	28 Aug 2020 (Study Day 2) - 28 Aug 2020 (Study Day 2)	Headache
Guaifenesin	Sep 2020 - 29 Sep 2020 (Study Day 34)	Myocardial Infarction Post Cabg Treatment Protocol
Cabg x 2*	08 Sep 2020 (Study Day 13) - 08 Sep 2020 (Study Day 13)	Adverse Event
Amiodarone	12 Sep 2020 (Study Day 17) - 01 Jan 2021 (Study Day 128)	Myocardial Infarction Post Cabg Treatment Protocol
Ferrous sulfate	12 Sep 2020 (Study Day 17) - 12 Oct 2020 (Study Day 47)	Myocardial Infarction Post Cabg Treatment Protocol
Hydrocodone; paracetamol	12 Sep 2020 (Study Day 17) - 19 Sep 2020 (Study Day 24)	Myocardial Infarction- Post Cabg Treatment Protocol
Insulin lispro	12 Sep 2020 (Study Day 17) - Ongoing	Type II Diabetes
Metoprolol tartrate	12 Sep 2020 (Study Day 17) - 14 Jan 2021 (Study Day 141)	Myocardial Infarction Post Cabg Treatment Protocol
Milrinone	12 Sep 2020 (Study Day 17) - 14 Sep 2020 (Study Day 19)	Myocardial Infarction
Morphine	12 Sep 2020 (Study Day 17) - 13 Sep 2020 (Study Day 18)	Myocardial Infarction
Ondansetron	12 Sep 2020 (Study Day 17) - 09 Oct 2020 (Study Day 44)	Nausea
Pantoprazole	12 Sep 2020 (Study Day 17) - Nov 2020	Gerd
Sennoside a+b	12 Sep 2020 (Study Day 17) - Ongoing	Myocardial Infarction Post Cabg Treatment Protocol
Acetylsalicylic acid	13 Sep 2020 (Study Day 18) - Ongoing	Myocardial Infarction Post Cabg Treatment Protocol
Ascorbic acid	13 Sep 2020 (Study Day 18) - Nov 2020	General Health
Hydralazine	13 Sep 2020 (Study Day 18) - 13 Sep 2020 (Study Day 18)	Hypertension
Atorvastatin	14 Sep 2020 (Study Day 19) - 28 Jan 2021 (Study Day 155)	Myocardial Infarction Post Cabg Treatment Protocol
Docusate sodium	14 Sep 2020 (Study Day 19) - Ongoing	Myocardial Infarction Post Cabg Treatment Protocol
Enoxaparin	14 Sep 2020 (Study Day 19) - 18 Sep 2020 (Study Day 23)	Myocardial Infarction
Furosemide	14 Sep 2020 (Study Day 19) - 01 Jan 2021 (Study Day 128)	Myocardial Infarction Post Cabg Treatment Protocol
Ipratropium	14 Sep 2020 (Study Day 19) - 18 Sep 2020 (Study Day 23)	Wheezing
Myroxylon balsamum var. pereirae; ricinus communis oil	14 Sep 2020 (Study Day 19) - 12 Oct 2020 (Study Day 47)	Myocardial Infarction Post Cabg Treatment Protocol
Potassium chloride	14 Sep 2020 (Study Day 19) - 28 Oct 2020 (Study Day 63)	Myocardial Infarction Post Cabg Treatment Protocol
Salbutamol	14 Sep 2020 (Study Day 19) - 18 Sep 2020 (Study Day 23)	Wheezing

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Macroglol	15 Sep 2020 (Study Day 20) - Ongoing	Myocardial Infarction Post Cabg Treatment Protocol
Bisacodyl	16 Sep 2020 (Study Day 21) - 12 Oct 2020 (Study Day 47)	Myocardial Infarction Post Cabg Treatment Protocol
Influenza vaccine	04 Oct 2020 (Study Day 39) - 04 Oct 2020 (Study Day 39)	Influenza
Doxycycline	06 Oct 2020 (Study Day 41) - 08 Oct 2020 (Study Day 43)	Myocardial Infarction Post Cabg Treatment Protocol
Gabapentin	06 Oct 2020 (Study Day 41) - Ongoing	Myocardial Infarction Post Cabg Treatment Protocol
Magnesium oxide	06 Oct 2020 (Study Day 41) - 19 Nov 2020 (Study Day 85)	Myocardial Infarction Post Cabg Treatment Protocol
Sertraline	06 Oct 2020 (Study Day 41) - 14 Jan 2021 (Study Day 141)	Anxiety Post Cabg
Empagliflozin	12 Oct 2020 (Study Day 47) - Ongoing	Type II Diabetes
Promethazine	20 Oct 2020 (Study Day 55) - Ongoing	Nausea
Ampicillin	13 Nov 2020 (Study Day 79) - 27 Nov 2020 (Study Day 93)	Infected Wound- Bedsore
Event monitor (wore for 2 weeks)*	19 Nov 2020 (Study Day 85) - 19 Nov 2020 (Study Day 85)	Adverse Event
Echocardiogram*	20 Nov 2020 (Study Day 86) - 20 Nov 2020 (Study Day 86)	Adverse Event
Bedsore wound debridement*	27 Nov 2020 (Study Day 93) - 27 Nov 2020 (Study Day 93)	Adverse Event
Lisinopril	10 Dec 2020 (Study Day 106) - Ongoing	Hypertension
Bupropion hydrochloride	14 Jan 2021 (Study Day 141) - Ongoing	Anxiety Post Cabag
Furosemide	14 Jan 2021 (Study Day 141) - Ongoing	Bilateral Leg Swelling
Metoprolol succinate	14 Jan 2021 (Study Day 141) - 16 Apr 2021 (Study Day 233)	Hypertension
Wound vac placment*	20 Jan 2021 (Study Day 147) - 20 Jan 2021 (Study Day 147)	Adverse Event
Glipizide	28 Jan 2021 (Study Day 155) - Ongoing	Type II Diabetes
Rosuvastatin calcium	28 Jan 2021 (Study Day 155) - Ongoing	Hyperlipidemia
Ceftriaxone	19 Feb 2021 (Study Day 177) - 23 Feb 2021 (Study Day 181)	Wound Infection Left Buttock/Sepsis
Ct of abd and pelvis with contrast*	19 Feb 2021 (Study Day 177) - 19 Feb 2021 (Study Day 177)	Adverse Event
Hematology draw*	19 Feb 2021 (Study Day 177) - 19 Feb 2021 (Study Day 177)	Adverse Event
Metronidazole	19 Feb 2021 (Study Day 177) - 20 Feb 2021 (Study Day 178)	Sepsis/Wound Infection Left Buttock
Vancomycin	19 Feb 2021 (Study Day 177) - 19 Feb 2021 (Study Day 177)	Sepsis/Wound Infection Left Buttock
Hematology draw*	20 Feb 2021 (Study Day 178) - 20 Feb 2021 (Study Day 178)	Adverse Event
Blood culture*	21 Feb 2021 (Study Day 179) - 21 Feb 2021 (Study Day 179)	Adverse Event
Vancomycin	21 Feb 2021 (Study Day 179) - 24 Feb 2021 (Study Day 182)	Sepsis/Wound Infection Left Buttock

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amoxicillin; clavulanic acid	24 Feb 2021 (Study Day 182) - 10 Mar 2021 (Study Day 196)	Wound Infection- Left Buttock

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US353-2276 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 06 Jan 2021 (Study Day 119)
Second Dose of Vaccine in Part B: 03 Feb 2021 (Study Day 147)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Asthma/Asthma Exacerbation	SAE	Grade 4	Not related	04 Feb 2021 (Study Day 148) – 10 Feb 2021 (Study Day 154)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US353-2276, a 77-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 06 Jan 2021 (Study Day 119). The second dose was administered in the left arm on 03 Feb 2021 (Study Day 147).

Event Details

On 04 Feb 2021 (Study Day 148), 147 days after the first dose in Part A/29 days after the first dose in Part B and 119 days after the second dose in Part A/1 day after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of asthma. Action taken with the IP was not applicable. The event of asthma exacerbation lasted for 7 days, after which it was considered to be recovered/resolved on 10 Feb 2021 (Study Day 154). The investigator assessed the event of asthma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012810	Asthma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Eczema	Eczema	Not reported - Ongoing
Tonsillectomy	Tonsillectomy	1944 - 1944
Allergy to vaccine	Allergy to tetanus shot	1945 - Ongoing
Seasonal allergy	Seasonal allergies	1945 - Ongoing
Tenoplasty	Left knee tendon repair	1961 - 1961
Menopause	Menopause	1981 - Ongoing
Hysterectomy	Hysterectomy	1982 - 1982
Knee operation	Right knee lateral release	1989 - 1989
Cholecystectomy	Gall bladder removal	1990 - 1990
Tendon injury	Ruptured achilles tendon	1992 - Ongoing
Ankle operation	Right ankle surgery	1993 - 1993
Drug hypersensitivity	Allergy to antifungal drugs	2000 - Ongoing
Hypothyroidism	Hypothyroidism	2000 - Ongoing
Rotator cuff repair	Right rotator cuff repair	2003 - 2003
Osteoarthritis	Osteoarthritis	2005 - Ongoing
Knee arthroplasty	Left knee total replacement	2007 - 2007
Tendon operation	Left thumb tendon surgery	2007 - 2007
Asthma	Mild intermediate asthma	2009 - Ongoing
Knee arthroplasty	Right knee total replacement	Aug 2010 - Aug 2010
Gastroesophageal reflux disease	Gerd	2014 - Ongoing
Dry eye	Dry left eye	2015 - Ongoing
Drug hypersensitivity	Allergy to sulfa	2017 - Ongoing
Rotator cuff repair	Left rotator cuff repair	Mar 2017 - Mar 2017
Hypertension	Hypertension	2018 - Ongoing
Blood cholesterol increased	High cholesterol	2019 - Ongoing
Fungal skin infection	Candidal dermatitis	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colecalciferol	Not reported - Ongoing	General Health
Vitamin b12 nos	Not reported - Ongoing	General Health

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Estrogens conjugated	1985 - Ongoing	Hysterectomy
Fluticasone propionate	2000 - Ongoing	Seasonal Allergies
Levothyroxine	2000 - Ongoing	Hypothyroidism
Celecoxib	2005 - Ongoing	Osteoarthritis
Salbutamol	2009 - Ongoing	Mild Intermediate Asthma
Omeprazole	2010 - Ongoing	Gerd
Probiotics nos	2010 - Ongoing	General Health
Macrogol 400; propylene glycol	2015 - Ongoing	Dry Eye Left
Biotin	2017 - Ongoing	General Health
Losartan	2018 - Ongoing	Hypertension
Meloxicam	2019 - 2020	Right Knee Total Replacement
Atorvastatin	Nov 2019 - Ongoing	High Cholesterol
Methylcellulose	2020 - Ongoing	General Health
Ketoconazole	Jun 2020 - Ongoing	Candid Dermatitis
Amoxicillin	14 Oct 2020 (Study Day 35) - 15 Oct 2020 (Study Day 36)	Dental Procedures
Amoxicillin	28 Oct 2020 (Study Day 49) - 28 Oct 2020 (Study Day 49)	Prophylaxis For Dental Procedures
Broken crown on tooth repaired*	28 Oct 2020 (Study Day 49) - 28 Oct 2020 (Study Day 49)	Adverse Event
Influenza vaccine	17 Nov 2020 (Study Day 69) - 17 Nov 2020 (Study Day 69)	Influenza
Zinc	24 Dec 2020 (Study Day 106) - Ongoing	General Health
Codeine; guaifenesin	20 Jan 2021 (Study Day 133) - 23 Jan 2021 (Study Day 136)	Ae #5
Prednisone	20 Jan 2021 (Study Day 133) - 26 Jan 2021 (Study Day 139)	Ae #5
Methylprednisolone sodium succinate	08 Feb 2021 (Study Day 152) - 08 Feb 2021 (Study Day 152)	Asthma Exacerbation
Sodium chloride	08 Feb 2021 (Study Day 152) - 08 Feb 2021 (Study Day 152)	Asthma Exacerbation
Prednisone	09 Feb 2021 (Study Day 153) - 09 Feb 2021 (Study Day 153)	Asthma Exacerbation
Salbutamol	09 Feb 2021 (Study Day 153) - 09 Feb 2021 (Study Day 153)	Asthma Exacerbation
Methylprednisolone	10 Feb 2021 (Study Day 154) - 16 Feb 2021 (Study Day 160)	Mild Intermittent Asthma Exacerbation
Montelukast sodium	02 Mar 2021 (Study Day 174) - Ongoing	Asthma Exacerbation
Salmeterol	02 Mar 2021 (Study Day 174) - Ongoing	Asthma Exacerbation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	11 Jan 2021 (Study Day 124) - 03 Feb 2021 (Study Day 147)
Asthma	Grade 2/moderate	Not related	27 Feb 2021 (Study Day 171) - 15 Apr 2021 (Study Day 218)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US354-2029 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 20 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 17 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hyperkalaemia/ Hyperkalemia Due To Acute Kidney Injury Of Unknown Etiology	SAE	Grade 3/ severe	Not related	18 Feb 2021 (Study Day 183) – 20 Feb 2021 (Study Day 185)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US354-2029, a 61-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 25 Jan 2021. The participant was unblinded on 25 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 18 Feb 2021 (Study Day 183), 182 days after the first dose in Part A and 154 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of hyperkalaemia. Action taken with the IP was not applicable. The event of hyperkalemia due to acute kidney injury of unknown etiology lasted for 3 days, after which it was considered to be recovered/resolved on 20 Feb 2021 (Study Day 185). The investigator assessed the event of hyperkalaemia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-022322	Hyperkalaemia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post-menopausal	2004 - Ongoing
Diabetes mellitus	Diabetes mellitus	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Depression	Depression	2015 - Ongoing
Nephrolithiasis	Nephrolithiasis	2015 - Ongoing
Post-traumatic stress disorder	Ptsd	2015 - Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing
Atrial fibrillation	Paroxysmal atrial fibrillation	2016 - Ongoing
Osteoarthritis	Osteoarthritis in right knee	2017 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2019 - Ongoing
Hyperlipidaemia	Hyperlipidemia	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Alprazolam	2015 - Ongoing	Ptsd
Insulin degludec	2015 - Ongoing	Diabetes Mellitus
Insulin lispro	2015 - Ongoing	Diabetes Mellitus
Lisinopril	2015 - 18 Feb 2021 (Study Day 183)	Hypertension
Loratadine	2015 - Ongoing	Seasonal Allergies
Vilazodone hydrochloride	2017 - Ongoing	Depression
Meloxicam	2019 - Ongoing	Osteoarthritis
Metformin	2019 - Ongoing	Diabetes Mellitus
Vitamin d nos	2020 - Ongoing	Vitamin D Deficiency
Atorvastatin	Jan 2020 - 18 Feb 2021 (Study Day 183)	Hyperlipidemia
Ibuprofen	02 Sep 2020 (Study Day 14) - 12 Sep 2020 (Study Day 24)	Urinary Tract Infection
Amoxicillin	08 Sep 2020 (Study Day 20) - 15 Sep 2020 (Study Day 27)	Urinary Tract Infection
Ibuprofen	17 Sep 2020 (Study Day 29) - 19 Sep 2020 (Study Day 31)	Fatigue, Chills, Myalgia, Arthralgia
Influenza vaccine	17 Oct 2020 (Study Day 59) - 17 Oct 2020 (Study Day 59)	Flu Prevention

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amoxicillin	11 Dec 2020 (Study Day 114) - 17 Dec 2020 (Study Day 120)	Sinusitis
Azithromycin	18 Feb 2021 (Study Day 183) - 18 Feb 2021 (Study Day 183)	Community-Acquired Pneumonia
Ketorolac tromethamine	18 Feb 2021 (Study Day 183) - 18 Feb 2021 (Study Day 183)	Abdominal Pain
Acetylsalicylic acid	19 Feb 2021 (Study Day 184) - Ongoing	Atrial Fibrillation
Apixaban	19 Feb 2021 (Study Day 184) - Ongoing	Atrial Fibrillation
Calcium gluconate	19 Feb 2021 (Study Day 184) - 20 Feb 2021 (Study Day 185)	Hyperkalemia
Ceftriaxone	19 Feb 2021 (Study Day 184) - 21 Feb 2021 (Study Day 186)	Community-Acquired Pneumonia
Heparin	19 Feb 2021 (Study Day 184) - 19 Feb 2021 (Study Day 184)	Deep Vein Thrombosis Prophylaxis
Oxycodone	19 Feb 2021 (Study Day 184) - 21 Feb 2021 (Study Day 186)	Abdominal Pain
Paracetamol	19 Feb 2021 (Study Day 184) - 21 Feb 2021 (Study Day 186)	Abdominal Pain
Propafenone	19 Feb 2021 (Study Day 184) - Ongoing	Atrial Fibrillation
Sodium zirconium cyclosilicate	19 Feb 2021 (Study Day 184) - 19 Feb 2021 (Study Day 184)	Hyperkalemia
Azithromycin	20 Feb 2021 (Study Day 185) - 22 Feb 2021 (Study Day 187)	Community-Acquired Pneumonia
Furosemide	20 Feb 2021 (Study Day 185) - 22 Feb 2021 (Study Day 187)	Atrial Fibrillation
Hydrochlorothiazide	20 Feb 2021 (Study Day 185) - 22 Feb 2021 (Study Day 187)	Hypertension
Metoprolol	20 Feb 2021 (Study Day 185) - Ongoing	Atrial Fibrillation
Amoxicillin; clavulanic acid	22 Feb 2021 (Study Day 187) - 28 Feb 2021 (Study Day 193)	Community-Acquired Pneumonia
Atorvastatin	22 Feb 2021 (Study Day 187) - Ongoing	Hyperlipidemia
Furosemide	22 Feb 2021 (Study Day 187) - Ongoing	Atrial Fibrillation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Abdominal Pain	Grade 2/moderate	Not related	18 Feb 2021 (Study Day 183) - 22 Feb 2021 (Study Day 187)
Acute Kidney Injury	Grade 2/moderate	Not related	18 Feb 2021 (Study Day 183) - 19 Feb 2021 (Study Day 184)
Atrial Fibrillation	Grade 2/moderate	Not related	18 Feb 2021 (Study Day 183) - 19 Feb 2021 (Study Day 184)
Blood Lactic Acid Increased	Grade 2/moderate	Not related	18 Feb 2021 (Study Day 183) - 19 Feb 2021 (Study Day 184)
Pneumonia	Grade 2/moderate	Not related	18 Feb 2021 (Study Day 183) - 28 Feb 2021 (Study Day 193)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US354-2030 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 20 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 24 Sep 2020 (Study Day 36)
First Dose of Vaccine in Part B: 11 Jan 2021 (Study Day 145)
Second Dose of Vaccine in Part B: 08 Feb 2021 (Study Day 173)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hiatus Hernia/Hiatal Hernia	SAE	Grade 3/ severe	Not related	22 Apr 2021 (Study Day 246) – 23 Apr 2021 (Study Day 247)	Recovered/ resolved
Obesity/Morbid Obesity	SAE	Grade 3/ severe	Not related	22 Apr 2021 (Study Day 246) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US354-2030, a 56-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 11 Jan 2021 (Study Day 145). The second dose was administered in the left arm on 08 Feb 2021 (Study Day 173).

Event Details

On 22 Apr 2021 (Study Day 246), 245 days after the first dose in Part A/101 days after the first dose in Part B and 210 days after the second dose in Part A/73 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of hiatus hernia. Action taken with the IP was not applicable. The event of hiatal hernia lasted for 2 days, after which it was considered to be recovered/resolved on 23 Apr 2021 (Study Day 247). The investigator assessed the event of hiatus hernia to be not related to the IP.

On 22 Apr 2021 (Study Day 246), 245 days after the first dose in Part A/101 days after the first dose in Part B and 210 days after the second dose in Part A/73 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of obesity. Action

taken with the IP was not applicable. The event of morbid obesity was considered to be ongoing. The investigator assessed the event of obesity to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-091319	Obesity

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dental caries	Dental caries	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	1968 - Ongoing
Asthma	Mild intermittent asthma	1975 - Ongoing
Bile duct stent insertion	Common bile duct stent and repair	May 1996 - May 1996
Cholecystectomy	Cholecystectomy	May 1996 - May 1996
Migraine	Infrequent migraine headache	1998 - Ongoing
Diabetes mellitus	Diabetes mellitus	2005 - Ongoing
Osteoarthritis	Osteoarthritis of knees	2010 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2018 - Ongoing
Knee arthroplasty	Left knee replacement due to osteoarthritis	Oct 2019 - Oct 2019
Nephrolithiasis	Renal calculi	23 Jul 2020 (Study Day -28) - 23 Jul 2020 (Study Day -28)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1975 - Ongoing	Mild Asthma
Vitamins nos	1993 - Ongoing	Supplement
Acetylsalicylic acid; caffeine; paracetamol	1998 - Ongoing	Migraine Headache
Sumatriptan	1998 - Ongoing	Migraine Headache
Metformin	2005 - Ongoing	Diabetes Mellitus
Vitamin d nos	2012 - Ongoing	Supplement
Cetirizine hydrochloride	2015 - Ongoing	Seasonal Allergies

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone propionate	2015 - Ongoing	Seasonal Allergies
Pantoprazole	2018 - Ongoing	Gastroesophageal Reflux Disease
Acetylsalicylic acid	Jul 2018 - Ongoing	Cardioprotective
Celecoxib	Mar 2020 - Ongoing	Osteoarthritis
Diphenhydramine hydrochloride	28 Aug 2020 (Study Day 9) - 28 Aug 2020 (Study Day 9)	Insect Bites
Dexamethasone	29 Aug 2020 (Study Day 10) - 03 Sep 2020 (Study Day 15)	Cellulitis
Hydrocortisone	29 Aug 2020 (Study Day 10) - 03 Sep 2020 (Study Day 15)	Cellulitis
Sulfamethoxazole; trimethoprim	29 Aug 2020 (Study Day 10) - 07 Sep 2020 (Study Day 19)	Cellulitis
Ondansetron	04 Sep 2020 (Study Day 16) - 04 Sep 2020 (Study Day 16)	Gastroenteritis (Associated Nausea)
Paracetamol	05 Sep 2020 (Study Day 17) - 05 Sep 2020 (Study Day 17)	Gastroenteritis (Associated Headache)
Clindamycin	23 Sep 2020 (Study Day 35) - 23 Sep 2020 (Study Day 35)	Prophylaxis For Dental Work
Paracetamol	23 Sep 2020 (Study Day 35) - 27 Sep 2020 (Study Day 39)	Pain Management Secondary To Dental Work
Tooth crown replacement*	23 Sep 2020 (Study Day 35) - 23 Sep 2020 (Study Day 35)	Adverse Event
Hydrocodone bitartrate; paracetamol	25 Sep 2020 (Study Day 37) - 27 Sep 2020 (Study Day 39)	Pain Management Secondary To Dental Work
Dental filling replacement*	28 Sep 2020 (Study Day 40) - 28 Sep 2020 (Study Day 40)	Medical History
Influenza vaccine	09 Oct 2020 (Study Day 51) - 09 Oct 2020 (Study Day 51)	Flu Prevention
Acetylsalicylic acid; caffeine; paracetamol	19 Oct 2020 (Study Day 61) - 19 Oct 2020 (Study Day 61)	Tooth Pain
Azithromycin	19 Oct 2020 (Study Day 61) - 19 Oct 2020 (Study Day 61)	Dental Work Prophylaxis
Paracetamol	19 Oct 2020 (Study Day 61) - 19 Oct 2020 (Study Day 61)	Tooth Pain
Tooth crown repair*	19 Oct 2020 (Study Day 61) - 19 Oct 2020 (Study Day 61)	Adverse Event
Upper endoscopy*	17 Feb 2021 (Study Day 182) - 17 Feb 2021 (Study Day 182)	Diagnostic
Diphenhydramine hydrochloride; paracetamol	06 Mar 2021 (Study Day 199) - Ongoing	Pharyngitis
Paracetamol	07 Mar 2021 (Study Day 200) - Ongoing	Pharyngitis
Ibuprofen	09 Mar 2021 (Study Day 202) - 09 Mar 2021 (Study Day 202)	Tooth Pain
Root canal*	09 Mar 2021 (Study Day 202) - 09 Mar 2021 (Study Day 202)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pharyngitis	Grade 2/moderate	Not related	03 Mar 2021 (Study Day 196) - Ongoing
Toothache	Grade 1/mild	Not related	09 Mar 2021 (Study Day 202) - 09 Mar 2021 (Study Day 202)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US354-2053 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 25 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 21 Sep 2020 (Study Day 28)
First Dose of Vaccine in Part B: 08 Jan 2021 (Study Day 137)
Second Dose of Vaccine in Part B: 25 Feb 2021 (Study Day 185)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Flutter/Atrial Flutter	SAE	Grade 3/ severe	Not related	04 Feb 2021 (Study Day 164) – 08 Feb 2021 (Study Day 168)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US354-2053, a 59-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 08 Jan 2021. The participant was unblinded on 08 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 08 Jan 2021 (Study Day 137). The second dose was administered in the left arm on 25 Feb 2021 (Study Day 185).

Event Details

On 04 Feb 2021 (Study Day 164), 163 days after the first dose in Part A/27 days after the first dose in Part B and 136 days after the second dose in Part A/21 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of atrial flutter. The IP dose was delayed due to the atrial flutter. The event of atrial flutter lasted for 5 days, after which it was considered to be recovered/resolved on 08 Feb 2021 (Study Day 168). The investigator assessed the event of atrial flutter to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-013007	Atrial flutter

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Transient ischaemic attack	Transient ischemic attack	Not reported
Rheumatic fever	Rheumatic fever	1970 - Ongoing
Mitral valve replacement	Mitral valve replacement	1984 - 1984
Menopause	Menopause	2013 - Ongoing
Cholecystitis	Cholecystitis	Sep 2019 - Ongoing
Gastritis	Gastritis	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Warfarin	1984 - 04 Feb 2021 (Study Day 164)	Mitral Valve Replacement
Warfarin	1984 - 05 Feb 2021 (Study Day 165)	Mitral Valve Replacement
Famotidine	13 Sep 2020 (Study Day 20) - Ongoing	Gastritis
Omeprazole	13 Sep 2020 (Study Day 20) - Oct 2020	Gastritis
Lidocaine	26 Sep 2020 (Study Day 33) - 02 Oct 2020 (Study Day 39)	Back Pain, Lower
Influenza vaccine	24 Oct 2020 (Study Day 61) - 24 Oct 2020 (Study Day 61)	Flu Prevention
Cholecystectomy*	14 Dec 2020 (Study Day 112) - 14 Dec 2020 (Study Day 112)	Medical History
Cardioversion*	15 Dec 2020 (Study Day 113) - 15 Dec 2020 (Study Day 113)	Adverse Event
Metoprolol	15 Dec 2020 (Study Day 113) - 23 Dec 2020 (Study Day 121)	Atrial Fibrillation
Oxycodone	16 Dec 2020 (Study Day 114) - 16 Dec 2020 (Study Day 114)	Pain Secondary To Cholestectomy
Sacubitril valsartan sodium hydrate	Feb 2021 - Feb 2021	Acute Heart Failure
Acetylsalicylic acid	04 Feb 2021 (Study Day 164) - Ongoing	Cardiac Health/ Stroke Prevention
Atorvastatin	04 Feb 2021 (Study Day 164) - Ongoing	Cardiac Health/ Stroke Prevention
Furosemide	04 Feb 2021 (Study Day 164) - 04 Feb 2021 (Study Day 164)	Acute Heart Failure
Metoprolol	04 Feb 2021 (Study Day 164) - 04 Feb 2021 (Study Day 164)	Atrial Flutter
Metoprolol	04 Feb 2021 (Study Day 164) - 08 Feb 2021 (Study Day 168)	Atrial Flutter

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tte with doppler*	05 Feb 2021 (Study Day 165) - 05 Feb 2021 (Study Day 165)	Adverse Event
Warfarin	05 Feb 2021 (Study Day 165) - 07 Feb 2021 (Study Day 167)	Mitral Valve Replacement
Sotalol	07 Feb 2021 (Study Day 167) - 08 Feb 2021 (Study Day 168)	Atrial Flutter
Tte with doppler*	07 Feb 2021 (Study Day 167) - 07 Feb 2021 (Study Day 167)	Adverse Event
Cardioversion*	08 Feb 2021 (Study Day 168) - 08 Feb 2021 (Study Day 168)	Adverse Event
Sotalol	08 Feb 2021 (Study Day 168) - Ongoing	Atrial Flutter
Warfarin	08 Feb 2021 (Study Day 168) - Ongoing	Mitral Valve Replacement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cardiac Failure Acute	Grade 3/severe	Not related	04 Feb 2021 (Study Day 164) - 08 Feb 2021 (Study Day 168)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US354-2061 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 26 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 23 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 07 Jan 2021 (Study Day 135)
Second Dose of Vaccine in Part B: 04 Feb 2021 (Study Day 163)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pancreatitis Acute/Acute Pancreatitis	SAE	Grade 2/moderate	Not related	06 Apr 2021 (Study Day 224) – 16 Apr 2021 (Study Day 234)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US354-2061, a 69-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 07 Jan 2021. The participant was unblinded on 07 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 07 Jan 2021 (Study Day 135). The second dose was administered in the left arm on 04 Feb 2021 (Study Day 163).

Event Details

On 06 Apr 2021 (Study Day 224), 223 days after the first dose in Part A/89 days after the first dose in Part B and 195 days after the second dose in Part A/61 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of pancreatitis acute. Action taken with the IP was not applicable. The event of acute pancreatitis lasted for 11 days, after which it was considered to be recovered/resolved on 16 Apr 2021 (Study Day 234). The investigator assessed the event of pancreatitis acute to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-082385	Pancreatitis acute

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nephrolithiasis	Nephrolithiasis	Not reported - Ongoing
Blood cholesterol increased	Elevated cholesterol	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Coronary artery disease	Coronary artery disease	2007 - Ongoing
Myocardial infarction	Myocardial infarction	May 2007 - May 2007
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2015 - Ongoing
Botulinum toxin injection	Botox (left under eye	2017 - 2017
Prostate cancer	Prostate cancer	2019 - Ongoing
Hypertonic bladder	Overactive bladder	Aug 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	Not reported - Ongoing	Prevention Of Vitamin C Deficiency
Vitamin d nos	Not reported - Ongoing	Prevention Of Vitamin D Deficiency
Acetylsalicylic acid	2007 - Ongoing	Coronary Artery Disease
Amlodipine besilate; benazepril hydrochloride	2007 - 15 Apr 2021 (Study Day 233)	Hypertension
Atorvastatin	2007 - Ongoing	Elevated Cholesterol
Fluticasone propionate	2010 - Ongoing	Seasonal Allergies
Leuporelin acetate	08 Jul 2020 (Study Day -49) - 08 Jul 2020 (Study Day -49)	Prostate Cancer
Metformin	27 Jul 2020 (Study Day -30) - Ongoing	Diabetes
Mirabegron	Aug 2020 - Ongoing	Overactive Bladder
Bicalutamide	18 Aug 2020 (Study Day -8) - 13 Apr 2021 (Study Day 231)	Prostate Cancer
Influenza vaccine	23 Oct 2020 (Study Day 59) - 23 Oct 2020 (Study Day 59)	Flu Prevention
Ibuprofen	10 Jan 2021 (Study Day 138) - 17 Jan 2021 (Study Day 145)	Nephrolithiasis
Tramadol	15 Jan 2021 (Study Day 143) - 17 Jan 2021 (Study Day 145)	Nephrolithiasis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cefazolin	09 Feb 2021 (Study Day 168) - 09 Feb 2021 (Study Day 168)	Pre-Procedure Infection Prophylaxis
Dexamethasone	09 Feb 2021 (Study Day 168) - 09 Feb 2021 (Study Day 168)	Nephrolithotomy / Stent Placement
Ephedrine	09 Feb 2021 (Study Day 168) - 09 Feb 2021 (Study Day 168)	Nephrolithotomy / Stent Placement
Etomidate	09 Feb 2021 (Study Day 168) - 09 Feb 2021 (Study Day 168)	Nephrolithotomy / Stent Placement
Fentanyl	09 Feb 2021 (Study Day 168) - 09 Feb 2021 (Study Day 168)	Nephrolithotomy / Stent Placement
Lidocaine	09 Feb 2021 (Study Day 168) - 09 Feb 2021 (Study Day 168)	Nephrolithotomy / Stent Placement
Nephrolithotomy and right ureteral stent placement*	09 Feb 2021 (Study Day 168) - 09 Feb 2021 (Study Day 168)	Adverse Event
Ondansetron	09 Feb 2021 (Study Day 168) - 09 Feb 2021 (Study Day 168)	Nephrolithotomy / Stent Placement
Phenylephrine	09 Feb 2021 (Study Day 168) - 09 Feb 2021 (Study Day 168)	Nephrolithotomy / Stent Placement
Propofol	09 Feb 2021 (Study Day 168) - 09 Feb 2021 (Study Day 168)	Nephrolithotomy / Stent Placement
Rocuronium	09 Feb 2021 (Study Day 168) - 09 Feb 2021 (Study Day 168)	Nephrolithotomy / Stent Placement
Suxamethonium	09 Feb 2021 (Study Day 168) - 09 Feb 2021 (Study Day 168)	Nephrolithotomy / Stent Placement
Ibuprofen	10 Feb 2021 (Study Day 169) - 16 Feb 2021 (Study Day 175)	Nephrolithiasis
Oxycodone	10 Feb 2021 (Study Day 169) - 11 Feb 2021 (Study Day 170)	Nephrolithiasis
Paracetamol	10 Feb 2021 (Study Day 169) - Ongoing	Nephrolithiasis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nephrolithiasis	Grade 3/severe	Not related	09 Jan 2021 (Study Day 137) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US354-2131 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 02 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 07 Oct 2020 (Study Day 36)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Ileus/Ileus	SAE	Grade 3/ severe	Not related	05 Apr 2021 (Study Day 216) – 10 Apr 2021 (Study Day 221)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US354-2131, a 71-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 25 Jan 2021. The participant was unblinded on 25 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 05 Apr 2021 (Study Day 216), 215 days after the first dose in Part A and 180 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of ileus. Action taken with the IP was not applicable. The event of ileus lasted for 6 days, after which it was considered to be recovered/resolved on 10 Apr 2021 (Study Day 221). The investigator assessed the event of ileus to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-074474	Ileus

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cataract	Bilateral cataracts	Not reported - 03 Oct 2018 (Study Day -700)
Cervical radiculopathy	Cervical radiculopathy	Not reported - Ongoing
Endometriosis	Endometriosis	Not reported - Ongoing
Colitis ulcerative	Ulcerative colitis	1961 - Ongoing
Ileostomy	Ileostomy	1961 - 1961
Female sterilisation	Bilateral tubal ligation	Dec 1989 - Dec 1989
Blood triglycerides increased	Elevated triglycerides	2000 - Ongoing
Osteoporosis	Osteoporosis	2000 - 2008
Osteopenia	Osteopenia	2008 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gemfibrozil	2000 - Ongoing	Elevated Triglycerides
Paracetamol	02 Sep 2020 (Study Day 1) - 02 Sep 2020 (Study Day 1)	Injection Site Pain
Paracetamol	07 Oct 2020 (Study Day 36) - 08 Oct 2020 (Study Day 37)	Injection Site Pain
Influenza vaccine	28 Oct 2020 (Study Day 57) - 28 Oct 2020 (Study Day 57)	Flu Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US354-2332 (Part B)
Vaccination Group: mRNA-1273 in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 09 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: Not Administered
First Dose of Vaccine in Part B: 04 Feb 2021 (Study Day 119)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Seizure/Worsening Of Seizure Disorder	SAE	Grade 3/ severe	Not related	12 Apr 2021 (Study Day 186) – 13 Apr 2021 (Study Day 187)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US354-2332, a 56-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 09 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Feb 2021. The participant was unblinded on 04 Feb 2021 and consented to receive the second dose of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 04 Feb 2021 (Study Day 119). The second dose was not administered.

Event Details

On 12 Apr 2021 (Study Day 186), 185 days after the first dose in Part A/67 days after the first dose in Part B of the IP (second dose Part A not applicable/second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of seizure. Action taken with the IP was not applicable. The event of worsening of seizure disorder lasted for 2 days, after which it was considered to be recovered/resolved on 13 Apr 2021 (Study Day 187). The investigator assessed the event of seizure to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-000714	Seizure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seizure	Seizure disorder	Feb 1998 - Ongoing
Hypertension	Hypertension	2012 - Ongoing
Blood cholesterol increased	High cholesterol	2015 - Ongoing
Osteoarthritis	Right hand osteoarthritis	2015 - Ongoing
Cerebrovascular accident	Cva	Jan 2019 - Jan 2019
Hemiparesis	L sided weakness secondary to cva	Jan 2019 - Ongoing
Implantable cardiac monitor insertion	Implanted cardiac monitor to detect arrhythmias	Jan 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	2014 - Ongoing	Seizure Disorder
Levetiracetam	2014 - 06 Nov 2020 (Study Day 29)	Seizure Disorder
Lisinopril	2014 - Ongoing	Hypertension
Acetylsalicylic acid	2018 - Ongoing	Stroke Prevention
Simvastatin	2018 - Ongoing	High Cholesterol
Apixaban	Jan 2020 - Ongoing	Stroke Prevention
Zonisamide	Feb 2020 - Ongoing	Seizure Disorder
Influenza vaccine	04 Nov 2020 (Study Day 27) - 04 Nov 2020 (Study Day 27)	Influenza Prevention
Levetiracetam	07 Nov 2020 (Study Day 30) - 09 Nov 2020 (Study Day 32)	Seizure Disorder
Levetiracetam	07 Nov 2020 (Study Day 30) - 07 Nov 2020 (Study Day 30)	Worsening Seizure Disorder (Loading Dose)
Lorazepam	07 Nov 2020 (Study Day 30) - 07 Nov 2020 (Study Day 30)	Worsening Seizure Disorder
Paracetamol	07 Nov 2020 (Study Day 30) - 09 Nov 2020 (Study Day 32)	Right Hand Osteoarthritis
Vitamins nos	07 Nov 2020 (Study Day 30) - 09 Nov 2020 (Study Day 32)	Health Maintenance
Carbamazepine	08 Nov 2020 (Study Day 31) - Ongoing	Seizure Disorder
Carbamazepine	09 Nov 2020 (Study Day 32) - 09 Nov 2020 (Study Day 32)	Worsening Seizure Disorder

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	09 Nov 2020 (Study Day 32) - Ongoing	Right Hand Osteoarthritis
Levetiracetam	09 Nov 2020 (Study Day 32) - Ongoing	Seizure Disorder
Levetiracetam	21 Jan 2021 (Study Day 105) - 21 Jan 2021 (Study Day 105)	Breakthrough Seizure
Ct head*	02 Mar 2021 (Study Day 145) - 02 Mar 2021 (Study Day 145)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dizziness	Grade 2/moderate	Not related	02 Mar 2021 (Study Day 145) - 02 Mar 2021 (Study Day 145)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US355-2005 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 11 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 07 Sep 2020 (Study Day 28)
First Dose of Vaccine in Part B: 27 Jan 2021 (Study Day 170)
Second Dose of Vaccine in Part B: 22 Feb 2021 (Study Day 196)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Anaemia/Severe Anemia	SAE	Grade 4	Not related	07 Mar 2021 (Study Day 209) – 12 Mar 2021 (Study Day 214)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2005, a 65-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 07 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 27 Jan 2021. The participant was unblinded on 27 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 27 Jan 2021 (Study Day 170). The second dose was administered in the left arm on 22 Feb 2021 (Study Day 196).

Event Details

On 07 Mar 2021 (Study Day 209), 208 days after the first dose in Part A/39 days after the first dose in Part B and 181 days after the second dose in Part A/13 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of anaemia. Action taken with the IP was not applicable. The event of severe anemia lasted for 6 days, after which it was considered to be recovered/resolved on 12 Mar 2021 (Study Day 214). The investigator assessed the event of anaemia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-053481	Anaemia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cholelithiasis	Cholelithiasis	Not reported - 2016
Chronic gastritis	Chronic gastritis	Not reported - Ongoing
Ischaemic cardiomyopathy	Ischemic cardiomyopathy	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	1965 - Ongoing
Testicular cyst	Benign cyst testicular	1973 - 1973
Intervertebral disc protrusion	L5 disk herniation	1982 - 1982
Hypertension	Hypertension	1985 - Ongoing
Skin cyst excision	Left neck benign cyst removal	1985 - 1985
Hypercholesterolaemia	Hypercholesterolemia	1995 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	1997 - Ongoing
Intervertebral disc degeneration	C-3 degenerative disk disease	2000 - Ongoing
Intervertebral disc degeneration	T-3 degenerative disk disease	2000 - Ongoing
Coronary artery bypass	Quadruple bypass	2002 - 2002
Atrial fibrillation	Atrial fibrillation	2008 - Ongoing
Pulmonary hypertension	Pulmonary hypertension	2009 - Ongoing
Cholecystectomy	Cholecystectomy	2016 - 2016

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Spironolactone	1985 - Ongoing	Hypertension
Atorvastatin	1995 - Ongoing	Hypercholesterolemia
Metformin	1997 - Ongoing	Type 2 Diabetes
Liraglutide	1998 - 08 Mar 2021 (Study Day 210)	Type 2 Diabetes
Enalaprilat	2000 - Ongoing	Hypertension
Nebivolol hydrochloride	2000 - Ongoing	Hypertension
Furosemide	2004 - 08 Mar 2021 (Study Day 210)	Hypertension
Apixaban	2008 - 08 Mar 2021 (Study Day 210)	Atrial Fibrillation
Ambrisentan	Jan 2020 - Ongoing	Pulmonary Hypertension
Tadalafil	Jan 2020 - 08 Mar 2021 (Study Day 210)	Pulmonary Hypertension
Influenza vaccine	21 Sep 2020 (Study Day 42) - 21 Sep 2020 (Study Day 42)	Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pneumococcal vaccine	05 Oct 2020 (Study Day 56) - 05 Oct 2020 (Study Day 56)	Pneumonia Prophylactic
Colonoscopy*	07 Mar 2021 (Study Day 209) - 07 Mar 2021 (Study Day 209)	Adverse Event
Excision of internal and external hemorrhoids*	07 Mar 2021 (Study Day 209) - 07 Mar 2021 (Study Day 209)	Adverse Event
Upper gi endoscopy*	07 Mar 2021 (Study Day 209) - 07 Mar 2021 (Study Day 209)	Adverse Event
Red blood cells, concentrated	08 Mar 2021 (Study Day 210) - 12 Mar 2021 (Study Day 214)	Severe Anemia, Lightheadedness, Shortness Of Breath, Fatigue
Ferrous sulfate	12 Mar 2021 (Study Day 214) - Ongoing	Health
Furosemide	12 Mar 2021 (Study Day 214) - Ongoing	Acute Hypoxic Respiratory Failure
Hydrocodone bitartrate; paracetamol	12 Mar 2021 (Study Day 214) - Ongoing	Rectal Pain, Excision Of Internal And External Hemorrhoids
Lidocaine	12 Mar 2021 (Study Day 214) - Ongoing	Rectal Pain
Liraglutide	12 Mar 2021 (Study Day 214) - Ongoing	Type 2 Diabetes
Metformin	12 Mar 2021 (Study Day 214) - Ongoing	Type II Diabetes
Pantoprazole	12 Mar 2021 (Study Day 214) - Ongoing	Chronic Gastritis
Tadalafil	12 Mar 2021 (Study Day 214) - Ongoing	Pulmonary Hypertension
Tamsulosin	12 Mar 2021 (Study Day 214) - Ongoing	Acute Renal Failure
Apixaban	17 Mar 2021 (Study Day 219) - Ongoing	Atrial Fibrillation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dizziness	Grade 2/moderate	Not related	01 Mar 2021 (Study Day 203) - 12 Mar 2021 (Study Day 214)
Dyspnoea	Grade 2/moderate	Not related	01 Mar 2021 (Study Day 203) - 12 Mar 2021 (Study Day 214)
Fatigue	Grade 2/moderate	Not related	01 Mar 2021 (Study Day 203) - 12 Mar 2021 (Study Day 214)
Haemorrhoids	Grade 3/severe	Not related	07 Mar 2021 (Study Day 209) - 12 Mar 2021 (Study Day 214)
Haemorrhoids	Grade 3/severe	Not related	07 Mar 2021 (Study Day 209) - 12 Mar 2021 (Study Day 214)
Acute Kidney Injury	Grade 3/severe	Not related	08 Mar 2021 (Study Day 210) - 12 Mar 2021 (Study Day 214)
Acute Respiratory Failure	Grade 3/severe	Not related	08 Mar 2021 (Study Day 210) - 12 Mar 2021 (Study Day 214)
Proctalgia	Grade 2/moderate	Not related	08 Mar 2021 (Study Day 210) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US355-2010 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 12 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 07 Sep 2020 (Study Day 27)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Goitre/Thyroid Goiter	SAE	Grade 4	Not related	16 Mar 2021 (Study Day 217) – 01 Apr 2021 (Study Day 233)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2010, a 65-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 07 Sep 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 16 Mar 2021 (Study Day 217), 216 days after the first dose in Part A and 190 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of goitre. Action taken with the IP was not applicable. The event of thyroid goiter lasted for 17 days, after which it was considered to be recovered/resolved on 01 Apr 2021 (Study Day 233). The investigator assessed the event of goitre to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-053539	Goitre

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Goitre	Thyroid goiter	Not reported - Ongoing
Osteoarthritis	Bilateral knee osteoarthritis	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	1985 - Ongoing
Drug hypersensitivity	Sulfa allergy	1998 - Ongoing
Anxiety	Anxiety	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Tachycardia	Tachycardia	2000 - Ongoing
Asthma	Asthma	2001 - Ongoing
Basal cell carcinoma	Basal cell carcinoma	2001 - 2001
Postmenopause	Post menopausal	2005 - Ongoing
Arthroscopic surgery	Bilateral arthroscopic knee surgery	2008 - 2008
Hypercholesterolaemia	Hypercholesterolemia	2013 - Ongoing
Insomnia	Insomnia	2014 - Ongoing
Knee arthroplasty	Bilateral knee replacement	Apr 2017 - Apr 2017
Restless legs syndrome	Bilateral restless leg syndrome	Sep 2017 - Ongoing
Basal cell carcinoma	Basal cell carcinoma	Aug 2019 - Aug 2019
Herpes zoster	Shingles	Feb 2020 - Mar 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	Not reported - Ongoing	Osteoarthritis
Paracetamol	Not reported - Ongoing	Osteoarthritis
Diltiazem	2000 - Ongoing	Hypertension
Calcium carbonate	2005 - Ongoing	Health
Losartan	2005 - Ongoing	Hypertension
Cetirizine hydrochloride	2010 - Ongoing	Seasonal Allergies
Atorvastatin	2013 - Ongoing	High Cholesterol
Colecalciferol	2013 - Ongoing	Health
Hydrochlorothiazide	2013 - Ongoing	Hypertension
Alprazolam	2014 - Ongoing	Anxiety
Vitamins nos	2015 - Ongoing	Health
Melatonin	2017 - Ongoing	Insomnia
Ropinirole	Sep 2017 - Ongoing	Restless Leg Syndrome
Spironolactone	2019 - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Duloxetine	Jul 2019 - Ongoing	Anxiety
Bupropion	Sep 2019 - Ongoing	Anxiety
Budesonide; formoterol fumarate	Feb 2020 - 11 Aug 2020 (Study Day -1)	Asthma
Phenylephrine hydrochloride	Feb 2020 - Ongoing	Seasonal Allergies
Paracetamol	12 Aug 2020 (Study Day 1) - 13 Aug 2020 (Study Day 2)	Pain- Injection Site
Ibuprofen	07 Sep 2020 (Study Day 27) - 08 Sep 2020 (Study Day 28)	Injection Site Pain
Paracetamol	07 Sep 2020 (Study Day 27) - 08 Sep 2020 (Study Day 28)	Injection Site Pain
Influenza vaccine	27 Sep 2020 (Study Day 47) - 27 Sep 2020 (Study Day 47)	Influenza Prophylaxis
Prednisone	02 Feb 2021 (Study Day 175) - 04 Feb 2021 (Study Day 177)	Nerve Compression
Prednisone	05 Feb 2021 (Study Day 178) - 07 Feb 2021 (Study Day 180)	Nerve Compression
Carvedilol	06 Feb 2021 (Study Day 179) - 16 Mar 2021 (Study Day 217)	Hypertension, Worsening Hypertension
Prednisone	08 Feb 2021 (Study Day 181) - 09 Feb 2021 (Study Day 182)	Nerve Compression
Prednisone	10 Feb 2021 (Study Day 183) - 12 Feb 2021 (Study Day 185)	Nerve Compression
Aminophylline	17 Mar 2021 (Study Day 218) - 17 Mar 2021 (Study Day 218)	Pulmonary Nodule

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 2/moderate	Not related	25 Jan 2021 (Study Day 167) - Ongoing
Nerve Compression	Grade 2/moderate	Not related	25 Jan 2021 (Study Day 167) - Ongoing
Pulmonary Mass	Grade 1/mild	Not related	16 Mar 2021 (Study Day 217) - 24 Mar 2021 (Study Day 225)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US355-2232 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 29 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: Not Administered
First Dose of Vaccine in Part B: 26 Feb 2021 (Study Day 182)
Second Dose of Vaccine in Part B: 25 Mar 2021 (Study Day 209)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardiac Failure Congestive/Congestive Heart Failure	SAE	Grade 4	Not related	04 Apr 2021 (Study Day 219) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2232, a 70-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 29 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 26 Feb 2021. The participant was unblinded on 26 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 26 Feb 2021 (Study Day 182). The second dose was administered in the left arm on 25 Mar 2021 (Study Day 209).

Event Details

On 04 Apr 2021 (Study Day 219), 218 days after the first dose in Part A/37 days after the first dose in Part B and second dose Part A not applicable/10 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of cardiac failure congestive. Action taken with the IP was not applicable. The event of congestive heart failure was considered to be ongoing. The investigator assessed the event of cardiac failure congestive to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-069517	Cardiac failure congestive

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Exposure to communicable disease	Tuberculosis exposure	Not reported
Urinary tract infection	Recurrent urinary tract infections	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	1951 - Ongoing
Joint dislocation	Right shoulder dislocation	1975 - 1975
Hypertension	Hypertension	1992 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	1992 - Ongoing
Depression	Depression	13 Jun 2008 (Study Day -4460) - Ongoing
Insomnia	Insomnia	2010 - Ongoing
Gastritis	Gastritis	10 Oct 2011 (Study Day -3246) - 31 Oct 2011 (Study Day -3225)
Helicobacter infection	H. pylori infection	12 Oct 2011 (Study Day -3244) - 31 Oct 2011 (Study Day -3225)
Chronic kidney disease	Chronic kidney disease	24 Jan 2012 (Study Day -3140) - Ongoing
Coronary artery disease	Coronary artery disease	2013 - Ongoing
Cellulitis	Right lower extremity cellulitis	08 Jan 2014 (Study Day -2425) - Not reported
Pulmonary embolism	Pulmonary embolism	08 Jan 2014 (Study Day -2425) - 18 Jan 2014 (Study Day -2415)
Pyuria	Pyuria	08 Jan 2014 (Study Day -2425) - 18 Jan 2014 (Study Day -2415)
Iron deficiency anaemia	Iron deficiency anemia	13 Jan 2014 (Study Day -2420) - Ongoing
Diabetic neuropathy	Sensory diabetic neuropathy	21 Jul 2014 (Study Day -2231) - Ongoing
Back pain	Low back pain	2015 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Mitral valve incompetence	Mitral valve regurgitation	28 Apr 2016 (Study Day -1584) - Ongoing
Staphylococcus test positive	Mrsa positive	2017 - 2017
Coronary arterial stent insertion	Coronary artery stent	20 Apr 2018 (Study Day -862) - 20 Apr 2018 (Study Day -862)
Diabetic retinopathy	Diabetic retinopathy left eye	2019 - Ongoing
Lens disorder	Left lens erosion	2019 - Ongoing
Colon adenoma	Adenomatous colon polyp	17 Jun 2019 (Study Day -439) - 17 Jun 2019 (Study Day -439)
Colonoscopy	Colonoscopy	17 Jun 2019 (Study Day -439) - 17 Jun 2019 (Study Day -439)
Diverticulum intestinal	Diverticulosis of colon	17 Jun 2019 (Study Day -439) - 30 Jun 2019 (Study Day -426)
Benign prostatic hyperplasia	Benign prostatic hypertrophy	Nov 2019 - Ongoing
Urinary retention	Urinary retention	Nov 2019 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myocardial infarction	Myocardial infarction	01 Nov 2019 (Study Day -302) - 01 Nov 2019 (Study Day -302)
Wound	Wound right elbow	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Trazodone	2010 - Ongoing	Insomnia
Acetylsalicylic acid	2013 - 25 Sep 2020 (Study Day 28)	Coronary Artery Disease
Amlodipine	2013 - 15 Oct 2020 (Study Day 48)	Coronary Artery Disease
Clopidogrel bisulfate	2013 - 08 Oct 2020 (Study Day 41)	Coronary Artery Disease
Atorvastatin	2015 - Ongoing	Hyperlipidemia
Metformin	2015 - 08 Oct 2020 (Study Day 41)	Type 2 Diabetes
Liraglutide	2017 - Ongoing	Type 2 Diabetes
Insulin glargine	2018 - Ongoing	Type 2 Diabetes
Finasteride	Nov 2019 - Ongoing	Benign Prostatic Hypertension
Hydralazine	Feb 2020 - 29 Mar 2021 (Study Day 213)	Hypertension
Tamsulosin hydrochloride	Feb 2020 - Ongoing	Urinary Retention
Chlorphenamine maleate; dextromethorphan hydrobromide	22 Sep 2020 (Study Day 25) - 26 Sep 2020 (Study Day 29)	Seasonal Allergies/Nasal Congestion
Acetylsalicylic acid	26 Sep 2020 (Study Day 29) - 26 Sep 2020 (Study Day 29)	Non-St Elevated Myocardial Infarction
Azithromycin	26 Sep 2020 (Study Day 29) - 28 Sep 2020 (Study Day 31)	Pneumonia, Respiratory Failure
Ceftriaxone	26 Sep 2020 (Study Day 29) - 28 Sep 2020 (Study Day 31)	Pneumonia, Respiratory Failure
Dexamethasone	26 Sep 2020 (Study Day 29) - 27 Sep 2020 (Study Day 30)	Pneumonia, Respiratory Failure
Enoxaparin sodium	26 Sep 2020 (Study Day 29) - 28 Sep 2020 (Study Day 31)	Coagulation Prophylaxis
Insulin aspart	26 Sep 2020 (Study Day 29) - 08 Oct 2020 (Study Day 41)	Type 2 Diabetes
Magnesium	26 Sep 2020 (Study Day 29) - 26 Sep 2020 (Study Day 29)	Hypomagnesia
Acetylsalicylic acid	27 Sep 2020 (Study Day 30) - Ongoing	Coronary Artery Disease
Benzonatate	27 Sep 2020 (Study Day 30) - 29 Sep 2020 (Study Day 32)	Cough
Ondansetron	27 Sep 2020 (Study Day 30) - 27 Sep 2020 (Study Day 30)	Nausea
Levofloxacin	28 Sep 2020 (Study Day 31) - 28 Sep 2020 (Study Day 31)	Pneumonia, Respiratory Failure
Dextromethorphan hydrobromide; guaifenesin	29 Sep 2020 (Study Day 32) - 08 Oct 2020 (Study Day 41)	Pneumonia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrocodone bitartrate; paracetamol	29 Sep 2020 (Study Day 32) - 01 Oct 2020 (Study Day 34)	Pneumonia
Bronchoscopy*	30 Sep 2020 (Study Day 33) - 30 Sep 2020 (Study Day 33)	Diagnostic
Levosulbutamol	30 Sep 2020 (Study Day 33) - 02 Oct 2020 (Study Day 35)	Pneumonia, Respiratory Failure
Lidocaine	30 Sep 2020 (Study Day 33) - 30 Sep 2020 (Study Day 33)	Bronchoscopy
Salbutamol	30 Sep 2020 (Study Day 33) - 30 Sep 2020 (Study Day 33)	Bronchoscopy
Diltiazem	01 Oct 2020 (Study Day 34) - 01 Oct 2020 (Study Day 34)	Paroxysmal Atrial Fibrillation
Enoxaparin sodium	01 Oct 2020 (Study Day 34) - 02 Oct 2020 (Study Day 35)	Coronary Artery Disease
Prednisone	02 Oct 2020 (Study Day 35) - 15 Oct 2020 (Study Day 48)	Pneumonia, Respiratory Failure
Amiodarone	05 Oct 2020 (Study Day 38) - 05 Oct 2020 (Study Day 38)	Paroxysmal Atrial Fibrillation
Amiodarone	05 Oct 2020 (Study Day 38) - 06 Oct 2020 (Study Day 39)	Paroxysmal Atrial Fibrillation
Digoxin	05 Oct 2020 (Study Day 38) - 05 Oct 2020 (Study Day 38)	Paroxysmal Atrial Fibrillation
Amiodarone	06 Oct 2020 (Study Day 39) - Ongoing	Paroxysmal Atrial Fibrillation
Apixaban	08 Oct 2020 (Study Day 41) - Ongoing	Paroxysmal Atrial Fibrillation
Furosemide	08 Oct 2020 (Study Day 41) - 08 Oct 2020 (Study Day 41)	Hypertension
Metoprolol	08 Oct 2020 (Study Day 41) - Ongoing	Atrial Fibrillation
Venlafaxine hydrochloride	08 Oct 2020 (Study Day 41) - Ongoing	Depression
Amiodarone	15 Oct 2020 (Study Day 48) - 15 Oct 2020 (Study Day 48)	Paroxysmal Atrial Fibrillation
Benzonatate	15 Oct 2020 (Study Day 48) - 20 Nov 2020 (Study Day 84)	Cough
Diltiazem	15 Oct 2020 (Study Day 48) - 15 Oct 2020 (Study Day 48)	Paroxysmal Atrial Fibrillation
Enoxaparin sodium	15 Oct 2020 (Study Day 48) - 17 Oct 2020 (Study Day 50)	Coronary Artery Disease
Insulin aspart	16 Oct 2020 (Study Day 49) - 17 Oct 2020 (Study Day 50)	Diabetes Type 2
Prednisone	17 Oct 2020 (Study Day 50) - 24 Oct 2020 (Study Day 57)	Pneumonia, Respiratory Failure
Prednisone	25 Oct 2020 (Study Day 58) - 01 Nov 2020 (Study Day 65)	Pneumonia
Influenza vaccine	14 Dec 2020 (Study Day 108) - 14 Dec 2020 (Study Day 108)	Influenza Prophylaxis
Codeine phosphate; paracetamol	Jan 2021 - 29 Mar 2021 (Study Day 213)	Back Pain
Chlorphenamine maleate; dextromethorphan hydrobromide	18 Jan 2021 (Study Day 143) - 01 Feb 2021 (Study Day 157)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US355-2355 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 05 Oct 2020 (Study Day 28)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Lower Limb Fracture/Open Fracture Of Right Fibula With Displaced Fracture Of Right Tibia	SAE	Grade 4	Not related	25 Mar 2021 (Study Day 199) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2355, a 53-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 05 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Jan 2021. The participant was unblinded on 21 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 25 Mar 2021 (Study Day 199), 198 days after the first dose in Part A and 171 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of lower limb fracture. Action taken with the IP was not applicable. The event of open fracture of right fibula with displaced fracture of right tibia was considered to be ongoing. The investigator assessed the event of lower limb fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-068013	Fibula fracture
MOD-2021-068013	Tibia fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Patella fracture	Chronic ununited fractures of patella	Not reported - Ongoing
Tibia fracture	Chronic ununited fractures of proximal tibia	Not reported - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	Jun 2002 - Ongoing
Endometrial ablation	Uterine ablation	Oct 2007 - Oct 2007
Postmenopause	Post-menopausal	Oct 2007 - Ongoing
Anxiety	Anxiety	Mar 2009 - Ongoing
Facial bones fracture	Left periorbital fracture	Mar 2016 - Mar 2016
Hypertension	Hypertension	Oct 2016 - Ongoing
Seasonal allergy	Seasonal allergies	Oct 2016 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit disorder	Nov 2019 - Ongoing
Psoriatic arthropathy	Psoriatic arthritis	Feb 2020 - Ongoing
Carpal tunnel syndrome	Right carpal tunnel syndrome	Apr 2020 - Apr 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Spironolactone	Not reported - Ongoing	Hypertension
Trazodone	Not reported - Ongoing	Anxiety
Atorvastatin	Jun 2002 - Ongoing	Hypercholesterolemia
Colecalciferol	Jun 2002 - Ongoing	Health
Venlafaxine	Mar 2009 - Ongoing	Anxiety
Other dermatologicals	2016 - Ongoing	Post Left Periorbital Fracture
Chlortalidone	Oct 2016 - Ongoing	Hypertension
Lisinopril	Oct 2016 - Ongoing	Hypertension
Fish oil	Jan 2018 - Ongoing	Health
Lisdexamfetamine mesilate	Nov 2019 - Ongoing	Attention Deficit Disorder
Clobetasol	Feb 2020 - Ongoing	Psoriatic Arthritis
Cetirizine hydrochloride	21 Sep 2020 (Study Day 14) - 08 Oct 2020 (Study Day 31)	Seasonal Allergies
Paracetamol	21 Sep 2020 (Study Day 14) - 21 Sep 2020 (Study Day 14)	Seasonal Allergies/Headache

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	06 Oct 2020 (Study Day 29) - 06 Oct 2020 (Study Day 29)	Injection Site Pain
Diphenhydramine hydrochloride	07 Oct 2020 (Study Day 30) - 07 Oct 2020 (Study Day 30)	Swollen Eyes
Influenza vaccine	26 Oct 2020 (Study Day 49) - 26 Oct 2020 (Study Day 49)	Influenza Prophylaxis
Bifidobacterium infantis	01 Feb 2021 (Study Day 147) - Ongoing	Health Promotion
Doxycycline	24 Feb 2021 (Study Day 170) - 10 Mar 2021 (Study Day 184)	Dermatitis Around Base Of Nose
Apixaban	25 Mar 2021 (Study Day 199) - 17 Apr 2021 (Study Day 222)	Open Reduction Internal Fixation
Calcium chloride; potassium chloride; sodium lactate	25 Mar 2021 (Study Day 199) - 25 Mar 2021 (Study Day 199)	Open Reduction Internal Fixation
Cefalexin	25 Mar 2021 (Study Day 199) - Ongoing	Open Reduction Internal Fixation
Cefazolin	25 Mar 2021 (Study Day 199) - 25 Mar 2021 (Study Day 199)	Open Reduction Internal Fixation
Dexamethasone	25 Mar 2021 (Study Day 199) - 25 Mar 2021 (Study Day 199)	Open Reduction Internal Fixation
Dexmedetomidine	25 Mar 2021 (Study Day 199) - 25 Mar 2021 (Study Day 199)	Open Reduction Internal Fixation
Fentanyl	25 Mar 2021 (Study Day 199) - 25 Mar 2021 (Study Day 199)	Open Reduction Internal Fixation
Hydromorphone	25 Mar 2021 (Study Day 199) - 25 Mar 2021 (Study Day 199)	Open Reduction Internal Fixation
Lidocaine	25 Mar 2021 (Study Day 199) - 25 Mar 2021 (Study Day 199)	Open Reduction Internal Fixation
Magnesium sulfate	25 Mar 2021 (Study Day 199) - 25 Mar 2021 (Study Day 199)	Open Reduction Internal Fixation
Midazolam	25 Mar 2021 (Study Day 199) - 25 Mar 2021 (Study Day 199)	Open Reduction Internal Fixation
Morphine	25 Mar 2021 (Study Day 199) - 25 Mar 2021 (Study Day 199)	Open Reduction Internal Fixation
Ondansetron	25 Mar 2021 (Study Day 199) - 25 Mar 2021 (Study Day 199)	Open Reduction Internal Fixation
Open reduction internal fixation*	25 Mar 2021 (Study Day 199) - 25 Mar 2021 (Study Day 199)	Adverse Event
Oxycodone	25 Mar 2021 (Study Day 199) - Ongoing	Open Reduction Internal Fixation
Paracetamol	25 Mar 2021 (Study Day 199) - Ongoing	Open Reduction Internal Fixation
Propofol	25 Mar 2021 (Study Day 199) - 25 Mar 2021 (Study Day 199)	Open Reduction Internal Fixation
Rocuronium	25 Mar 2021 (Study Day 199) - 25 Mar 2021 (Study Day 199)	Open Reduction Internal Fixation
Sennoside a+b	25 Mar 2021 (Study Day 199) - Ongoing	Open Reduction Internal Fixation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Perioral Dermatitis	Grade 2/moderate	Not related	24 Feb 2021 (Study Day 170) - 10 Mar 2021 (Study Day 184)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US355-2386 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 13 Oct 2020 (Study Day 35)
First Dose of Vaccine in Part B: 14 Jan 2021 (Study Day 128)
Second Dose of Vaccine in Part B: 08 Feb 2021 (Study Day 153)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Retinal Tear/Right Eye Retinal Tear	SAE	Grade 4	Not related	29 Mar 2021 (Study Day 202) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2386, a 57-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 13 Oct 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 14 Jan 2021 (Study Day 128). The second dose was administered in the left arm on 08 Feb 2021 (Study Day 153).

Event Details

On 29 Mar 2021 (Study Day 202), 201 days after the first dose in Part A/74 days after the first dose in Part B and 167 days after the second dose in Part A/49 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of retinal tear. Action taken with the IP was not applicable. The event of right eye retinal tear was considered to be ongoing. The investigator assessed the event of retinal tear to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-073388	Retinal tear

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypermetropia	Hyperopia	Not reported - Ongoing
Strabismus	Strabismus	Not reported
Myalgia	Generalized myalgia	1980 - Ongoing
Seizure	Seizures	1985 - Ongoing
Rubber sensitivity	Allergy to latex	1988 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	1989 - Ongoing
Migraine with aura	Migraines with aura	1989 - Ongoing
Seasonal allergy	Seasonal allergies	1989 - Ongoing
Back pain	Chronic back pain	2000 - Ongoing
Transient ischaemic attack	Transient ischemic attack	2003 - 2004
Dysfunctional uterine bleeding	Dysfunctional uterine bleeding	2010 - 2010
Hysterectomy	Hysterectomy	2010 - 2010
Palpitations	Heart palpitations	2012 - Ongoing
Anaemia	Anemia	Nov 2018 - Feb 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	1980 - 06 Sep 2020 (Study Day -3)	Generalized Myalgia
Fluticasone propionate	1990 - Ongoing	Seasonal Allergies
Oxcarbazepine	2010 - Ongoing	Seizures
Fexofenadine hydrochloride	2017 - Ongoing	Seasonal Allergies
Calcium; vitamin d nos	01 Oct 2018 (Study Day -709) - Ongoing	Health Promotion
Vitamins nos	2019 - Ongoing	Health Promotion
Influenza vaccine	24 Sep 2020 (Study Day 16) - 24 Sep 2020 (Study Day 16)	Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US356-2228 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 14 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 11 Nov 2020 (Study Day 29)
First Dose of Vaccine in Part B: 29 Jan 2021 (Study Day 108)
Second Dose of Vaccine in Part B: 25 Feb 2021 (Study Day 135)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia/Bilateral Pneumonia	SAE	Grade 3/ severe	Not related	12 Mar 2021 (Study Day 150) – 25 Mar 2021 (Study Day 163)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US356-2228, a 69-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 14 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 11 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 29 Jan 2021. The participant was unblinded on 29 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 29 Jan 2021 (Study Day 108). The second dose was administered in the left arm on 25 Feb 2021 (Study Day 135).

Event Details

On 12 Mar 2021 (Study Day 150), 149 days after the first dose in Part A/42 days after the first dose in Part B and 121 days after the second dose in Part A/15 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of bilateral pneumonia lasted for 14 days, after which it was considered to be recovered/resolved on 25 Mar 2021 (Study Day 163). The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-055352	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Contrast media allergy	Allergic to iv dye	1972 - Ongoing
Fallopian tube perforation	Ruptured fallopian tube	1985 - 1985
Hysterectomy	Partial hysterectomy	1985 - 1985
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Skin cosmetic procedure	Skin cosmetic procedure	2010 - 2010
Type 2 diabetes mellitus	Type II diabetes mellitus	2010 - Ongoing
Anxiety	Anxiety	2014 - Ongoing
Device breakage	Ruptured implant, right breast	Jan 2020 - Jan 2020
Breast capsulectomy	Capsulectomy with implant exchange	26 Aug 2020 (Study Day -49) - 26 Aug 2020 (Study Day -49)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Estradiol	1990 - Ongoing	Post Menopausal Symptoms
Hydrochlorothiazide	2010 - Ongoing	Hypertension
Lisinopril	2010 - Ongoing	Hypertension
Lovastatin	2010 - Ongoing	Hyperlipidemia
Metformin	2010 - Ongoing	Diabetes Mellitus Type II
Sertraline	2014 - Ongoing	Anxiety
Pioglitazone	2015 - Ongoing	Type II Diabetes Mellitus
Ibuprofen	16 Oct 2020 (Study Day 3) - 21 Oct 2020 (Study Day 8)	Fatigue
Ibuprofen	16 Oct 2020 (Study Day 3) - 21 Oct 2020 (Study Day 8)	Headache
Ibuprofen	16 Oct 2020 (Study Day 3) - 21 Oct 2020 (Study Day 8)	Joint Aches
Benzonatate	13 Mar 2021 (Study Day 151) - 23 Mar 2021 (Study Day 161)	Bilateral Pneumonia
Levofloxacin	13 Mar 2021 (Study Day 151) - 20 Mar 2021 (Study Day 158)	Bilateral Pneumonia
Prednisone	13 Mar 2021 (Study Day 151) - 17 Mar 2021 (Study Day 155)	Bilateral Pneumonia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	13 Mar 2021 (Study Day 151) - 25 Mar 2021 (Study Day 163)	Bilateral Pneumonia
Acetylsalicylic acid	22 Mar 2021 (Study Day 160) - Ongoing	Cardiac Prophylaxis
Acetylsalicylic acid	22 Mar 2021 (Study Day 160) - 22 Mar 2021 (Study Day 160)	Cardiac Prophylaxis
Azithromycin	22 Mar 2021 (Study Day 160) - 22 Mar 2021 (Study Day 160)	Suspected Pneumonia
Ceftriaxone	22 Mar 2021 (Study Day 160) - 22 Mar 2021 (Study Day 160)	Suspected Pneumonia
Chest ct scan*	22 Mar 2021 (Study Day 160) - 22 Mar 2021 (Study Day 160)	Adverse Event
Covid 19 sars-cov2/ influenza a & b pcr/rsc pcr*	22 Mar 2021 (Study Day 160) - 22 Mar 2021 (Study Day 160)	Adverse Event
Glucagon	22 Mar 2021 (Study Day 160) - 23 Mar 2021 (Study Day 161)	Worsening Diabetes Type II
Glucose	22 Mar 2021 (Study Day 160) - 23 Mar 2021 (Study Day 161)	Worsening Diabetes Type II
Insulin lispro	22 Mar 2021 (Study Day 160) - 23 Mar 2021 (Study Day 161)	Worsening Diabetes Type II
Ondansetron	22 Mar 2021 (Study Day 160) - 23 Mar 2021 (Study Day 161)	Nausea Prophylaxis
Ultrasounds chest*	22 Mar 2021 (Study Day 160) - 22 Mar 2021 (Study Day 160)	Adverse Event
Chest x ray 1 view*	23 Mar 2021 (Study Day 161) - 23 Mar 2021 (Study Day 161)	Adverse Event
Morphine	23 Mar 2021 (Study Day 161) - 23 Mar 2021 (Study Day 161)	Pain Prophylaxis
Naloxone	23 Mar 2021 (Study Day 161) - 23 Mar 2021 (Study Day 161)	Respiratory Depression Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Atelectasis	Grade 1/mild	Not related	13 Mar 2021 (Study Day 151) - 23 Mar 2021 (Study Day 161)
Renal Injury	Grade 1/mild	Not related	22 Mar 2021 (Study Day 160) - 23 Mar 2021 (Study Day 161)
Type 2 Diabetes Mellitus	Grade 1/mild	Not related	22 Mar 2021 (Study Day 160) - 23 Mar 2021 (Study Day 161)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US356-2229 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 15 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 12 Nov 2020 (Study Day 29)
First Dose of Vaccine in Part B: 12 Jan 2021 (Study Day 90)
Second Dose of Vaccine in Part B: 11 Feb 2021 (Study Day 120)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Paraesthesia/Mild Weakness Of Right Side Paresthesia	SAE	Grade 4	Not related	16 Apr 2021 (Study Day 184) – 18 Apr 2021 (Study Day 186)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US356-2229, a 55-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 15 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 12 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 30 Dec 2020. The participant was unblinded on 30 Dec 2020 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 12 Jan 2021 (Study Day 90). The second dose was administered in the left arm on 11 Feb 2021 (Study Day 120).

Event Details

On 16 Apr 2021 (Study Day 184), 183 days after the first dose in Part A/94 days after the first dose in Part B and 155 days after the second dose in Part A/64 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of paraesthesia. Action taken with the IP was not applicable. The event of mild weakness of right side paresthesia lasted for 3 days, after which it was considered to be recovered/resolved on 18 Apr 2021 (Study Day 186). The investigator assessed the event of paraesthesia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-084460	Paraesthesia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2003 - Ongoing
Hypothyroidism	Hypothyroidism	2007 - Ongoing
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Asthma	Mild asthma	2016 - Ongoing
Menopausal symptoms	Post menopause symptoms	2018 - Ongoing
Postmenopause	Post menopause	2018 - Ongoing
Drug hypersensitivity	Allergic to keflex	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	2003 - Ongoing	Gastroesophageal Reflux Disease
Levothyroxine	2007 - Ongoing	Hypothyroidism
Cetirizine	2010 - Ongoing	Seasonal Allergies
Formoterol fumarate; mometasone furoate	2016 - Ongoing	Mild Asthma
Salbutamol sulfate	2016 - Ongoing	Mild Asthma
Estradiol	2018 - Ongoing	Post Menopause Symptoms
Progesterone	2018 - Ongoing	Post Menopausal Symptoms

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dizziness	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 110) - 01 Mar 2021 (Study Day 138)
Balance Disorder	Grade 2/moderate	Not related	01 Mar 2021 (Study Day 138) - 01 Mar 2021 (Study Day 138)
Fall	Grade 2/moderate	Not related	01 Mar 2021 (Study Day 138) - 01 Mar 2021 (Study Day 138)
Muscle Spasms	Grade 2/moderate	Not related	01 Mar 2021 (Study Day 138) - Ongoing
Paraesthesia	Grade 2/moderate	Not related	01 Mar 2021 (Study Day 138) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US357-2170 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 21 Jan 2021 (Study Day 134)
Second Dose of Vaccine in Part B: 19 Feb 2021 (Study Day 163)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Gastroesophageal Reflux Disease/ Gastroesophageal Reflux Disease	SAE	Grade 4	Not related	29 Mar 2021 (Study Day 201) – Ongoing	Not recovered/not resolved
Acute Myocardial Infarction/Nstemi	SAE	Grade 4	Not related	10 Apr 2021 (Study Day 213) – 10 Apr 2021 (Study Day 213)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US357-2170, a 71-year-old Hispanic or Latino male, received the first dose of Placebo in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Jan 2021. The participant was unblinded on 21 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 21 Jan 2021 (Study Day 134). The second dose was administered in the left arm on 19 Feb 2021 (Study Day 163).

Event Details

On 29 Mar 2021 (Study Day 201), 200 days after the first dose in Part A/67 days after the first dose in Part B and 172 days after the second dose in Part A/38 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of gastroesophageal reflux disease. Action taken with the IP was not applicable. The event of gastroesophageal reflux disease was considered to be ongoing. The investigator assessed the event of gastroesophageal reflux disease to be not related to the IP.

On 10 Apr 2021 (Study Day 213), 212 days after the first dose in Part A/79 days after the first dose in Part B and 184 days after the second dose in Part A/50 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of acute myocardial infarction.

Action taken with the IP was not applicable. The event of nstemi lasted for 1 days, after which it was considered to be recovered/resolved on 10 Apr 2021 (Study Day 213). The investigator assessed the event of acute myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-075779	Gastrooesophageal reflux disease
MOD-2021-075779	Acute myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Hyperlipidemia	01 Jan 1970 (Study Day -18515) - Ongoing
Hypertension	Hypertension	01 Jan 1970 (Study Day -18515) - Ongoing
Atrial fibrillation	Paroxysmal atrial fibrillation (afib)	01 Jan 1980 (Study Day -14863) - Ongoing
Type 2 diabetes mellitus	Diabetes type ii	01 Jan 2000 (Study Day -7558) - Ongoing
Glaucoma	Glaucoma	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Propranolol	1990 - Ongoing	Atrial Fibrillation
Glimepiride	2000 - Ongoing	Diabetes Mellitus Ii
Losartan	2008 - Ongoing	Hypertension
Atorvastatin	2015 - Ongoing	Hyperlipidemia
Potassium citrate	2015 - Ongoing	Renal Calculi Prevention Supplement
Brimonidine tartrate; timolol maleate	2018 - Ongoing	Glaucoma
Insulin detemir	2018 - Ongoing	Diabetes Mellitus Ii
Latanoprost	2018 - Ongoing	Glaucoma

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fall	Grade 1/mild	Not related	17 Feb 2021 (Study Day 161) - 17 Feb 2021 (Study Day 161)
Neck Injury	Grade 1/mild	Not related	17 Feb 2021 (Study Day 161) - 03 Mar 2021 (Study Day 175)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US357-2330 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 21 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 26 Oct 2020 (Study Day 36)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Gastric Bypass/Elective Gastric Bypass	SAE	Grade 1/ mild	Not related	16 Jan 2021 (Study Day 118) – 18 Jan 2021 (Study Day 120)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US357-2330, a 38-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 21 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 26 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 18 Dec 2020. The participant was unblinded on 18 Dec 2020 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 16 Jan 2021 (Study Day 118), 117 days after the first dose in Part A and 82 days after the second dose in Part A of the IP, the participant experienced a Grade 1/mild serious adverse event of gastric bypass. Action taken with the IP was not applicable. The event of elective gastric bypass lasted for 3 days, after which it was considered to be recovered/resolved on 18 Jan 2021 (Study Day 120). The investigator assessed the event of gastric bypass to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	01 Jan 2019 (Study Day -629) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Losartan	01 Jan 2019 (Study Day -629) - Ongoing	Hypertension
Antibiotics	15 Jan 2021 (Study Day 117) - 17 Jan 2021 (Study Day 119)	Prophylaxis Pre-Op For Gastric Bypass Surgery
Gastric bypass*	16 Jan 2021 (Study Day 118) - 16 Jan 2021 (Study Day 118)	Other, Weight Reduction

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US358-2102 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 01 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 14 Jan 2021 (Study Day 134)
Second Dose of Vaccine in Part B: 08 Feb 2021 (Study Day 159)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cerebrovascular Accident/Acute Left Middle Cerebral Artery Stroke	SAE	Grade 3/ severe	Not related	21 Feb 2021 (Study Day 172) – 21 Feb 2021 (Study Day 172)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US358-2102, a 77-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 13 Jan 2021. The participant was unblinded on 13 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 14 Jan 2021 (Study Day 134). The second dose was administered in the left arm on 08 Feb 2021 (Study Day 159).

Event Details

On 21 Feb 2021 (Study Day 172), 171 days after the first dose in Part A/38 days after the first dose in Part B and 143 days after the second dose in Part A/13 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of cerebrovascular accident. Action taken with the IP was not applicable. The event of acute left middle cerebral artery stroke lasted for 1 days, after which it was considered to be recovered/resolved with sequelae on 21 Feb 2021 (Study Day 172). The investigator assessed the event of cerebrovascular accident to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-021733	Cerebrovascular accident

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Atrial septal defect	Atrial septal defect	1983 - Dec 2011
Nephrolithiasis	Kidney stones	1985 - Ongoing
Musculoskeletal stiffness	Stiffness in back, shoulders, hips, knees	1995 - Ongoing
Gastroesophageal reflux disease	Reflux	2003 - Ongoing
Atrial flutter	Atrial flutter/atrial fibrillation	15 Oct 2004 (Study Day -5802) - Ongoing
Hypertension	Hypertension	18 Oct 2004 (Study Day -5799) - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	14 Nov 2008 (Study Day -4311) - Ongoing
Coronary artery disease	Coronary artery disease	2011 - Ongoing
Ventricular septal defect	Ventricular septal defect	Dec 2011 - Ongoing
Seborrheic dermatitis	Seborrheic dermatitis	16 Jul 2013 (Study Day -2606) - Ongoing
Mitral valve incompetence	Moderate mitral regurgitation	13 Feb 2015 (Study Day -2029) - Ongoing
Pulmonary hypertension	Mild pulmonary hypertension	13 Feb 2015 (Study Day -2029) - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	16 Feb 2015 (Study Day -2026) - Ongoing
Pulmonary mass	Pulmonary nodule	06 Mar 2015 (Study Day -2008) - Ongoing
Thyroid mass	Thyroid nodules	06 Mar 2015 (Study Day -2008) - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	13 May 2015 (Study Day -1940) - Not reported
Cardiac failure	Heart failure	14 Dec 2015 (Study Day -1725) - Ongoing
Hyperlipidaemia	Hyperlipidemia	14 Dec 2015 (Study Day -1725) - Ongoing
Anaemia	Anemia	21 Mar 2017 (Study Day -1262) - Ongoing
Gastric polyps	Stomach polyp	02 May 2017 (Study Day -1220) - Ongoing
Barrett's oesophagus	Barrett's esophagus	09 May 2017 (Study Day -1213) - Ongoing
Large intestine polyp	Colon polyps	09 May 2017 (Study Day -1213) - Ongoing
Open angle glaucoma	Open angle glaucoma	01 Oct 2018 (Study Day -703) - Ongoing
Goitre	Thyromegaly	28 Oct 2019 (Study Day -311) - Ongoing
Hypokalaemia	Hypokalemia	24 Feb 2020 (Study Day -192) - Ongoing
Cyst	Cyst on buttock	23 Jul 2020 (Study Day -42) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	1995 - Ongoing	Stiffness In Back, Shoulders, Hips, Knees
Allopurinol	07 Apr 1997 (Study Day -8550) - Ongoing	Kidney Stones
Omeprazole	25 Nov 2003 (Study Day -6127) - Ongoing	Reflux
Diosmin	09 Apr 2005 (Study Day -5626) - Ongoing	Atrial Flutter
Warfarin sodium	15 Nov 2008 (Study Day -4310) - 13 Feb 2021 (Study Day 164)	Atrial Flutter And Ventricular Septal Defect
Losartan potassium	29 Sep 2009 (Study Day -3992) - Ongoing	Hypertension
Ketoconazole	2013 - Ongoing	Seborrheic Dermatitis
Calcium; colecalciferol	2015 - Ongoing	Health Maintenance
Unspecified herbal and traditional medicine	2015 - Ongoing	Benign Prostatic Hyperplasia
Atorvastatin	14 Dec 2015 (Study Day -1725) - Ongoing	Hyperlipidemia
Furosemide	14 Dec 2015 (Study Day -1725) - Ongoing	Heart Failure
Ferrous sulfate	24 Mar 2017 (Study Day -1259) - 29 Dec 2020 (Study Day 118)	Anemia
Latanoprost	01 Oct 2018 (Study Day -703) - Ongoing	Open Angle Glaucoma
Potassium chloride	24 Feb 2020 (Study Day -192) - Ongoing	Hypokalemia
Influenza vaccine	31 Oct 2020 (Study Day 59) - 31 Oct 2020 (Study Day 59)	Health Maintenance
Amoxicillin	15 Dec 2020 (Study Day 104) - 22 Dec 2020 (Study Day 111)	Chipped Teeth And Laceration To Gingiva
Chlorhexidine gluconate	15 Dec 2020 (Study Day 104) - 22 Dec 2020 (Study Day 111)	Chipped Teeth And Laceration To Gingiva
Dental bonding of 6 chipped teeth*	15 Dec 2020 (Study Day 104) - 15 Dec 2020 (Study Day 104)	Adverse Event
Ct of head (due to exacerbation of anemia)*	29 Dec 2020 (Study Day 118) - 29 Dec 2020 (Study Day 118)	Adverse Event
Ferrous sulfate	29 Dec 2020 (Study Day 118) - Ongoing	Anemia
Macrogol 3350; potassium chloride; sodium bicarbonate; sodium chloride; sodium sulfate	17 Feb 2021 (Study Day 168) - 18 Feb 2021 (Study Day 169)	Anemia Exacerbation
Colonoscopy*	18 Feb 2021 (Study Day 169) - 18 Feb 2021 (Study Day 169)	Adverse Event
Fentanyl	18 Feb 2021 (Study Day 169) - 18 Feb 2021 (Study Day 169)	Anemia Exacerbation
Lidocaine	18 Feb 2021 (Study Day 169) - 18 Feb 2021 (Study Day 169)	Anemia Exacerbation
Midazolam	18 Feb 2021 (Study Day 169) - 18 Feb 2021 (Study Day 169)	Anemia Exacerbation
Upper endoscopy*	18 Feb 2021 (Study Day 169) - 18 Feb 2021 (Study Day 169)	Adverse Event
Warfarin sodium	20 Feb 2021 (Study Day 171) - 20 Feb 2021 (Study Day 171)	Atrial Flutter And Ventricular Septal Defect

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chest x-ray*	21 Feb 2021 (Study Day 172) - 21 Feb 2021 (Study Day 172)	Adverse Event
Ct head without contrast*	21 Feb 2021 (Study Day 172) - 21 Feb 2021 (Study Day 172)	Adverse Event
Cta head and neck*	21 Feb 2021 (Study Day 172) - 21 Feb 2021 (Study Day 172)	Adverse Event
Ekg*	21 Feb 2021 (Study Day 172) - 21 Feb 2021 (Study Day 172)	Adverse Event
Iohexol	21 Feb 2021 (Study Day 172) - 21 Feb 2021 (Study Day 172)	Acute Left Middle Cerebral Artery Stroke
Mri brain without contrast*	21 Feb 2021 (Study Day 172) - 21 Feb 2021 (Study Day 172)	Adverse Event
Acetylsalicylic acid	23 Feb 2021 (Study Day 174) - 03 Mar 2021 (Study Day 182)	Atrial Flutter, Ventricular Septal Defect, Acute Left Middle Cerebral Artery Stroke
Ekg*	23 Feb 2021 (Study Day 174) - 23 Feb 2021 (Study Day 174)	Adverse Event
Ct head without contrast*	24 Feb 2021 (Study Day 175) - 24 Feb 2021 (Study Day 175)	Adverse Event
Warfarin sodium	25 Feb 2021 (Study Day 176) - Ongoing	Atrial Flutter/Atrial Fibrillation, Ventricular Septal Defect

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Aphasia	Grade 2/moderate	Not related	21 Feb 2021 (Study Day 172) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US359-2061 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 08 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 05 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 12 Jan 2021 (Study Day 158)
Second Dose of Vaccine in Part B: 10 Feb 2021 (Study Day 187)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Suicidal Ideation/ Suicidal Ideations	SAE	Grade 2/ moderate	Not related	25 Mar 2021 (Study Day 230) – 28 Mar 2021 (Study Day 233)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US359-2061, a 44-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 08 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 05 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 12 Jan 2021 (Study Day 158). The second dose was administered in the left arm on 10 Feb 2021 (Study Day 187).

Event Details

On 25 Mar 2021 (Study Day 230), 229 days after the first dose in Part A/72 days after the first dose in Part B and 201 days after the second dose in Part A/43 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of suicidal ideation. Action taken with the IP was not applicable. The event of suicidal ideations lasted for 4 days, after which it was considered to be recovered/resolved on 28 Mar 2021 (Study Day 233). The investigator assessed the event of suicidal ideation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-064940	Suicidal ideation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraines	1983 - Ongoing
Anxiety	Anxiety	1985 - Ongoing
Depression	Depression	1985 - Ongoing
Astigmatism	Bilateral astigmatism	1989 - Ongoing
Myopia	Myopia bilateral	1989 - Ongoing
Insomnia	Insomnia	Jan 2005 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2016 - Ongoing
Eczema	Eczema generalized	2018 - Ongoing
Seasonal allergy	Seasonal allergies	Jan 2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Zolpidem tartrate	01 Jan 2005 (Study Day -5698) - Ongoing	Insomnia
Lisdexamfetamine mesilate	01 Jan 2016 (Study Day -1681) - Ongoing	Attention Deficit Hyperactivity Disorder
Cetirizine hydrochloride	01 Jan 2018 (Study Day -950) - Ongoing	Seasonal Allergies
Desvenlafaxine succinate	01 Jan 2018 (Study Day -950) - Ongoing	Depression
Levonorgestrel	01 Jan 2018 (Study Day -950) - Ongoing	Contraception
Omega-3 nos	01 Jan 2018 (Study Day -950) - Ongoing	Nutritional Supplement
Probiotics nos	01 Jan 2018 (Study Day -950) - Ongoing	Nutritional Supplement
Vitamin b12 nos	01 Jan 2018 (Study Day -950) - Ongoing	Nutritional Supplement
Doxepin	01 Jul 2020 (Study Day -38) - Ongoing	Insomnia
Paracetamol	13 Aug 2020 (Study Day 6) - 13 Aug 2020 (Study Day 6)	Headache
Paracetamol	25 Aug 2020 (Study Day 18) - 25 Aug 2020 (Study Day 18)	Headache
Paracetamol	05 Sep 2020 (Study Day 29) - 05 Sep 2020 (Study Day 29)	Headache
Ibuprofen	06 Sep 2020 (Study Day 30) - 06 Sep 2020 (Study Day 30)	Headache
Terbinafine	16 Sep 2020 (Study Day 40) - Ongoing	Eczema Generalized
Bismuth subsalicylate	21 Oct 2020 (Study Day 75) - 22 Oct 2020 (Study Day 76)	Diarrhea

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	14 Nov 2020 (Study Day 99) - 14 Nov 2020 (Study Day 99)	Headache
Influenza vaccine	23 Nov 2020 (Study Day 108) - 23 Nov 2020 (Study Day 108)	Influenza Prophylaxis
Buspirone hydrochloride	25 Mar 2021 (Study Day 230) - Ongoing	Major Depressive Disorder, Severe, Recurrent
Hydroxyzine	25 Mar 2021 (Study Day 230) - Ongoing	Major Depressive Disorder, Severe, Recurrent

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US359-2238 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 29 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 26 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hyperglycaemia/ Hyperglycemia	SAE	Grade 2/ moderate	Not related	23 Mar 2021 (Study Day 207) – 26 Mar 2021 (Study Day 210)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The MedDRA Preferred Term/Verbatim Term of Hyperglycaemia/Hyperglycemia was updated to Hyperglycaemic Hyperosmolar Nonketotic Syndrome/Hyperosmolar Hyperglycemic State after the database lock.

Participant US359-2238, a 61-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 29 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 26 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 08 Feb 2021. The participant was unblinded on 08 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 23 Mar 2021 (Study Day 207), 206 days after the first dose in Part A and 178 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of hyperglycaemia. Action taken with the IP was not applicable. The event of hyperglycemia lasted for 4 days, after which it was considered to be recovered/resolved with sequelae on 26 Mar 2021 (Study Day 210). The investigator assessed the event of hyperglycaemia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-069334	Hyperglycaemic hyperosmolar nonketotic syndrome

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypermetropia	Hyperopia	1965 - Ongoing
Renal aplasia	Renal agenesis (left remains)	1996 - Ongoing
Vasectomy	Vasectomy	1996 - 1996
Gout	Gout	2000 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Deep vein thrombosis	History of deep vein thrombosis	2006 - Ongoing
Glucose tolerance impaired	Pre-diabetic	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Allopurinol sodium	2000 - Ongoing	Gout
Amlodipine besilate	2000 - Ongoing	Hypertension
Metoprolol succinate	2000 - Ongoing	Hypertension
Olmesartan medoxomil	2000 - Ongoing	Hypertension
Simvastatin	2000 - Ongoing	Hyperlipidemia
Rivaroxaban	2006 - Ongoing	History Of Deep Vein Thrombosis
Metformin	2017 - Ongoing	Prediabetic
Influenza vaccine	15 Oct 2020 (Study Day 48) - 15 Oct 2020 (Study Day 48)	Influenza Prophylaxis
Insulin glargine	23 Mar 2021 (Study Day 207) - Ongoing	Hyperglycemia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Type 2 Diabetes Mellitus	Grade 2/moderate	Not related	23 Mar 2021 (Study Day 207) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US360-2123 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 02 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 27 Oct 2020 (Study Day 26)
First Dose of Vaccine in Part B: 12 Jan 2021 (Study Day 103)
Second Dose of Vaccine in Part B: 09 Feb 2021 (Study Day 131)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Immune Thrombocytopenia/ Worsening Of Immune Thrombocytopenia	SAE	Grade 3/ severe	Not related	12 Feb 2021 (Study Day 134) – 15 Feb 2021 (Study Day 137)	Recovered/resolved
Platelet Count Decreased/Significant Drop Of The Platelet Count	SAE	Grade 3/ severe	Not related	12 Feb 2021 (Study Day 134) – 15 Feb 2021 (Study Day 137)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US360-2123, a 46-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 02 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 27 Oct 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was positive. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 12 Jan 2021 (Study Day 103). The second dose was administered in the left arm on 09 Feb 2021 (Study Day 131).

Event Details

On 12 Feb 2021 (Study Day 134), 133 days after the first dose in Part A/31 days after the first dose in Part B and 108 days after the second dose in Part A/3 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of immune thrombocytopenia. Action taken with the IP was not applicable. The event of worsening of immune thrombocytopenia lasted for 4 days, after which it was considered to be recovered/resolved on 15 Feb 2021 (Study Day 137). The investigator assessed the event of immune thrombocytopenia to be not related to the IP.

On 12 Feb 2021 (Study Day 134), 133 days after the first dose in Part A/31 days after the first dose in Part B and 108 days after the second dose in Part A/3 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of platelet count decreased. Action taken with the IP was not applicable. The event of significant drop of the platelet count lasted for 4 days, after which it was considered to be recovered/resolved on 15 Feb 2021 (Study Day 137). The investigator assessed the event of platelet count decreased to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014588	Immune thrombocytopenia
MOD-2021-014588	Platelet count decreased

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Caesarean section	C-section	1999 - 1999
Immune thrombocytopenia	Immune thrombocytopenia	1999 - Ongoing
Cholecystectomy	Cholecystectomy	2000 - 2000
Splenectomy	Splenectomy	2000 - 2000
Blood cholesterol increased	Borderline high cholesterol	2018 - Ongoing
Hypertension	Hypertension controlled with oral medication	2018 - Ongoing
Seasonal allergy	Seasonal allergies	2018 - Ongoing
Vitamin D decreased	Borderline low vitamin d deficiency	2018 - Ongoing
Mammoplasty	Breast augmentation	2020 - 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Phentermine	Not reported - 28 Sep 2020 (Study Day -4)	Dietary Supplement To Prevent Weight Gain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; ferrous fumarate; norethisterone acetate	2017 - Ongoing	For Contraception
Amlodipine	2018 - Ongoing	For Htn
Cetirizine hydrochloride	2018 - Ongoing	For Seasonal Allergies
Ascorbic acid	2019 - Ongoing	For Supplement
Magnesium	2019 - Ongoing	For Supplement
Potassium	2019 - Ongoing	For Supplement
Paracetamol	05 Oct 2020 (Study Day 4) - 06 Oct 2020 (Study Day 5)	Headache During Day 5 Reported On Safety Call Day 8 - A.E
Paracetamol	06 Oct 2020 (Study Day 5) - 06 Oct 2020 (Study Day 5)	Headache - Reported For Diary Dose 1 On Day 5 On 10/6 Via E-Diary
Calcium carbonate	07 Oct 2020 (Study Day 6) - Ongoing	A.E: Heart Burn - Reported In Safety Day #8
Calcium carbonate	07 Oct 2020 (Study Day 6) - Ongoing	A.E: Queasy Stomach - Reported In Safety Day #8
Blood work*	09 Feb 2021 (Study Day 131) - 09 Feb 2021 (Study Day 131)	Adverse Event
Valaciclovir hydrochloride	09 Feb 2021 (Study Day 131) - 16 Feb 2021 (Study Day 138)	Presumptive Shingles
Cough and cold preparations	10 Feb 2021 (Study Day 132) - 12 Feb 2021 (Study Day 134)	Fever 100.7
Paracetamol	10 Feb 2021 (Study Day 132) - 12 Feb 2021 (Study Day 134)	Fever 100.7, Headache, Redness To Left Arm - Injection Site, Swelling To Left Arm - Injection Site, Pain To Left Arm - Injection Site, Tenderness To Left Arm - Injection Site, Bruise To Left Arm
Blood work*	12 Feb 2021 (Study Day 134) - 12 Feb 2021 (Study Day 134)	Adverse Event
Blood work-up*	15 Feb 2021 (Study Day 137) - 15 Feb 2021 (Study Day 137)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US360-2154 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 15 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 12 Nov 2020 (Study Day 29)
First Dose of Vaccine in Part B: 09 Feb 2021 (Study Day 118)
Second Dose of Vaccine in Part B: 09 Mar 2021 (Study Day 146)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Non-Cardiac Chest Pain/Non - Cardiac Chest Pain	SAE	Grade 3/ severe	Not related	26 Feb 2021 (Study Day 135) – 27 Feb 2021 (Study Day 136)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US360-2154, a 42-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 15 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 12 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 09 Feb 2021. The participant was unblinded on 09 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 09 Feb 2021 (Study Day 118). The second dose was administered in the left arm on 09 Mar 2021 (Study Day 146).

Event Details

On 26 Feb 2021 (Study Day 135), 134 days after the first dose in Part A/17 days after the first dose in Part B and 106 days after the second dose in Part A/11 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of non-cardiac chest pain. The IP dose was not changed due to the non - cardiac chest pain. The event of non - cardiac chest pain lasted for 2 days, after which it was considered to be recovered/resolved on 27 Feb 2021 (Study Day 136). The investigator assessed the event of non-cardiac chest pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-036302	Non-cardiac chest pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin d nos	2018 - Ongoing	For Dietary Supplement
Dextromethorphan hydrobromide; guaifenesin	08 Jan 2021 (Study Day 86) - 08 Jan 2021 (Study Day 86)	Cough - Captured In Symptom Log Tracker
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	10 Jan 2021 (Study Day 88) - 10 Jan 2021 (Study Day 88)	Sinus/Nasal Congestion - Captured In Symptom Log Tracker
Dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	10 Jan 2021 (Study Day 88) - 10 Jan 2021 (Study Day 88)	Cough, Nasal Congestion, And Runny Nose - Captured In Symptom Tracker
Acetylsalicylic acid	27 Feb 2021 (Study Day 136) - Ongoing	Cardiac Prevention
Pantoprazole sodium sesquihydrate	27 Feb 2021 (Study Day 136) - Ongoing	Gerd

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US361-2005 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 29 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 04 Jan 2021 (Study Day 126)
Second Dose of Vaccine in Part B: 02 Feb 2021 (Study Day 155)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/ Myocardial Infarction	SAE	Grade 4	Not related	13 Apr 2021 (Study Day 225) – 17 Apr 2021 (Study Day 229)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US361-2005, a 75-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Jan 2021. The participant was unblinded on 04 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 04 Jan 2021 (Study Day 126). The second dose was administered in the left arm on 02 Feb 2021 (Study Day 155).

Event Details

On 13 Apr 2021 (Study Day 225), 224 days after the first dose in Part A/99 days after the first dose in Part B and 196 days after the second dose in Part A/70 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction lasted for 5 days, after which it was considered to be recovered/resolved on 17 Apr 2021 (Study Day 229). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-082381	Myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Arthralgia	Left knee pain	Not reported
Arthralgia	Right knee pain	Not reported
Nephrolithiasis	Kidney stones	15 Jul 1981 (Study Day -14293) - Ongoing
Thrombosis	Blood clots	15 Jul 2005 (Study Day -5527) - Not reported
Cardiac arrest	Cardiac arrest	28 Dec 2007 (Study Day -4631) - 28 Dec 2007 (Study Day -4631)
Arthroscopy	Right knee arthroscopy	Jun 2010 - Jun 2010
Arthroscopy	Left knee arthroscopy	04 Aug 2010 (Study Day -3681) - 04 Aug 2010 (Study Day -3681)
Sepsis	Sepsis	2018 - 2018
Blood cholesterol increased	High cholesterol	15 Feb 2019 (Study Day -564) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Allopurinol	15 Jul 1981 (Study Day -14293) - 14 Apr 2021 (Study Day 226)	Kidney Stones
Hydrochlorothiazide	15 Jul 1981 (Study Day -14293) - 14 Apr 2021 (Study Day 226)	Kidney Stones
Warfarin	15 Jul 2005 (Study Day -5527) - Ongoing	Blood Clots
Celecoxib	15 Feb 2019 (Study Day -564) - Ongoing	Bilateral Knee Aches
Fenofibrate	15 Feb 2019 (Study Day -564) - 14 Apr 2021 (Study Day 226)	High Cholesterol
Influenza vaccine	04 Nov 2020 (Study Day 65) - 04 Nov 2020 (Study Day 65)	Immunization
Ofloxacin	02 Jan 2021 (Study Day 124) - 09 Jan 2021 (Study Day 131)	Right Otitis Externa

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US361-2060 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 30 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 06 Jan 2021 (Study Day 99)
Second Dose of Vaccine in Part B: 02 Feb 2021 (Study Day 126)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Shoulder Arthroplasty/Total Shoulder Arthroplasty	SAE	Grade 3/ severe	Not related	31 Mar 2021 (Study Day 183) – 02 Apr 2021 (Study Day 185)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US361-2060, a 69-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 30 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 28 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 06 Jan 2021 (Study Day 99). The second dose was administered in the left arm on 02 Feb 2021 (Study Day 126).

Event Details

On 31 Mar 2021 (Study Day 183), 182 days after the first dose in Part A/84 days after the first dose in Part B and 154 days after the second dose in Part A/57 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of shoulder arthroplasty. Action taken with the IP was not applicable. The event of total shoulder arthroplasty lasted for 3 days, after which it was considered to be recovered/resolved on 02 Apr 2021 (Study Day 185). The investigator assessed the event of shoulder arthroplasty to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-075948	Arthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Intervertebral disc degeneration	Degenerative disc disease	Not reported - 2018
Mitral valve incompetence	Mitral valve regurgitation	Not reported - 28 May 2017 (Study Day -1221)
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Knee arthroplasty	Total knee replacement, left	1995 - 1995
Knee arthroplasty	Total knee replacement, right	1998 - 1998
Hypertension	Hypertension	2000 - Ongoing
Prostate cancer	Prostate cancer	2001 - 2001
Prostatectomy	Prostatectomy	2001 - 2001
Arthritis	Right shoulder arthritis	Jun 2016 - Ongoing
Musculoskeletal pain	Right shoulder pain	Jun 2016 - Ongoing
Mitral valve repair	Mitral valve repair	28 May 2017 (Study Day -1221) - 28 May 2017 (Study Day -1221)
Spinal fusion surgery	Spinal fusion	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Allergens nos	Not reported - Ongoing	Seasonal Allergies
Omega 9 fatty acids; omega-3 fatty acids; omega-6 fatty acids	Not reported - Ongoing	Supplement
Vitamins nos	Not reported - Ongoing	Supplement
Amlodipine; atorvastatin	2000 - Ongoing	Hypertension
Tadalafil	2001 - Ongoing	Prostatectomy
Azelastine hydrochloride	2010 - Ongoing	Seasonal Allergies
Fluticasone	2010 - Ongoing	Seasonal Allergies
Acetylsalicylic acid	2017 - Ongoing	Stroke Prevention
Paracetamol	2018 - Ongoing	Knee And Back Pain
Emg (electromyographic nerve study)*	29 Dec 2020 (Study Day 91) - 29 Dec 2020 (Study Day 91)	Diagnostic
Paracetamol	29 Dec 2020 (Study Day 91) - 12 Jan 2021 (Study Day 105)	Right Hand Pain/Carpal Tunnel
Right carpal tunnel surgery*	31 Dec 2020 (Study Day 93) - 31 Dec 2020 (Study Day 93)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US362-2142 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 01 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 15 Jan 2021 (Study Day 135)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	SAE, COVID-19	Grade 4	Not related	26 Jan 2021 (Study Day 146) – 15 Feb 2021 (Study Day 166)	Recovered/ resolved with sequelae
Acute Respiratory Failure/Acute Hypoxemic Respiratory Failure Secondary To COVID-19	SAE	Grade 4	Not related	06 Feb 2021 (Study Day 157) – 09 Feb 2021 (Study Day 160)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US362-2142, a 69-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 15 Jan 2021. The participant was unblinded on 15 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 15 Jan 2021 (Study Day 135). The second dose was not administered.

Severe COVID-19 Details

On 26 Jan 2021 (Study Day 146), 145 days after the first dose in Part A/11 days after the first dose in Part B and 117 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 4 serious adverse event of COVID-19.

On 06 Feb 2021 (Study Day 157), 156 days after the first dose in Part A/22 days after the first dose in Part B and 128 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 4 serious adverse event of acute hypoxemic respiratory failure secondary to COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 01 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 29 Jan 2021 (Study Day 149), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
26 Jan 2021 (Study Day 146)	Cough	Mild
26 Jan 2021 (Study Day 146)	Shortness of Breath	Moderate
27 Jan 2021 (Study Day 147)	Cough	Mild
27 Jan 2021 (Study Day 147)	Shortness of Breath	Moderate
28 Jan 2021 (Study Day 148)	Cough	Mild
28 Jan 2021 (Study Day 148)	Nasal Congestion	Mild
28 Jan 2021 (Study Day 148)	Runny Nose (Rhinorrhea)	Mild
28 Jan 2021 (Study Day 148)	Shortness of Breath	Moderate
29 Jan 2021 (Study Day 149)	Cough	Mild
29 Jan 2021 (Study Day 149)	O2 Saturation (%)	90
29 Jan 2021 (Study Day 149)	Shortness of Breath	Severe
30 Jan 2021 (Study Day 150)	Cough	Mild
30 Jan 2021 (Study Day 150)	Shortness of Breath	Severe
31 Jan 2021 (Study Day 151)	Cough	Mild
31 Jan 2021 (Study Day 151)	Shortness of Breath	Severe
01 Feb 2021 (Study Day 152)	Cough	Mild
01 Feb 2021 (Study Day 152)	Shortness of Breath	Severe
02 Feb 2021 (Study Day 153)	Cough	Mild
02 Feb 2021 (Study Day 153)	Shortness of Breath	Severe
03 Feb 2021 (Study Day 154)	Cough	Mild
03 Feb 2021 (Study Day 154)	Shortness of Breath	Moderate
04 Feb 2021 (Study Day 155)	Cough	Mild
04 Feb 2021 (Study Day 155)	Shortness of Breath	Moderate
05 Feb 2021 (Study Day 156)	Shortness of Breath	Mild
06 Feb 2021 (Study Day 157)	Shortness of Breath	Mild
10 Feb 2021 (Study Day 161)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
29 Jan 2021 (Study Day 149)	Oxygen Saturation	90%
29 Jan 2021 - 29 Jan 2021 (Study Day 149-149)	Clinical Evidence of Pneumonia	Yes
29 Jan 2021 - 29 Jan 2021 (Study Day 149-149)	Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level	Yes

Dates	Severity Indication	Result
29 Jan 2021 - 29 Jan 2021 (Study Day 149-149)	Radiographical Evidence of Pneumonia	Yes

The IP dose was not changed due to the COVID-19. The event of COVID-19 lasted for 21 days, after which it was considered to be recovered/resolved with sequelae on 15 Feb 2021 (Study Day 166). The investigator assessed the event of COVID-19 to be not related to the IP.

The IP dose was not changed due to the acute hypoxemic respiratory failure secondary to COVID-19. The event of acute hypoxemic respiratory failure secondary to COVID-19 lasted for 4 days, after which it was considered to be recovered/resolved with sequelae on 09 Feb 2021 (Study Day 160). The investigator assessed the event of acute respiratory failure to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010314	COVID-19
MOD-2021-010314	Acute respiratory failure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post menopause	Not reported - Ongoing
Asthma	Asthma (mild)	(b) (6) 1951 - Ongoing
Hypertension	Hypertension	1985 - Ongoing
Diabetes mellitus	Diabetes	2012 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	2012 - Ongoing	Prophylaxis
Metformin	2012 - Ongoing	Diabetes
Vitamin e nos	2012 - Ongoing	Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone propionate; salmeterol xinafoate	Feb 2017 - Ongoing	Asthma
Losartan	2018 - Ongoing	Hypertension
Influenza vaccine	15 Aug 2020 (Study Day -19) - 15 Aug 2020 (Study Day -19)	Prophylaxis
Azithromycin	26 Jan 2021 (Study Day 146) - 28 Jan 2021 (Study Day 148)	COVID-19
Ascorbic acid	29 Jan 2021 (Study Day 149) - 15 Feb 2021 (Study Day 166)	COVID-19
Chest x-ray*	29 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 149)	Diagnostic
Colchicine	29 Jan 2021 (Study Day 149) - 06 Feb 2021 (Study Day 157)	COVID-19
Complete metabolic panel*	29 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 149)	Diagnostic
Convalescent plasma*	29 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 149)	Adverse Event
Crp lab*	29 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 149)	Diagnostic
D-dimer lab*	29 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 149)	Diagnostic
Dexamethasone	29 Jan 2021 (Study Day 149) - 06 Feb 2021 (Study Day 157)	COVID-19
Doxycycline	29 Jan 2021 (Study Day 149) - 06 Feb 2021 (Study Day 157)	COVID-19
Ekg*	29 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 149)	Diagnostic
Inr lab*	29 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 149)	Diagnostic
Pt lab*	29 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 149)	Diagnostic
Remdesivir	29 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 149)	COVID-19
Sars-cov-2rna test*	29 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 149)	Diagnostic
Vitamin d nos	29 Jan 2021 (Study Day 149) - 15 Feb 2021 (Study Day 166)	COVID-19
Zinc sulfate	29 Jan 2021 (Study Day 149) - 15 Feb 2021 (Study Day 166)	COVID-19
Enoxaparin sodium	30 Jan 2021 (Study Day 150) - 30 Jan 2021 (Study Day 150)	Prevention Of Clots
Remdesivir	30 Jan 2021 (Study Day 150) - 30 Jan 2021 (Study Day 150)	COVID-19
Diphenhydramine hydrochloride	31 Jan 2021 (Study Day 151) - 31 Jan 2021 (Study Day 151)	Generalized Itchy; Rash (Related To Remdesivir)
Insulin glargine	31 Jan 2021 (Study Day 151) - 31 Jan 2021 (Study Day 151)	Worsening Hyperglycemia
Insulin lispro	31 Jan 2021 (Study Day 151) - 31 Jan 2021 (Study Day 151)	Worsening Hyperglycemia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole sodium sesquihydrate	31 Jan 2021 (Study Day 151) - 31 Jan 2021 (Study Day 151)	Prevention Of Reflux
Chest x-ray*	06 Feb 2021 (Study Day 157) - 06 Feb 2021 (Study Day 157)	Diagnostic
Complete metabolic panel*	06 Feb 2021 (Study Day 157) - 06 Feb 2021 (Study Day 157)	Diagnostic
Crp lab*	06 Feb 2021 (Study Day 157) - 06 Feb 2021 (Study Day 157)	Diagnostic
D-dimer lab*	06 Feb 2021 (Study Day 157) - 06 Feb 2021 (Study Day 157)	Diagnostic
Dexamethasone	06 Feb 2021 (Study Day 157) - 07 Feb 2021 (Study Day 158)	Pneumonia
Doxycycline	06 Feb 2021 (Study Day 157) - 06 Feb 2021 (Study Day 157)	Pneumonia
Ekg*	06 Feb 2021 (Study Day 157) - 06 Feb 2021 (Study Day 157)	Diagnostic
Guaifenesin	06 Feb 2021 (Study Day 157) - 09 Feb 2021 (Study Day 160)	COVID-19
Lactic acid lab*	06 Feb 2021 (Study Day 157) - 06 Feb 2021 (Study Day 157)	Diagnostic
Oxygen	06 Feb 2021 (Study Day 157) - 09 Feb 2021 (Study Day 160)	Acute Hypoxemic Respiratory Failure Secondary To COVID-19
Potassium chloride	06 Feb 2021 (Study Day 157) - 06 Feb 2021 (Study Day 157)	Hypokalemia
Salbutamol	06 Feb 2021 (Study Day 157) - 09 Feb 2021 (Study Day 160)	Acute Hypoxemic Respiratory Failure Secondary To COVID-19
Vancomycin	06 Feb 2021 (Study Day 157) - 06 Feb 2021 (Study Day 157)	Pneumonia
Acetylsalicylic acid	07 Feb 2021 (Study Day 158) - 09 Feb 2021 (Study Day 160)	Prevention Of Blood Clots
Ascorbic acid	07 Feb 2021 (Study Day 158) - 09 Feb 2021 (Study Day 160)	COVID-19
Chest x-ray*	07 Feb 2021 (Study Day 158) - 07 Feb 2021 (Study Day 158)	Diagnostic
Colchicine	07 Feb 2021 (Study Day 158) - 07 Feb 2021 (Study Day 158)	COVID-19
Enoxaparin sodium	07 Feb 2021 (Study Day 158) - 09 Feb 2021 (Study Day 160)	Prevention Of Blood Clots
Insulin lispro	07 Feb 2021 (Study Day 158) - 09 Feb 2021 (Study Day 160)	Worsening Hyperglycemia
Vitamin d nos	07 Feb 2021 (Study Day 158) - 07 Feb 2021 (Study Day 158)	COVID-19
Zinc sulfate	07 Feb 2021 (Study Day 158) - 09 Feb 2021 (Study Day 160)	COVID-19
Furosemide	08 Feb 2021 (Study Day 159) - 09 Feb 2021 (Study Day 160)	Bilateral Lower Extremity Edema
Cta chest with contrast*	09 Feb 2021 (Study Day 160) - 09 Feb 2021 (Study Day 160)	Diagnostic
Echocardiogram*	09 Feb 2021 (Study Day 160) - 09 Feb 2021 (Study Day 160)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Furosemide	09 Feb 2021 (Study Day 160) - 04 Mar 2021 (Study Day 183)	Bilateral Lower Extremity Edema
Iopamidol	09 Feb 2021 (Study Day 160) - 09 Feb 2021 (Study Day 160)	Contrast For Cta
Levothyroxine	12 Mar 2021 (Study Day 191) - Ongoing	Hypothyroidism

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 1/mild	Related	15 Jan 2021 (Study Day 135) - 15 Jan 2021 (Study Day 135)
Dyspnoea	Grade 2/moderate	Not related	26 Jan 2021 (Study Day 146) - 02 Mar 2021 (Study Day 181)
Drug Eruption	Grade 2/moderate	Not related	29 Jan 2021 (Study Day 149) - 31 Jan 2021 (Study Day 151)
Hyperglycaemia	Grade 3/severe	Not related	29 Jan 2021 (Study Day 149) - 09 Feb 2021 (Study Day 160)
Hyponatraemia	Grade 3/severe	Not related	29 Jan 2021 (Study Day 149) - 12 Mar 2021 (Study Day 191)
Pneumonia	Grade 3/severe	Not related	29 Jan 2021 (Study Day 149) - 12 Mar 2021 (Study Day 191)
Pruritus	Grade 2/moderate	Not related	29 Jan 2021 (Study Day 149) - 31 Jan 2021 (Study Day 151)
Hypokalaemia	Grade 1/mild	Not related	06 Feb 2021 (Study Day 157) - 08 Feb 2021 (Study Day 159)
Lactic Acidosis	Grade 1/mild	Not related	06 Feb 2021 (Study Day 157) - 12 Mar 2021 (Study Day 191)
Oedema Peripheral	Grade 1/mild	Not related	08 Feb 2021 (Study Day 159) - 01 Mar 2021 (Study Day 180)
Hypothyroidism	Grade 1/mild	Not related	12 Mar 2021 (Study Day 191) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US362-2160 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 05 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 03 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Back Pain/Back Pain	SAE	Grade 4	Not related	04 Apr 2021 (Study Day 212) – Ongoing	Not recovered/not resolved
Chest Pain/Chest Pain	SAE	Grade 4	Not related	04 Apr 2021 (Study Day 212) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US362-2160, a 51-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 05 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 03 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 02 Feb 2021. The participant was unblinded on 02 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 04 Apr 2021 (Study Day 212), 211 days after the first dose in Part A and 183 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of back pain. Action taken with the IP was not applicable. The event of back pain was considered to be ongoing. The investigator assessed the event of back pain to be not related to the IP.

On 04 Apr 2021 (Study Day 212), 211 days after the first dose in Part A and 183 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of chest pain. Action taken with the IP was not applicable. The event of chest pain was considered to be ongoing. The investigator assessed the event of chest pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-068782	Back pain
MOD-2021-068782	Chest pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
HIV infection	Hiv infection	1987 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Back pain	Back pain	2001 - Ongoing
Bronchitis chronic	Chronic bronchitis	2007 - Ongoing
Gastroesophageal reflux disease	Gerd	2009 - Ongoing
Neuropathy peripheral	Peripheral neuropathy	2009 - Ongoing
Rheumatoid arthritis	Chronic arthritis (rheumatoid)	2009 - Ongoing
Acute coronary syndrome	Acute coronary syndrome	2010 - Ongoing
Angina pectoris	Angina	2010 - Ongoing
Cholelithiasis	Gallstones	2010 - 2011
Coronary artery disease	Coronary artery disease	2010 - Ongoing
Diabetes mellitus	Diabetes	2010 - Ongoing
Myocardial infarction	Myocardial infarction	2010 - 2010
Hyperlipidaemia	Hyperlipidemia	2011 - Ongoing
Emphysema	Emphysema	2017 - Ongoing
Postmenopause	Post menopause	2017 - Ongoing
Asthma	Asthma (moderate)	2018 - Ongoing
Glaucoma	Glaucoma	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cobicistat; darunavir ethanolate; emtricitabine; tenofovir alafenamide fumarate	1987 - Ongoing	Hiv
Diltiazem	2000 - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol succinate	2000 - Ongoing	Hypertension
Celecoxib	2009 - Ongoing	Rheumatoid Arthritis
Gabapentin	2009 - Ongoing	Peripheral Bilateral Lower Extremity Neuropathy
Omeprazole	2009 - Ongoing	Gerd
Acetylsalicylic acid	2010 - Ongoing	Acute Coronary Syndrome
Glyceryl trinitrate	2010 - Ongoing	Angina
Sitagliptin	2010 - Ongoing	Diabetes
Atorvastatin	2011 - Ongoing	Hyperlipidemia
Rosuvastatin calcium	2011 - Ongoing	Hyperlipidemia
Clopidogrel	2017 - Aug 2020	Acute Coronary Syndrome
Montelukast sodium	2017 - Ongoing	Copd
Ipratropium bromide	2018 - Ongoing	Copd/Asthma
Salbutamol	2018 - Ongoing	Copd/Asthma
Salbutamol sulfate	2018 - Ongoing	Copd/Asthma
Colecalciferol	2020 - Ongoing	Supplement
Tramadol	2020 - Ongoing	Back Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US362-2206 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 19 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Oct 2020 (Study Day 28)
First Dose of Vaccine in Part B: 12 Jan 2021 (Study Day 116)
Second Dose of Vaccine in Part B: 09 Feb 2021 (Study Day 144)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteomyelitis Bacterial/ Osteomyelitis With Gas Gangrene Distal Right Middle Phalanx 2nd Digit	SAE	Grade 4	Not related	11 Mar 2021 (Study Day 174) – 16 Mar 2021 (Study Day 179)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US362-2206, a 45-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 19 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 16 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 12 Jan 2021 (Study Day 116). The second dose was administered in the left arm on 09 Feb 2021 (Study Day 144).

Event Details

On 11 Mar 2021 (Study Day 174), 173 days after the first dose in Part A/58 days after the first dose in Part B and 146 days after the second dose in Part A/30 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of osteomyelitis bacterial. Action taken with the IP was not applicable. The event of osteomyelitis with gas gangrene distal right middle phalanx 2nd digit lasted for 6 days, after which it was considered to be recovered/resolved on 16 Mar 2021 (Study Day 179). The investigator assessed the event of osteomyelitis bacterial to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-046813	Osteomyelitis bacterial

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Diabetes mellitus	Diabetes	1998 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin aspart	1998 - Ongoing	Diabetes
Insulin detemir	1998 - Ongoing	Diabetes
Fish oil	2018 - Ongoing	Supplement
Probiotics nos	2018 - Ongoing	Supplement
Vitamins nos	2018 - Ongoing	Supplement
(r) foot x-ray*	11 Mar 2021 (Study Day 174) - 11 Mar 2021 (Study Day 174)	Diagnostic
Insulin	11 Mar 2021 (Study Day 174) - 16 Mar 2021 (Study Day 179)	Uncontrolled Diabetes
Ketorolac tromethamine	11 Mar 2021 (Study Day 174) - 11 Mar 2021 (Study Day 174)	(R) Foot Pain (Related To Osteomyelitis/Gangrene)
Paracetamol	11 Mar 2021 (Study Day 174) - Ongoing	(R) Foot Pain (Related To Osteomyelitis/Gangrene)
Piperacillin sodium; tazobactam sodium	11 Mar 2021 (Study Day 174) - 11 Mar 2021 (Study Day 174)	Osteomyelitis/Gangrene
Sodium chloride	11 Mar 2021 (Study Day 174) - 11 Mar 2021 (Study Day 174)	Iv Fluids For Hydration
Vancomycin	11 Mar 2021 (Study Day 174) - 13 Mar 2021 (Study Day 176)	Osteomyelitis/Gangrene
Amlodipine besilate	12 Mar 2021 (Study Day 175) - Ongoing	Hypertension
Amputation of (r) foot 2nd digit*	12 Mar 2021 (Study Day 175) - 12 Mar 2021 (Study Day 175)	Adverse Event
Echo 2d w/ doppler*	12 Mar 2021 (Study Day 175) - 12 Mar 2021 (Study Day 175)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ekg @ 617*	12 Mar 2021 (Study Day 175) - 12 Mar 2021 (Study Day 175)	Diagnostic
Ekg @ 920*	12 Mar 2021 (Study Day 175) - 12 Mar 2021 (Study Day 175)	Diagnostic
Enoxaparin sodium	12 Mar 2021 (Study Day 175) - Ongoing	Prevent Blood Clots
Lisinopril	12 Mar 2021 (Study Day 175) - Ongoing	Hypertension
Mri (r) foot*	12 Mar 2021 (Study Day 175) - 12 Mar 2021 (Study Day 175)	Diagnostic
Us ble's*	12 Mar 2021 (Study Day 175) - 12 Mar 2021 (Study Day 175)	Diagnostic
X-ray post op*	12 Mar 2021 (Study Day 175) - 12 Mar 2021 (Study Day 175)	Adverse Event
Delayed wound debridement and closure*	15 Mar 2021 (Study Day 178) - 15 Mar 2021 (Study Day 178)	Adverse Event
Amoxicillin; clavulanate potassium	16 Mar 2021 (Study Day 179) - 25 Mar 2021 (Study Day 188)	Osteomyelitis/Gangrene

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diabetes Mellitus Inadequate Control	Grade 3/severe	Not related	11 Mar 2021 (Study Day 174) - Ongoing
Hypertension	Grade 2/moderate	Not related	12 Mar 2021 (Study Day 175) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US362-2282 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 21 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: Not Administered
First Dose of Vaccine in Part B: 09 Feb 2021 (Study Day 112)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteomyelitis/Bone Infection	SAE	Grade 4	Not related	25 Feb 2021 (Study Day 128) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US362-2282, a 51-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 21 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 09 Feb 2021. The participant was unblinded on 09 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 09 Feb 2021 (Study Day 112). The second dose was not administered.

Event Details

On 25 Feb 2021 (Study Day 128), 127 days after the first dose in Part A/16 days after the first dose in Part B of the IP (second dose Part A not applicable/second dose Part B not applicable), the participant experienced a Grade 4 serious adverse event of osteomyelitis. The IP dose was not changed due to the bone infection. The event of bone infection was considered to be ongoing. The investigator assessed the event of osteomyelitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-026230	Osteomyelitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	Not reported - Ongoing
Diabetes mellitus	Diabetes	Not reported - Ongoing
Seizure	Seizures	Not reported - Ongoing
Tobacco user	Smoker	Not reported - Ongoing
Asthma	Asthma (severe)	1971 - Ongoing
Anxiety	Anxiety	1985 - Ongoing
Bipolar disorder	Bipolar disorder	1985 - Ongoing
Paranoia	Paranoia	1985 - Ongoing
Post-traumatic stress disorder	Post-traumatic stress disorder	1985 - Ongoing
HIV infection	Hiv infection	1997 - Ongoing
Schizophrenia	Schizophrenia	2000 - Ongoing
Nerve injury	Nerve damage (neuropathy)	2001 - Ongoing
Postmenopause	Post menopause	2013 - Ongoing
Deep vein thrombosis	Deep vein thrombosis (site unknown)	2019 - Not reported
Ankle fracture	Right ankle fracture	Sep 2020 - 03 Oct 2020 (Study Day -18)
Arthralgia	Right ankle pain	Sep 2020 - Ongoing
Infection	Right ankle infection	Oct 2020 - Ongoing
Ankle operation	Right ankle surgery	03 Oct 2020 (Study Day -18) - 03 Oct 2020 (Study Day -18)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Budesonide	Not reported - Ongoing	Asthma
Montelukast	2000 - Ongoing	Asthma, Chronic Obstructive Pulmonary Disease
Quetiapine fumarate	2000 - 11 Nov 2020 (Study Day 22)	Paranoia
Valproate semisodium	2000 - 06 Nov 2020 (Study Day 17)	Anxiety, Schizophrenia, Seizures
Salbutamol sulfate	2005 - Ongoing	Asthma
Abacavir sulfate; dolutegravir sodium; lamivudine	2010 - 06 Nov 2020 (Study Day 17)	Hiv
Pregabalin	2010 - Ongoing	Nerve Damage
Ipratropium bromide	2011 - Ongoing	Asthma
Ipratropium bromide; salbutamol sulfate	2015 - 06 Nov 2020 (Study Day 17)	Asthma
Salbutamol	2015 - 06 Nov 2020 (Study Day 17)	Asthma
Rivaroxaban	2017 - 13 Nov 2020 (Study Day 24)	Prophylaxis For Dvt

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lurasidone hydrochloride	2020 - 06 Nov 2020 (Study Day 17)	Bipolar Disorder
Paracetamol	Oct 2020 - Ongoing	Right Ankle Pain
Bacitracin; neomycin sulfate; polymyxin b sulfate	03 Oct 2020 (Study Day -18) - 06 Nov 2020 (Study Day 17)	Right Ankle Infection
Ibuprofen	03 Oct 2020 (Study Day -18) - 06 Nov 2020 (Study Day 17)	Right Ankle Pain
Paracetamol	21 Oct 2020 (Study Day 1) - 22 Oct 2020 (Study Day 2)	Fever
Paracetamol	21 Oct 2020 (Study Day 1) - 22 Oct 2020 (Study Day 2)	Headaches, Muscle Aches, Joint Aches, Chills, Fever
Alprazolam	06 Nov 2020 (Study Day 17) - 10 Nov 2020 (Study Day 21)	Anxiety
Arterial blood gases*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Blood culture*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Budesonide	06 Nov 2020 (Study Day 17) - 25 Nov 2020 (Study Day 36)	Asthma/Intermittent Wheezing
C-reactive protein*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Cefepime	06 Nov 2020 (Study Day 17) - 09 Nov 2020 (Study Day 20)	Right Ankle Cellulitis/Sepsis/UTI
Chest x ray*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Clindamycin	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Right Ankle Cellulitis/Sepsis
Complete blood count and differential*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Complete metabolic panel*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Ct tib-fib right with iv contrast*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Electrocardiogram (ekg)*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Insulin lispro	06 Nov 2020 (Study Day 17) - Ongoing	Diabetes
Iohexol	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Iv Contrast (Right Leg Ct Scan)
Ketorolac	06 Nov 2020 (Study Day 17) - 10 Nov 2020 (Study Day 21)	Right Leg Pain - Cellulitis
Naloxone hydrochloride	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Lethargy - Suspected Opioid Abuse
Oxygen	06 Nov 2020 (Study Day 17) - 26 Nov 2020 (Study Day 37)	Unknown
Pantoprazole	06 Nov 2020 (Study Day 17) - 25 Nov 2020 (Study Day 36)	Prophylaxis For Gastrointestinal (GI) Bleed
Paracetamol	06 Nov 2020 (Study Day 17) - 25 Nov 2020 (Study Day 36)	Pain Right Ankle
Right ankle x ray*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Right foot x ray*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Ultrasound bilateral upper extremities*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Urinalysis*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Valproate semisodium	06 Nov 2020 (Study Day 17) - 17 Nov 2020 (Study Day 28)	Seizures
Vancomycin	06 Nov 2020 (Study Day 17) - 08 Nov 2020 (Study Day 19)	Right Ankle Cellulitis/Sepsis/Uti
Vancomycin	08 Nov 2020 (Study Day 19) - 11 Nov 2020 (Study Day 22)	Right Ankle Cellulitis/Sepsis
Calcium chloride; potassium chloride; sodium lactate	10 Nov 2020 (Study Day 21) - 18 Nov 2020 (Study Day 29)	Blood Pressure Support - Hypotension
Calcium chloride; potassium chloride; sodium lactate	10 Nov 2020 (Study Day 21) - 11 Nov 2020 (Study Day 22)	Hypotension
Ct brain without iv contrast*	10 Nov 2020 (Study Day 21) - 10 Nov 2020 (Study Day 21)	Diagnostic
Mri brain without iv contrast*	10 Nov 2020 (Study Day 21) - 10 Nov 2020 (Study Day 21)	Diagnostic
Naloxone hydrochloride	10 Nov 2020 (Study Day 21) - 10 Nov 2020 (Study Day 21)	Lethargy - Suspected Opioid Abuse
Nicotine	10 Nov 2020 (Study Day 21) - 25 Nov 2020 (Study Day 36)	Smoking Cessation
Sodium chloride	10 Nov 2020 (Study Day 21) - 13 Nov 2020 (Study Day 24)	Hypotension
Sodium chloride	10 Nov 2020 (Study Day 21) - 22 Nov 2020 (Study Day 33)	Hypotension (1st Episode) And Hypotension (2nd Episode)
Ampicillin; sulbactam	11 Nov 2020 (Study Day 22) - 13 Nov 2020 (Study Day 24)	Right Ankle Cellulitis/Sepsis
Bedside eeg monitoring continuous*	11 Nov 2020 (Study Day 22) - 11 Nov 2020 (Study Day 22)	Diagnostic
Ct abd/pelvis without iv contrast*	11 Nov 2020 (Study Day 22) - 11 Nov 2020 (Study Day 22)	Diagnostic
Ipratropium bromide; salbutamol	11 Nov 2020 (Study Day 22) - 24 Nov 2020 (Study Day 35)	Asthma - Intermittent Wheezing, Atelectasis
Mid line insertion - ultrasound guided*	11 Nov 2020 (Study Day 22) - 11 Nov 2020 (Study Day 22)	Adverse Event
Portable eeg*	11 Nov 2020 (Study Day 22) - 11 Nov 2020 (Study Day 22)	Diagnostic
Transthoracic echo*	11 Nov 2020 (Study Day 22) - 11 Nov 2020 (Study Day 22)	Diagnostic
Valproate semisodium	11 Nov 2020 (Study Day 22) - 17 Nov 2020 (Study Day 28)	Seizures
Vancomycin	11 Nov 2020 (Study Day 22) - 15 Nov 2020 (Study Day 26)	Right Ankle Cellulitis/Sepsis
Calcium gluconate	12 Nov 2020 (Study Day 23) - 12 Nov 2020 (Study Day 23)	Hypocalcemia (2nd Episode)
Chest x ray*	12 Nov 2020 (Study Day 23) - 12 Nov 2020 (Study Day 23)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Electrolytes nos	12 Nov 2020 (Study Day 23) - 12 Nov 2020 (Study Day 23)	Electrolyte Imbalance
Magnesium bloodwork*	12 Nov 2020 (Study Day 23) - 12 Nov 2020 (Study Day 23)	Diagnostic
Magnesium sulfate	12 Nov 2020 (Study Day 23) - 12 Nov 2020 (Study Day 23)	Hypomagnesemia
Piperacillin sodium; tazobactam sodium	12 Nov 2020 (Study Day 23) - 12 Nov 2020 (Study Day 23)	Right Ankle Cellulitis/Sepsis
Abacavir	13 Nov 2020 (Study Day 24) - 17 Nov 2020 (Study Day 28)	Hiv
Dolutegravir	13 Nov 2020 (Study Day 24) - 17 Nov 2020 (Study Day 28)	Hiv
Lamivudine	13 Nov 2020 (Study Day 24) - 17 Nov 2020 (Study Day 28)	Hiv
Sulfamethoxazole; trimethoprim	13 Nov 2020 (Study Day 24) - 17 Nov 2020 (Study Day 28)	Prophylaxis For Pcp
Aciclovir	14 Nov 2020 (Study Day 25) - 16 Nov 2020 (Study Day 27)	Potential Cns Infection
Ampicillin	14 Nov 2020 (Study Day 25) - 16 Nov 2020 (Study Day 27)	Right Ankle Cellulitis/Sepsis
Cefepime	14 Nov 2020 (Study Day 25) - 16 Nov 2020 (Study Day 27)	Potential Cns Infection
Haloperidol	14 Nov 2020 (Study Day 25) - 18 Nov 2020 (Study Day 29)	Episodes Of Agitation
Lidocaine	15 Nov 2020 (Study Day 26) - 15 Nov 2020 (Study Day 26)	Lumbar Puncture
Lumbar puncture*	15 Nov 2020 (Study Day 26) - 15 Nov 2020 (Study Day 26)	Diagnostic
Vancomycin	15 Nov 2020 (Study Day 26) - 16 Nov 2020 (Study Day 27)	Potential Cns Infection
Chest x ray*	16 Nov 2020 (Study Day 27) - 16 Nov 2020 (Study Day 27)	Diagnostic
Glucose	16 Nov 2020 (Study Day 27) - 18 Nov 2020 (Study Day 29)	Hypoglycemia
Lorazepam	16 Nov 2020 (Study Day 27) - 16 Nov 2020 (Study Day 27)	Episodes Of Agitation
Magnesium bloodwork*	16 Nov 2020 (Study Day 27) - 16 Nov 2020 (Study Day 27)	Diagnostic
Rivaroxaban	16 Nov 2020 (Study Day 27) - 17 Nov 2020 (Study Day 28)	Dvt Prophylaxis
Complete metabolic panel*	17 Nov 2020 (Study Day 28) - 17 Nov 2020 (Study Day 28)	Diagnostic
Ct brain without iv contrast*	17 Nov 2020 (Study Day 28) - 17 Nov 2020 (Study Day 28)	Diagnostic
Quetiapine	17 Nov 2020 (Study Day 28) - 25 Nov 2020 (Study Day 36)	Paranoia
Calcium alginate	18 Nov 2020 (Study Day 29) - 24 Nov 2020 (Study Day 35)	Right Ankle Wound Care
Enoxaparin	18 Nov 2020 (Study Day 29) - 25 Nov 2020 (Study Day 36)	Deep Vein Thrombosis Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Miconazole	18 Nov 2020 (Study Day 29) - Ongoing	Bilateral Inguinal Areas And Pannus Fold
Potassium chloride	18 Nov 2020 (Study Day 29) - 19 Nov 2020 (Study Day 30)	Hypokalemia
Valproate sodium	18 Nov 2020 (Study Day 29) - 25 Nov 2020 (Study Day 36)	Seizures
Zinc oxide	18 Nov 2020 (Study Day 29) - Ongoing	Intergluteal Fold Fissure Wound Care
Glucose; sodium chloride	19 Nov 2020 (Study Day 30) - 24 Nov 2020 (Study Day 35)	Unknown
Magnesium sulfate	19 Nov 2020 (Study Day 30) - 19 Nov 2020 (Study Day 30)	Hypomagnesemia
Ampicillin; sulbactam	20 Nov 2020 (Study Day 31) - 23 Nov 2020 (Study Day 34)	Sepsis
Hydromorphone	20 Nov 2020 (Study Day 31) - 21 Nov 2020 (Study Day 32)	Right Ankle Pain
Chest x ray*	21 Nov 2020 (Study Day 32) - 21 Nov 2020 (Study Day 32)	Diagnostic
Magnesium sulfate	21 Nov 2020 (Study Day 32) - 21 Nov 2020 (Study Day 32)	Hypomagnesemia (2nd Episode)
Abacavir	22 Nov 2020 (Study Day 33) - 25 Nov 2020 (Study Day 36)	Hiv
Chest x ray*	22 Nov 2020 (Study Day 33) - 22 Nov 2020 (Study Day 33)	Diagnostic
Dolutegravir	22 Nov 2020 (Study Day 33) - 25 Nov 2020 (Study Day 36)	Hiv
Lamivudine	22 Nov 2020 (Study Day 33) - 25 Nov 2020 (Study Day 36)	Hiv
Magnesium sulfate	23 Nov 2020 (Study Day 34) - 23 Nov 2020 (Study Day 34)	Hypomagnesemia (2nd Episode)
Potassium chloride	23 Nov 2020 (Study Day 34) - 23 Nov 2020 (Study Day 34)	Hypokalemia (3rd Episode)
Potassium; sodium phosphate	23 Nov 2020 (Study Day 34) - 23 Nov 2020 (Study Day 34)	Hypokalemia (3rd Episode)
Docusate sodium; sennoside a+b	24 Nov 2020 (Study Day 35) - 25 Nov 2020 (Study Day 36)	Constipation
Lidocaine	24 Nov 2020 (Study Day 35) - 25 Nov 2020 (Study Day 36)	Right Ankle Pain
Macrogol	24 Nov 2020 (Study Day 35) - 25 Nov 2020 (Study Day 36)	Constipation
Meglumine gadoterate	24 Nov 2020 (Study Day 35) - 24 Nov 2020 (Study Day 35)	Mri Right Ankle With And Without Contrast
Mri right ankle with and without iv contrast*	24 Nov 2020 (Study Day 35) - 24 Nov 2020 (Study Day 35)	Diagnostic
Us dvt lower bilateral extremities*	25 Nov 2020 (Study Day 36) - 25 Nov 2020 (Study Day 36)	Diagnostic
Us dvt upper bilateral extremities*	25 Nov 2020 (Study Day 36) - 25 Nov 2020 (Study Day 36)	Diagnostic
Abacavir sulfate; dolutegravir sodium; lamivudine	26 Nov 2020 (Study Day 37) - Ongoing	Hiv

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	26 Nov 2020 (Study Day 37) - Ongoing	Right Foot Pain
Quetiapine fumarate	26 Nov 2020 (Study Day 37) - Ongoing	Paranoia
Rivaroxaban	26 Nov 2020 (Study Day 37) - Ongoing	Prophylaxis For Deep Vein Thrombosis
Valproate semisodium	26 Nov 2020 (Study Day 37) - Ongoing	Anxiety
Amoxicillin trihydrate; clavulanate potassium	25 Jan 2021 (Study Day 97) - 03 Feb 2021 (Study Day 106)	Right Ankle Cellulitis
Alprazolam	Feb 2021 - Ongoing	Anxiety
Metformin	Feb 2021 - Ongoing	Diabetes

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US363-2052 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 06 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Prostate Cancer/ Prostate Cancer	SAE	Grade 3/ severe	Not related	22 Mar 2021 (Study Day 196) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US363-2052, a 61-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 06 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Jan 2021. The participant was unblinded on 04 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 22 Mar 2021 (Study Day 196), 195 days after the first dose in Part A and 167 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of prostate cancer. Action taken with the IP was not applicable. The event of prostate cancer was considered to be ongoing. The investigator assessed the event of prostate cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-065748	Prostate cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2014 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2016 - Ongoing
Insomnia	Insomnia	2016 - Ongoing
Tinnitus	Tinnitus in both ears	2016 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hypertrophy	2018 - Ongoing
Seasonal allergy	Seasonal allergies	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2014 - Ongoing	Hypercholesterolemia
Hydrochlorothiazide	2014 - Ongoing	Hypertension
Atorvastatin calcium	2016 - Ongoing	Hypercholesterolemia
Zolpidem tartrate	2016 - Ongoing	Insomnia
Beclometasone dipropionate	2018 - Ongoing	Seasonal Allergies
Finasteride	2019 - Feb 2021	Benign Prostatic Hypertrophy
Levocetirizine	2019 - Ongoing	Seasonal Allergies
Multivitamins, other combinations	2019 - Ongoing	Tinnitus Both Ears
Vitamins nos	2020 - Feb 2021	General Health
Paracetamol	14 Sep 2020 (Study Day 7) - 14 Sep 2020 (Study Day 7)	Mild Headache
Paracetamol	06 Oct 2020 (Study Day 29) - 10 Oct 2020 (Study Day 33)	Pain At Injection Site
Diclofenac	13 Oct 2020 (Study Day 36) - 15 Feb 2021 (Study Day 161)	Acute Thumb Joint Pain
Naproxen sodium	24 Oct 2020 (Study Day 47) - Ongoing	Soreness From Yard Work
Influenza vaccine	28 Oct 2020 (Study Day 51) - 28 Oct 2020 (Study Day 51)	General Health
Endoscopy*	05 Feb 2021 (Study Day 151) - 05 Feb 2021 (Study Day 151)	Adverse Event
Omeprazole	12 Feb 2021 (Study Day 158) - Ongoing	Globus Pharyngeus
Colonoscopy*	18 Feb 2021 (Study Day 164) - 18 Feb 2021 (Study Day 164)	Other, Routine Colonoscopy For Age
Prostate biopsy*	04 Mar 2021 (Study Day 178) - 04 Mar 2021 (Study Day 178)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US363-2075 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 65 Years
First Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 13 Oct 2020 (Study Day 33)
First Dose of Vaccine in Part B: 04 Jan 2021 (Study Day 116)
Second Dose of Vaccine in Part B: 04 Feb 2021 (Study Day 147)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardiac Failure/ Worsening Heart Failure	SAE	Grade 3/ severe	Not related	12 Feb 2021 (Study Day 155) – 03 Mar 2021 (Study Day 174)	Recovered/resolved with sequelae
Myocardial Infarction/ Myocardial Infarction	SAE	Grade 4	Not related	12 Feb 2021 (Study Day 155) – 03 Mar 2021 (Study Day 174)	Recovered/resolved
Renal Failure/Worsening Renal Failure	SAE	Grade 4	Not related	14 Feb 2021 (Study Day 157) – 03 Mar 2021 (Study Day 174)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US363-2075, a 79-year-old not Hispanic or Latino male, received the first dose of Placebo in the right arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 13 Oct 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Jan 2021. The participant was unblinded on 04 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 04 Jan 2021 (Study Day 116). The second dose was administered in the right arm on 04 Feb 2021 (Study Day 147).

Event Details

On 12 Feb 2021 (Study Day 155), 154 days after the first dose in Part A/39 days after the first dose in Part B and 122 days after the second dose in Part A/8 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of cardiac failure. The IP dose was not changed due to the worsening heart failure. The event of worsening heart failure lasted for 20 days, after which it was considered to be recovered/resolved with sequelae on 03 Mar 2021 (Study Day 174). The investigator assessed the event of cardiac failure to be not related to the IP.

On 12 Feb 2021 (Study Day 155), 154 days after the first dose in Part A/39 days after the first dose in Part B and 122 days after the second dose in Part A/8 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of myocardial infarction. The IP dose was not changed due to the myocardial infarction. The event of myocardial infarction lasted for 20 days, after which it was considered to be recovered/resolved on 03 Mar 2021 (Study Day 174). The investigator assessed the event of myocardial infarction to be not related to the IP.

On 14 Feb 2021 (Study Day 157), 156 days after the first dose in Part A/41 days after the first dose in Part B and 124 days after the second dose in Part A/10 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of renal failure. The IP dose was not changed due to the worsening renal failure. The event of worsening renal failure lasted for 18 days, after which it was considered to be recovered/resolved with sequelae on 03 Mar 2021 (Study Day 174). The investigator assessed the event of renal failure to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-018680	Cardiac failure
MOD-2021-018680	Myocardial infarction
MOD-2021-018680	Renal failure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Acute kidney injury	Acute renal failure	Not reported - 01 Aug 2020 (Study Day -41)
Biliary dyskinesia	Biliary dyskinesia	Not reported - 2013
Biliary sphincterotomy	Sphincterotomy common bile duct entering the duodenum	Not reported - 2013
Catheter placement	Retrograde cannulation	Not reported - 2013
Cholecystectomy	Laparoscopic cholecystectomy	Not reported - 2013
Hernia repair	Repair of hernia	Not reported - 2014
Influenza immunisation	Flu shot	Not reported - 27 Sep 2020 (Study Day 17)
Pancreatitis	Pancreatitis	Not reported - 2013
Appendectomy	Appendectomy	1945 - 1945
Tonsillectomy	Tonsillectomy	1950 - 1950
Toe amputation	Right toe amputation	1959 - 1959
Type 2 diabetes mellitus	Type 2 diabetes	01 Jan 1989 (Study Day -11576) - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Peripheral arterial occlusive disease	Peripheral artery pad	1990 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Hyperlipidaemia	Hyperlipidemia	01 Jan 2000 (Study Day -7559) - Ongoing
Nephropathy	Severe renal disease	01 Jan 2001 (Study Day -7193) - Ongoing
Neuropathic arthropathy	Charcot foot	2003 - 2004
Leg amputation	Left leg amputation	2004 - 2004
Arterial bypass operation	Distal arterial bypass	01 Jan 2004 (Study Day -6098) - 01 Jan 2004 (Study Day -6098)
Coronary artery disease	Coronary artery disease (unreconstructable)	01 Jan 2004 (Study Day -6098) - Ongoing
Cardiac failure	Heart failure	2005 - Ongoing
Peripheral swelling	Chronic swelling of r leg	01 Jan 2005 (Study Day -5732) - Ongoing
Peripheral swelling	Chronic swelling of right leg	01 Jan 2005 (Study Day -5732) - Ongoing
Cervical spinal stenosis	Narrowing of c5 & c6	2010 - Ongoing
Myocardial infarction	Heart attack	01 Jan 2010 (Study Day -3906) - 01 Jan 2010 (Study Day -3906)
Abdominal pain	Severe abdominal pain	2013 - 2013
Cardiac pacemaker insertion	Pacemaker placement	01 Jan 2013 (Study Day -2810) - 01 Jan 2013 (Study Day -2810)
Sinus bradycardia	Sinus bradycardia	01 Jan 2013 (Study Day -2810) - Ongoing
Atrial fibrillation	Atrial fibrillation	01 Jan 2015 (Study Day -2080) - Ongoing
Lymphoedema	Right leg lymphedema	01 Jan 2015 (Study Day -2080) - Ongoing
Cataract operation	Cataract surgery on left eye	2017 - 2017
Localised infection	Right leg sepsis	2017 - Ongoing
Peripheral venous disease	Venous insufficiency in right leg	2017 - Ongoing
Herpes zoster	Herpes zoster	Aug 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylcysteine	2001 - Ongoing	Type 2 Diabetes
Isosorbide	2005 - Ongoing	Coronary Artery Disease
Vitis vinifera seed	2005 - Ongoing	Type 2 Diabetes
Sitagliptin	2010 - Ongoing	Type 2 Diabetes
Acetylsalicylic acid	2015 - Ongoing	Mi Prevention
Atorvastatin	2015 - Ongoing	Coronary Artery Disease
Carvedilol	2015 - 12 Feb 2021 (Study Day 155)	Coronary Artery Disease
Carnitine	2017 - Ongoing	Coronary Artery Disease
D-ribose	2017 - Ongoing	Coronary Artery Disease
Furosemide	2018 - 01 Jan 2021 (Study Day 113)	Left Leg Amputation
Ubiquinol	2018 - Ongoing	Coronary Artery Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin d nos	2018 - Ongoing	General Supplement
Montelukast	2020 - Ongoing	Severe Renal Disease
Aciclovir	01 Sep 2020 (Study Day -10) - 30 Dec 2020 (Study Day 111)	Herpes Zoster
Influenza vaccine	27 Sep 2020 (Study Day 17) - 27 Sep 2020 (Study Day 17)	Seasonal Flu Shot
Metronidazole	15 Oct 2020 (Study Day 35) - 15 Oct 2020 (Study Day 35)	Diarrhea
Metronidazole	23 Oct 2020 (Study Day 43) - 23 Oct 2020 (Study Day 43)	Diarrhea (Ae)
Furosemide	29 Jan 2021 (Study Day 141) - 12 Feb 2021 (Study Day 155)	Left Leg Amputation
12 lead ekg*	12 Feb 2021 (Study Day 155) - 12 Feb 2021 (Study Day 155)	Adverse Event
Acetylsalicylic acid	12 Feb 2021 (Study Day 155) - 12 Feb 2021 (Study Day 155)	Myocardial Infarction
Portable chest xray- 1 view*	12 Feb 2021 (Study Day 155) - 12 Feb 2021 (Study Day 155)	Adverse Event
12-lead ekg*	13 Feb 2021 (Study Day 156) - 13 Feb 2021 (Study Day 156)	Adverse Event
Ceftriaxone	13 Feb 2021 (Study Day 156) - 19 Feb 2021 (Study Day 162)	Cystitis
Ct abdomen and pelvis without iv contrast*	13 Feb 2021 (Study Day 156) - 13 Feb 2021 (Study Day 156)	Adverse Event
Ct chest without contrast*	13 Feb 2021 (Study Day 156) - 13 Feb 2021 (Study Day 156)	Adverse Event
Furosemide	13 Feb 2021 (Study Day 156) - 13 Feb 2021 (Study Day 156)	Myocardial Infarction
Heparin	13 Feb 2021 (Study Day 156) - 22 Feb 2021 (Study Day 165)	Myocardial Infarction
Carvedilol	14 Feb 2021 (Study Day 157) - 23 Feb 2021 (Study Day 166)	Myocardial Infarction
Furosemide	14 Feb 2021 (Study Day 157) - 22 Feb 2021 (Study Day 165)	Worsening Renal Failure
Magnesium sulfate	14 Feb 2021 (Study Day 157) - 14 Feb 2021 (Study Day 157)	Myocardial Infarction
Sodium bicarbonate	14 Feb 2021 (Study Day 157) - 23 Feb 2021 (Study Day 166)	Worsening Renal Failure
Transthoracic echocardiogram*	14 Feb 2021 (Study Day 157) - 14 Feb 2021 (Study Day 157)	Adverse Event
Milrinone	17 Feb 2021 (Study Day 160) - 21 Feb 2021 (Study Day 164)	Worsening Heart Failure
Right heart catheterization*	17 Feb 2021 (Study Day 160) - 17 Feb 2021 (Study Day 160)	Adverse Event
Carvedilol	23 Feb 2021 (Study Day 166) - Ongoing	Myocardial Infarction
Transthoracic echocardiogram*	23 Feb 2021 (Study Day 166) - 23 Feb 2021 (Study Day 166)	Adverse Event
Torasemide	27 Feb 2021 (Study Day 170) - Ongoing	Worsening Renal Failure
Hydralazine	03 Mar 2021 (Study Day 174) - Ongoing	Worsening Heart Failure (Ae)
Isosorbide dinitrate	03 Mar 2021 (Study Day 174) - Ongoing	Worsening Heart Failure (Ae)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Patiromer	03 Mar 2021 (Study Day 174) - Ongoing	Worsening Renal Failure (Ae)
Warfarin sodium	03 Mar 2021 (Study Day 174) - Ongoing	Atrial Fibrillation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Lymphoedema	Grade 2/moderate	Not related	29 Jan 2021 (Study Day 141) - Ongoing
Cystitis	Grade 1/mild	Not related	12 Feb 2021 (Study Day 155) - 19 Feb 2021 (Study Day 162)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US364-2076 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 30 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: 21 Jan 2021 (Study Day 143)
Second Dose of Vaccine in Part B: 05 Mar 2021 (Study Day 186)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Metastases To Lung/ Possible Relapse Of Renal Cell Carcinoma Metastasized To His Lungs	SAE	Grade 3/ severe	Not related	22 Feb 2021 (Study Day 175) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US364-2076, a 65-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 08 Jan 2021. The participant was unblinded on 08 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 21 Jan 2021 (Study Day 143). The second dose was administered in the left arm on 05 Mar 2021 (Study Day 186).

Event Details

On 22 Feb 2021 (Study Day 175), 174 days after the first dose in Part A/32 days after the first dose in Part B and 145 days after the second dose in Part A/11 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of metastases to lung. The IP dose was not changed due to the possible relapse of renal cell carcinoma metastasized to his lungs. The event of possible relapse of renal cell carcinoma metastasized to his lungs was considered to be ongoing. The investigator assessed the event of metastases to lung to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-027980	Metastases to lung

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	1980 - Ongoing
Headache	Headaches	1980 - Ongoing
Prostatic disorder	Prostate issue	2010 - Ongoing
Fatigue	Fatigue	2015 - Ongoing
Renal cell carcinoma	Renal cell carcinoma	2015 - 2019
Thrombosis	Blood clots history	2015 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2015 - Ongoing
Neuropathy peripheral	Peripreral neuropathy	2017 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2018 - Ongoing
Nausea	Nausea related to opdivo	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	1980 - Ongoing	Headache
Doxazosin	2010 - Ongoing	Prostate Issue
Mirtazapine	2016 - Ongoing	Depression
Atorvastatin	2018 - Ongoing	Hyperlipidemia
Ondansetron hydrochloride	2018 - Ongoing	Nausea R/T Opdivo
Rivaroxaban	2018 - Ongoing	History Of Blood Clots
Vortioxetine hydrobromide	2018 - Ongoing	Depression
Ascorbic acid; biotin; calcium pantothenate; calcium phosphate dibasic; cyanocobalamin; folic acid; nicotinamide; pyridoxine hydrochloride; riboflavin; thiamine mononitrate; yeast dried	2019 - Ongoing	Supplement
Folic acid	2019 - Ongoing	Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Nivolumab	2019 - 2019	Renal Cell Carcinoma
Lamotrigine	01 Jun 2020 (Study Day -92) - Ongoing	Depression
Lamotrigine	08 Sep 2020 (Study Day 8) - Ongoing	Depression
Omeprazole	07 Jan 2021 (Study Day 129) - Ongoing	Nausea, Med Exposure
Tiotropium bromide	07 Jan 2021 (Study Day 129) - Ongoing	Fatigue Related To Shortness Of Breath Post Metastatic Renal Cell Carcinoma
Ct scan of abdomen and the brain*	22 Feb 2021 (Study Day 175) - 22 Feb 2021 (Study Day 175)	Diagnostic
Benzonatate	26 Feb 2021 (Study Day 179) - 01 Apr 2021 (Study Day 213)	Cough
Chlordiazepoxide	26 Feb 2021 (Study Day 179) - 28 Feb 2021 (Study Day 181)	Anxiety Related To Relapse Of Renal Cell Carcinoma Metastasized To His Lungs
Gabapentin	26 Feb 2021 (Study Day 179) - Ongoing	Possible Relapse Of Renal Cell Carcinoma Metastasized To His Lungs
Gabapentin	26 Feb 2021 (Study Day 179) - Ongoing	Relapse Of Renal Cell Carcinoma Metastasized To His Lungs
Guaifenesin	26 Feb 2021 (Study Day 179) - 01 Apr 2021 (Study Day 213)	Cough
Methylprednisolone	26 Feb 2021 (Study Day 179) - 01 Apr 2021 (Study Day 213)	Relapse Of Renal Cell Carcinoma Metastasized To His Lungs
Vitamin b1 nos	26 Feb 2021 (Study Day 179) - Ongoing	Relapse Of Renal Cell Carcinoma Metastasized To His Lungs

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cough	Grade 2/moderate	Not related	24 Feb 2021 (Study Day 177) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US364-2081 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 02 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 01 Oct 2020 (Study Day 30)
First Dose of Vaccine in Part B: 16 Jan 2021 (Study Day 137)
Second Dose of Vaccine in Part B: 13 Feb 2021 (Study Day 165)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abdominal Pain Upper/Epigastric Pain	SAE	Grade 3/ severe	Not related	28 Mar 2021 (Study Day 208) – 29 Mar 2021 (Study Day 209)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US364-2081, a 68-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 08 Jan 2021. The participant was unblinded on 08 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 16 Jan 2021 (Study Day 137). The second dose was administered in the left arm on 13 Feb 2021 (Study Day 165).

Event Details

On 28 Mar 2021 (Study Day 208), 207 days after the first dose in Part A/71 days after the first dose in Part B and 178 days after the second dose in Part A/43 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of abdominal pain upper. Action taken with the IP was not applicable. The event of epigastric pain lasted for 2 days, after which it was considered to be recovered/resolved on 29 Mar 2021 (Study Day 209). The investigator assessed the event of abdominal pain upper to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-066998	Abdominal pain upper

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post menopausal	Not reported - Ongoing
Breast cancer	Breast cancer	1982 - 2015
Migraine	Migraines	1990 - Ongoing
Cataract	Left cataract	2015 - Ongoing
Cataract	Right cataract	2015 - 2018
Vitamin D deficiency	Vitamin d deficiency	2015 - Ongoing
Cataract operation	Right cataract surgery	2018 - 2018
Hypercholesterolaemia	Hypercholesterolemia	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	1990 - Ongoing	Migraine Headaches
Vitamins nos	2010 - Ongoing	General Health
Vitamin d nos	2015 - Ongoing	Vitamin D Deficiency
Atorvastatin	2018 - Ongoing	Hypercholesterolemia
Ibuprofen	15 Sep 2020 (Study Day 14) - 15 Sep 2020 (Study Day 14)	Migraine Headache
Influenza vaccine	16 Sep 2020 (Study Day 15) - 16 Sep 2020 (Study Day 15)	Prophylaxis For Flu
Ibuprofen	04 Oct 2020 (Study Day 33) - 06 Oct 2020 (Study Day 35)	Headache
Valaciclovir	29 Jan 2021 (Study Day 150) - 06 Feb 2021 (Study Day 158)	Shingles Infection
Ibuprofen	14 Feb 2021 (Study Day 166) - 14 Feb 2021 (Study Day 166)	Fever
Left cataract surgery*	15 Mar 2021 (Study Day 195) - 15 Mar 2021 (Study Day 195)	Medical History
Ofloxacin	15 Mar 2021 (Study Day 195) - Ongoing	Left Cataract Surgery

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Herpes Zoster	Grade 2/moderate	Not related	26 Jan 2021 (Study Day 147) - 09 Feb 2021 (Study Day 161)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US364-2217 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 15 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 13 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intermittent Claudication/ Intermittent Claudication	SAE	Grade 3/ severe	Not related	01 Feb 2021 (Study Day 140) – 16 Feb 2021 (Study Day 155)	Recovered/ resolved
Peripheral Arterial Occlusive Disease/ Atherosclerosis Of Bilateral Legs	SAE	Grade 3/ severe	Not related	01 Feb 2021 (Study Day 140) – 16 Feb 2021 (Study Day 155)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US364-2217, a 72-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 15 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 13 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Jan 2021. The participant was unblinded on 21 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 01 Feb 2021 (Study Day 140), 139 days after the first dose in Part A and 111 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of intermittent claudication. Action taken with the IP was not applicable. The event of intermittent claudication lasted for 16 days, after which it was considered to be recovered/resolved on 16 Feb 2021 (Study Day 155). The investigator assessed the event of intermittent claudication to be not related to the IP.

On 01 Feb 2021 (Study Day 140), 139 days after the first dose in Part A and 111 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of peripheral arterial occlusive disease. Action taken with the IP was not applicable. The event of atherosclerosis of bilateral legs lasted for 16 days, after which it was considered to be

recovered/resolved on 16 Feb 2021 (Study Day 155). The investigator assessed the event of peripheral arterial occlusive disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-016964	Intermittent claudication
MOD-2021-016964	Peripheral arterial occlusive disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Chronic back pain	Not reported - Ongoing
Chronic kidney disease	Chronic kidney disease stage 3a	Not reported - Ongoing
Ligament rupture	Chronic tear of acl	Not reported - Ongoing
Lumbar radiculopathy	Lumbar radiculopathy	Not reported - Ongoing
Microalbuminuria	Microalbuminuria	Not reported - Ongoing
Onychomycosis	Onychomycosis	Not reported - Ongoing
Hypertension	Hypertension	1985 - Ongoing
Postmenopause	Post menopausal	1985 - Ongoing
Dermal filler injection	Juvederm cosmetic injection	1997 - 1997
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Peripheral vascular disorder	Peripheral vascular disease	2014 - Ongoing
Pulmonary mass	Pulmonary nodules	Sep 2014 - Ongoing
Arterial stenosis	Arterial stenosis	2015 - Ongoing
Chronic obstructive pulmonary disease	Copd	2015 - Ongoing
Coronary artery disease	Coronary artery disease	2015 - Ongoing
Peripheral artery bypass	Femoral bypass surgery	2015 - 2015
Bundle branch block left	Left bundle branch block	2016 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2016 - Ongoing
Aortic arteriosclerosis	Atherosclerosis of aorta	Aug 2016 - Ongoing
Cardiomyopathy	Cardiomyopathy	Sep 2017 - Ongoing
Anxiety	Anxiety	2018 - Ongoing
Emphysema	Emphysema	2018 - Ongoing
Seasonal allergy	Seasonal allergies	2019 - Ongoing
Cardiac failure	Heart failure with a normal ejection fraction	Aug 2019 - Ongoing
Arthralgia	Hip pain right	May 2020 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vulvovaginal dryness	Vaginal dryness	May 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2010 - 06 Nov 2020 (Study Day 53)	Hyperlipidemia
Acetylsalicylic acid	2015 - Ongoing	Heart Prophylaxis
Spironolactone	2015 - 20 Jan 2021 (Study Day 128)	Hypertension
Metformin	2016 - Ongoing	Type 2 Diabetes
Amlodipine	2018 - Ongoing	Hypertension
Bupropion	2018 - Ongoing	Anxiety
Cinnamomum verum	2018 - Ongoing	Supplement
Cetirizine	2019 - Ongoing	Seasonal Allergy
Losartan	2019 - Ongoing	Hypertension
Magnesium	2019 - Ongoing	Supplement
Multivitamins with minerals [umbrella term]	2019 - Ongoing	Supplement
Vitamins nos	2019 - Ongoing	Supplement
Estradiol	May 2020 - Ongoing	Vaginal Dryness
Paracetamol	19 Sep 2020 (Study Day 5) - 19 Sep 2020 (Study Day 5)	Hip Pain (Right)
Paracetamol	06 Oct 2020 (Study Day 22) - Ongoing	Piriformis Syndrome
Prednisone	06 Oct 2020 (Study Day 22) - 08 Oct 2020 (Study Day 24)	Piriformis Syndrome
Prednisone	09 Oct 2020 (Study Day 25) - 11 Oct 2020 (Study Day 27)	Piriformis Syndrome
Ibuprofen	21 Oct 2020 (Study Day 37) - Ongoing	Piriformis Syndrome
Influenza vaccine	30 Oct 2020 (Study Day 46) - 30 Oct 2020 (Study Day 46)	Prophylaxis For Flu
Atorvastatin	06 Nov 2020 (Study Day 53) - Ongoing	Hyperlipidemia
Mri of lower leg*	31 Dec 2020 (Study Day 108) - 31 Dec 2020 (Study Day 108)	Adverse Event
Mri of back*	01 Jan 2021 (Study Day 109) - 01 Jan 2021 (Study Day 109)	Medical History
Spironolactone	20 Jan 2021 (Study Day 128) - Ongoing	Hypertension
Angioplasty with stent insertion*	16 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 155)	Medical History
Calcium chloride; potassium chloride; sodium lactate	16 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 155)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Cefazolin	16 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 155)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Cefazolin	16 Feb 2021 (Study Day 155) - 17 Feb 2021 (Study Day 156)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Clopidogrel bisulfate	16 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 155)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Dexmedetomidine	16 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 155)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Ephedrine	16 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 155)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Fentanyl	16 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 155)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Glyceryl trinitrate	16 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 155)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Heparin	16 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 155)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Lidocaine	16 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 155)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Ondansetron	16 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 155)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Paracetamol	16 Feb 2021 (Study Day 155) - 17 Feb 2021 (Study Day 156)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Phenylephrine	16 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 155)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Propofol	16 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 155)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Rocuronium	16 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 155)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Sugammadex	16 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 155)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Tramadol	16 Feb 2021 (Study Day 155) - Ongoing	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Clopidogrel bisulfate	17 Feb 2021 (Study Day 156) - Ongoing	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Gabapentin	17 Feb 2021 (Study Day 156) - 12 Apr 2021 (Study Day 210)	Bilateral Leg Tingling
Heparin	17 Feb 2021 (Study Day 156) - 17 Feb 2021 (Study Day 156)	Atherosclerosis Of Bilateral Legs With Intermittent Claudication
Doxycycline	01 Mar 2021 (Study Day 168) - 15 Mar 2021 (Study Day 182)	Left Inner Thigh Surgical Site Infection
Vitamin b12 nos	01 Mar 2021 (Study Day 168) - Ongoing	Prophylaxis For Vitamin B12 Deficiency

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Postoperative Wound Infection	Grade 3/severe	Not related	01 Mar 2021 (Study Day 168) - 19 Mar 2021 (Study Day 186)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US366-2023 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 16 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 05 Jan 2021 (Study Day 112)
Second Dose of Vaccine in Part B: 05 Feb 2021 (Study Day 143)
Reason for Narrative: Severe COVID-19

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID-19	COVID-19	Grade 2/ moderate	Not related	07 Jan 2021 (Study Day 114) – 16 Jan 2021 (Study Day 123)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US366-2023, a 65-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 16 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 14 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 05 Jan 2021. The participant was unblinded on 05 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 05 Jan 2021 (Study Day 112). The second dose was administered in the left arm on 05 Feb 2021 (Study Day 143).

Severe COVID-19 Details

On 07 Jan 2021 (Study Day 114), 113 days after the first dose in Part A/2 days after the first dose in Part B and 85 days after the second dose in Part A/29 days before the second dose in Part B of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 14 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 05 Jan 2021 (Study Day 112), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
07 Jan 2021 (Study Day 114)	Chills	Mild
07 Jan 2021 (Study Day 114)	Fatigue	Mild
08 Jan 2021 (Study Day 115)	Muscle Aches (Myalgia)	Mild
09 Jan 2021 (Study Day 116)	Cough	Mild
09 Jan 2021 (Study Day 116)	Muscle Aches (Myalgia)	Mild
10 Jan 2021 (Study Day 117)	Cough	Moderate
10 Jan 2021 (Study Day 117)	Fatigue	Mild
10 Jan 2021 (Study Day 117)	Headache	Moderate
10 Jan 2021 (Study Day 117)	Runny Nose (Rhinorrhea)	Mild
11 Jan 2021 (Study Day 118)	Chills	Mild
11 Jan 2021 (Study Day 118)	Cough	Mild
11 Jan 2021 (Study Day 118)	Fatigue	Moderate
12 Jan 2021 (Study Day 119)	Fatigue	Moderate
12 Jan 2021 (Study Day 119)	Headache	Mild
12 Jan 2021 (Study Day 119)	New Loss of Smell	Mild
12 Jan 2021 (Study Day 119)	New Loss of Taste	Mild
13 Jan 2021 (Study Day 120)	Cough	Mild
13 Jan 2021 (Study Day 120)	Fatigue	Moderate
13 Jan 2021 (Study Day 120)	New Loss of Smell	Severe
13 Jan 2021 (Study Day 120)	New Loss of Taste	Mild
14 Jan 2021 (Study Day 121)	Cough	Mild
14 Jan 2021 (Study Day 121)	Fatigue	Moderate
14 Jan 2021 (Study Day 121)	New Loss of Smell	Moderate
14 Jan 2021 (Study Day 121)	New Loss of Taste	Moderate
14 Jan 2021 (Study Day 121)	O2 Saturation (%)	93
15 Jan 2021 (Study Day 122)	Cough	Mild
15 Jan 2021 (Study Day 122)	Fatigue	Mild
15 Jan 2021 (Study Day 122)	O2 Saturation (%)	93

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
14 Jan 2021 (Study Day 121)	Oxygen Saturation	93%
14 Jan 2021 - 15 Jan 2021 (Study Day 121-122)	Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level	Yes

The IP dose was not changed due to the symptomatic COVID-19. The event of symptomatic COVID-19 lasted for 10 days, after which it was considered to be recovered/resolved on

16 Jan 2021 (Study Day 123). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002724	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Coronary artery disease	Coronary artery disease	15 Jul 2002 (Study Day -6638) - Ongoing
Hypertension	Hypertension	15 Jul 2009 (Study Day -4081) - Ongoing
Insomnia	Insomnia	15 Jul 2016 (Study Day -1524) - Ongoing
Dyspepsia	Heartburn	15 Jul 2018 (Study Day -794) - Ongoing
Anxiety	Anxiety	15 Feb 2020 (Study Day -214) - Ongoing
Bipolar disorder	Bipolar disorder	15 Feb 2020 (Study Day -214) - Ongoing
Spondylitis	Other arthritis, back	15 Feb 2020 (Study Day -214) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	15 Jul 2002 (Study Day -6638) - Ongoing	Heart Health
Lisinopril	15 Jul 2016 (Study Day -1524) - Ongoing	Hypertension
Trazodone hydrochloride	15 Jul 2016 (Study Day -1524) - Ongoing	Insomnia
Gabapentin	15 Feb 2020 (Study Day -214) - Ongoing	Anxiety
Lamotrigine	15 Feb 2020 (Study Day -214) - Ongoing	Bipolar
Omeprazole	11 Aug 2020 (Study Day -36) - 31 Oct 2020 (Study Day 46)	Heartburn
Famotidine	01 Nov 2020 (Study Day 47) - Ongoing	Heartburn
Paracetamol	12 Jan 2021 (Study Day 119) - 12 Jan 2021 (Study Day 119)	Headache
Capsaicin	26 Jan 2021 (Study Day 133) - Ongoing	Arthritis, Back Pain, Osteoarthritis
Abnormal ultrasound*	08 Feb 2021 (Study Day 146) - 08 Feb 2021 (Study Day 146)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	07 Jan 2021 (Study Day 114) - 16 Jan 2021 (Study Day 123)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US366-2032 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 29 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 11 Jan 2021 (Study Day 133)
Second Dose of Vaccine in Part B: 18 Feb 2021 (Study Day 171)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Medical Device Site Joint Infection/ Infection/ Inflammation Reaction Due To Internal Left Hip Prosthesis	SAE	Grade 3/ severe	Not related	08 Apr 2021 (Study Day 220) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US366-2032, a 54-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 11 Jan 2021 (Study Day 133). The second dose was administered in the left arm on 18 Feb 2021 (Study Day 171).

Event Details

On 08 Apr 2021 (Study Day 220), 219 days after the first dose in Part A/87 days after the first dose in Part B and 191 days after the second dose in Part A/49 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of medical device site joint infection. Action taken with the IP was not applicable. The event of infection/inflammation reaction due to internal left hip prosthesis was considered to be ongoing. The investigator assessed the event of medical device site joint infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-075623	Medical device site joint infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension nec	01 Jul 2006 (Study Day -5176) - Ongoing
Osteoarthritis	Osteoarthritis of left hip	06 Feb 2017 (Study Day -1303) - Ongoing
Arthralgia	Ankle soreness	01 Jul 2018 (Study Day -793) - Ongoing
Arthralgia	Knee soreness	01 Jul 2018 (Study Day -793) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Clonidine	01 Jul 2006 (Study Day -5176) - Ongoing	Hypertension
Hydrochlorothiazide	01 Jul 2006 (Study Day -5176) - Ongoing	Hypertension
Losartan	01 Jul 2006 (Study Day -5176) - Ongoing	Hypertension
Ibuprofen	01 Jul 2018 (Study Day -793) - Ongoing	Ankle/Knees Soreness
Vitamins nos	01 Jul 2018 (Study Day -793) - Ongoing	Supplement
Acetylsalicylic acid	15 Jul 2018 (Study Day -779) - Ongoing	Heart Health
Hip bilateral 3 or 4 view xray*	06 Nov 2020 (Study Day 67) - 06 Nov 2020 (Study Day 67)	Medical History
Ibuprofen	19 Feb 2021 (Study Day 172) - 27 Feb 2021 (Study Day 180)	(J18.9) Community Acquired Pneumonia Of Right Lower Lobe Of Lung
Paracetamol	19 Feb 2021 (Study Day 172) - 27 Feb 2021 (Study Day 180)	(J18.9) Community Acquired Pneumonia Of Right Lower Lobe Of Lung
Azithromycin	26 Feb 2021 (Study Day 179) - Ongoing	Community Acquired Pneumonia Of Right Lower Lobe Of Lung
Cefpodoxime proxetil	26 Feb 2021 (Study Day 179) - 05 Mar 2021 (Study Day 186)	Community Acquired Pneumonia Of Right Lower Lobe Of Lung
Atorvastatin	03 Mar 2021 (Study Day 184) - Ongoing	Hypercholesterolemia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chest 2 view pa and lat xray*	03 Mar 2021 (Study Day 184) - 03 Mar 2021 (Study Day 184)	Adverse Event
Knee bilateral 1 or 2 views xray*	03 Mar 2021 (Study Day 184) - 03 Mar 2021 (Study Day 184)	Other, Pre Op Prevention Site Fracture Care Protocol
Acetylsalicylic acid	05 Mar 2021 (Study Day 186) - 23 Mar 2021 (Study Day 204)	Post Surgical Prophylaxis
Calcium chloride; potassium chloride; sodium lactate	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Left Total Hip Arthroplasty
Cefazolin	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Left Total Hip Arthroplasty
Dexamethasone	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Left Total Hip Arthroplasty
Docusate sodium	05 Mar 2021 (Study Day 186) - 23 Mar 2021 (Study Day 204)	Post Surgical Prophylaxis Left Total Hip Arthroplasty
Famotidine	05 Mar 2021 (Study Day 186) - 23 Mar 2021 (Study Day 204)	Post Surgical Prophylaxis Left Total Hip Arthroplasty
Fentanyl	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Left Total Hip Arthroplasty
Fluro extremity scan of left hip*	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Other, Post Surgery Procedure For Confirmation
Gabapentin	05 Mar 2021 (Study Day 186) - 23 Mar 2021 (Study Day 204)	Left Hip Pain, S/P Left Total Hip Arthroplasty
Hydralazine hydrochloride	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Left Total Hip Arthroplasty
Hydrocodone bitartrate; paracetamol	05 Mar 2021 (Study Day 186) - 18 Mar 2021 (Study Day 199)	Left Hip Pain S/P Left Total Hip Arthroplasty
Hydromorphone hydrochloride	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Left Total Hip Arthroplasty
Ketorolac tromethamine	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Left Total Hip Arthroplasty
Labetalol hydrochloride	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Left Total Hip Arthroplasty
Left hip and pelvis xray*	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Adverse Event
Left total hip arthroplasty*	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Adverse Event
Meloxicam	05 Mar 2021 (Study Day 186) - 18 Mar 2021 (Study Day 199)	Left Hip Pain, S/P Left Hip Arthroplasty
Methocarbamol	05 Mar 2021 (Study Day 186) - 23 Mar 2021 (Study Day 204)	Left Total Hip Arthroplasty
Midazolam	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Left Total Hip Arthroplasty
Morphine	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Left Total Hip Arthroplasty
Ondansetron	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Left Total Hip Arthroplasty
Paracetamol	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Left Hip Pain, S/P Left Total Hip Arthroplasty
Rivaroxaban	05 Mar 2021 (Study Day 186) - 18 Mar 2021 (Study Day 199)	Post Surgical Prophylaxis Left Total Hip Arthroplasty

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tobramycin	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Left Total Hip Arthroplasty
Tranexamic acid	05 Mar 2021 (Study Day 186) - 05 Mar 2021 (Study Day 186)	Left Total Hip Arthroplasty
Left hip xray*	10 Mar 2021 (Study Day 191) - 10 Mar 2021 (Study Day 191)	Other, Post Surgical Follow Up

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Epistaxis	Grade 1/mild	Not related	19 Feb 2021 (Study Day 172) - 24 Feb 2021 (Study Day 177)
Ear Canal Erythema	Grade 1/mild	Not related	24 Feb 2021 (Study Day 177) - Ongoing
Rhinovirus Infection	Grade 1/mild	Not related	24 Feb 2021 (Study Day 177) - 27 Feb 2021 (Study Day 180)
Pneumonia	Grade 2/moderate	Not related	26 Feb 2021 (Study Day 179) - 05 Mar 2021 (Study Day 186)
Osteoarthritis	Grade 3/severe	Not related	03 Mar 2021 (Study Day 184) - 05 Mar 2021 (Study Day 186)
Epistaxis	Grade 1/mild	Not related	05 Mar 2021 (Study Day 186) - 18 Mar 2021 (Study Day 199)
Procedural Pain	Grade 2/moderate	Not related	05 Mar 2021 (Study Day 186) - Ongoing
Incision Site Discharge	Grade 1/mild	Not related	18 Mar 2021 (Study Day 199) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US366-2049 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 30 Sep 2020 (Study Day 28)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Presyncope/ Hypotension With Near Syncope	SAE	Grade 3 /severe	Not related	09 Apr 2021 (Study Day 219) – 09 Apr 2021 (Study Day 219)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US366-2049, a 65-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 09 Apr 2021 (Study Day 219), 218 days after the first dose in Part A and 191 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of presyncope. Action taken with the IP was not applicable. The event of hypotension with near syncope lasted for 1 days, after which it was considered to be recovered/resolved on 09 Apr 2021 (Study Day 219). The investigator assessed the event of presyncope to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-073442	Presyncope

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
HIV infection	Human immunodeficiency virus	18 Jun 1996 (Study Day -8843) - Ongoing
Hyperlipidaemia	Other and unspecified hyperlipidemia	10 Feb 1999 (Study Day -7876) - Ongoing
Depression	Depressive disorder nec	01 Jul 1999 (Study Day -7735) - Ongoing
Hypogonadism	Hypogonadism	20 Oct 1999 (Study Day -7624) - Ongoing
Essential hypertension	Unspecified essential hypertension	04 Oct 2000 (Study Day -7274) - Ongoing
Inguinal hernia	Inguinal hernia without obstruction/gangrene, bilateral	04 Oct 2000 (Study Day -7274) - Ongoing
Lipodystrophy acquired	Lipodystrophy	06 Feb 2002 (Study Day -6784) - Ongoing
Seborrheic dermatitis	Unspecified seborrheic dermatitis	19 Mar 2008 (Study Day -4551) - Ongoing
Hyperkeratosis	Corns and callosities, left foot	05 Mar 2009 (Study Day -4200) - Ongoing
Osteoporosis	Unspecified osteoporosis	26 Aug 2009 (Study Day -4026) - Ongoing
Amnesia	Memory loss	26 Aug 2010 (Study Day -3661) - Ongoing
Fatigue	Fatigue	26 Aug 2010 (Study Day -3661) - Ongoing
Anogenital dysplasia	Anal dysplasia	25 Jun 2013 (Study Day -2627) - Ongoing
Plantar fasciitis	Plantar fasciitis with heel spur left foot	09 May 2014 (Study Day -2309) - Ongoing
Arthropathy	Other, specify drops things a lot with right hand	01 Jul 2015 (Study Day -1891) - Ongoing
Arthralgia	Pain left extremities joints	12 Feb 2016 (Study Day -1665) - Ongoing
Hypoaesthesia	Numbness left extremities	12 Feb 2016 (Study Day -1665) - Ongoing
Muscular weakness	Weakness muscles left extremities	12 Feb 2016 (Study Day -1665) - Ongoing
Pollakiuria	Urinary frequency in the morning and at night	15 Apr 2016 (Study Day -1602) - Ongoing
Benign prostatic hyperplasia	Hypertrophy of prostate	09 Aug 2016 (Study Day -1486) - Ongoing
Hypertonic bladder	Hypertonicity of bladder	09 Aug 2016 (Study Day -1486) - Ongoing
Back pain	Pain mid lower back	01 Oct 2017 (Study Day -1068) - Ongoing
Dyspepsia	Burning in epigastrium	02 Feb 2020 (Study Day -214) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	16 Oct 2014 (Study Day -2149) - 14 Apr 2021 (Study Day 224)	Hypertension
Testosterone	21 Jul 2015 (Study Day -1871) - Ongoing	Hypogonadism
Ascorbic acid	01 Jul 2019 (Study Day -430) - Ongoing	Supplement
Vitamins nos	01 Jul 2019 (Study Day -430) - Ongoing	Supplement
Vitamin d nos	28 Jul 2019 (Study Day -403) - Ongoing	Supplement
Pravastatin sodium	06 Aug 2019 (Study Day -394) - Ongoing	Hyperlipidemia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tamsulosin hydrochloride	29 Aug 2019 (Study Day -371) - 04 Mar 2021 (Study Day 183)	Overactive Bladder
Bictegravir sodium; emtricitabine; tenofovir alafenamide fumarate	31 Aug 2019 (Study Day -369) - Ongoing	Hiv
Trazodone hydrochloride	21 Feb 2020 (Study Day -195) - 03 Feb 2021 (Study Day 154)	Depression
Omeprazole	22 Feb 2020 (Study Day -194) - Ongoing	Burning In Epigastrium
Trazodone hydrochloride	04 Feb 2021 (Study Day 155) - Ongoing	Depressive Disorder
Doxazosin mesilate	05 Mar 2021 (Study Day 184) - 09 Apr 2021 (Study Day 219)	Overactive Bladder

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US366-2101 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 16 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Salivary Gland Cancer Stage IV/Malignant Neoplasm Of Parotid Gland Stage IVa	SAE	Grade 3/severe	Not related	17 Feb 2021 (Study Day 155) – Not reported	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US366-2101, a 65-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 16 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 14 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 17 Feb 2021 (Study Day 155), 154 days after the first dose in Part A and 126 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of salivary gland cancer stage IV. Action taken with the IP was not applicable. The event of malignant neoplasm of parotid gland stage IVa was considered to be ongoing. The investigator assessed the event of salivary gland cancer stage iv to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-073206	Salivary gland cancer stage IV

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Coronary artery disease	Coronary artery disease	01 Jul 2003 (Study Day -6287) - Ongoing
Hyperlipidaemia	Hyperlipidemia, unspecified	01 Jul 2003 (Study Day -6287) - Ongoing
Hypertension	Hypertension nec	01 Jul 2003 (Study Day -6287) - Ongoing
Myalgia	Muscle pain	01 Jul 2010 (Study Day -3730) - Ongoing
Type 2 diabetes mellitus	Type II diabetes mellitus	01 Jul 2015 (Study Day -1904) - Ongoing
Prostatomegaly	Enlarged prostate	01 Jul 2019 (Study Day -443) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	01 Jul 2003 (Study Day -6287) - Ongoing	Coronary Artery Disease
Atorvastatin calcium	01 Jul 2003 (Study Day -6287) - Ongoing	High Cholesterol
Losartan	01 Jul 2003 (Study Day -6287) - Ongoing	Hypertension
Ezetimibe	01 Jul 2008 (Study Day -4460) - Ongoing	High Cholesterol
Ibuprofen	01 Jul 2010 (Study Day -3730) - Ongoing	Muscle Soreness
Metformin hydrochloride; sitagliptin	01 Jul 2015 (Study Day -1904) - 21 Jan 2021 (Study Day 128)	Type 2 Diabetes
Tadalafil	01 Jul 2019 (Study Day -443) - Ongoing	Enlarged Prostate
Tamsulosin hydrochloride	01 Jul 2019 (Study Day -443) - Ongoing	Enlarged Prostate
Testosterone	01 Jul 2019 (Study Day -443) - Ongoing	Enlarged Prostate
Calcium	01 Jun 2020 (Study Day -107) - Ongoing	Dietary Supplement
Ibuprofen	14 Oct 2020 (Study Day 29) - 15 Oct 2020 (Study Day 30)	Headache
Ibuprofen	17 Oct 2020 (Study Day 32) - 17 Oct 2020 (Study Day 32)	Headache
Hydrochlorothiazide	07 Dec 2020 (Study Day 83) - Ongoing	Hypertension
Ct lung screening*	14 Jan 2021 (Study Day 121) - 14 Jan 2021 (Study Day 121)	Other, Screening, History Of Smoking
Metformin	22 Jan 2021 (Study Day 129) - Ongoing	Type 2 Diabetes
Echo stress test*	11 Feb 2021 (Study Day 149) - 11 Feb 2021 (Study Day 149)	Medical History
Ct neck with contrast*	25 Feb 2021 (Study Day 163) - 25 Feb 2021 (Study Day 163)	Adverse Event
Fna needle biopsy*	05 Mar 2021 (Study Day 171) - 05 Mar 2021 (Study Day 171)	Adverse Event
Mri head w/without contrast*	11 Mar 2021 (Study Day 177) - 11 Mar 2021 (Study Day 177)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Mri orbit face neck w/without contrast*	11 Mar 2021 (Study Day 177) - 11 Mar 2021 (Study Day 177)	Adverse Event
Nm det ct skull thigh*	11 Mar 2021 (Study Day 177) - 11 Mar 2021 (Study Day 177)	Adverse Event
Calcium chloride; potassium chloride; sodium lactate	16 Mar 2021 (Study Day 182) - 16 Mar 2021 (Study Day 182)	Incisional Biopsy
Dexamethasone	16 Mar 2021 (Study Day 182) - 16 Mar 2021 (Study Day 182)	Incisional Biopsy
Ephedrine	16 Mar 2021 (Study Day 182) - 16 Mar 2021 (Study Day 182)	Incisional Biopsy
Epinephrine hydrochloride	16 Mar 2021 (Study Day 182) - 16 Mar 2021 (Study Day 182)	Incisional Biopsy
Epinephrine hydrochloride; lidocaine hydrochloride	16 Mar 2021 (Study Day 182) - 16 Mar 2021 (Study Day 182)	Incisional Biopsy
Fentanyl	16 Mar 2021 (Study Day 182) - 16 Mar 2021 (Study Day 182)	Incisional Biopsy
Glycopyrronium	16 Mar 2021 (Study Day 182) - 16 Mar 2021 (Study Day 182)	Incisional Biopsy
Incisional biopsy of neck mass*	16 Mar 2021 (Study Day 182) - 16 Mar 2021 (Study Day 182)	Adverse Event
Lidocaine hydrochloride	16 Mar 2021 (Study Day 182) - 16 Mar 2021 (Study Day 182)	Incisional Biopsy
Midazolam hydrochloride	16 Mar 2021 (Study Day 182) - 16 Mar 2021 (Study Day 182)	Incisional Biopsy
Ondansetron	16 Mar 2021 (Study Day 182) - 16 Mar 2021 (Study Day 182)	Incisional Biopsy
Remifentanyl	16 Mar 2021 (Study Day 182) - 16 Mar 2021 (Study Day 182)	Incisional Biopsy
Suxamethonium chloride	16 Mar 2021 (Study Day 182) - 16 Mar 2021 (Study Day 182)	Incisional Biopsy

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US366-2116 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 18 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Small Intestinal Obstruction/Small Bowel Obstruction	SAE	Grade 3/ severe	Not related	10 Feb 2021 (Study Day 146) – 16 Feb 2021 (Study Day 152)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US366-2116, a 54-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 18 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 16 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 19 Jan 2021. The participant was unblinded on 19 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 10 Feb 2021 (Study Day 146), 145 days after the first dose in Part A and 117 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of small intestinal obstruction. Action taken with the IP was not applicable. The event of small bowel obstruction lasted for 7 days, after which it was considered to be recovered/resolved on 16 Feb 2021 (Study Day 152). The investigator assessed the event of small intestinal obstruction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-144540	Small intestinal obstruction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension nec	01 Jul 2001 (Study Day -7019) - Ongoing
Aortic dissection	Infra-renal aortic dissection	01 Apr 2014 (Study Day -2362) - Ongoing
Gallbladder cancer	Malignant neoplasm of gallbladder	10 Apr 2014 (Study Day -2353) - 03 Feb 2015 (Study Day -2054)
Cholecystectomy	Cholecystectomy with partial hepatectomy	09 May 2014 (Study Day -2324) - 09 May 2014 (Study Day -2324)
Obesity	Morbid obesity	08 Jul 2014 (Study Day -2264) - Ongoing
Incisional hernia	Incisional hernia without obstruction or gangrene	13 Mar 2015 (Study Day -2016) - Ongoing
Anxiety	Anxiety state unspecified	25 Jan 2016 (Study Day -1698) - Ongoing
Insomnia	Insomnia	25 Jan 2016 (Study Day -1698) - Ongoing
Pulmonary embolism	Pulmonary embolism acute	11 May 2017 (Study Day -1226) - 09 May 2018 (Study Day -863)
Adnexa uteri mass	Adenexal mass	15 Dec 2017 (Study Day -1008) - 31 May 2018 (Study Day -841)
Hysterectomy	Complete abdominal hysterectomy	31 May 2018 (Study Day -841) - 31 May 2018 (Study Day -841)
Herpes simplex	Herpes simplex virus 2	11 Jan 2019 (Study Day -616) - Ongoing
Gastroesophageal reflux disease	Gastro-esophageal reflux disease	22 Mar 2019 (Study Day -546) - Ongoing
Pain	Chronic generalized pain	01 Nov 2019 (Study Day -322) - Ongoing
Arthralgia	Left knee pain	01 Jul 2020 (Study Day -79) - Ongoing
Exostosis	Exostosis - bone spur left knee	07 Jul 2020 (Study Day -73) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine besilate	01 Jul 2001 (Study Day -7019) - Ongoing	Hypertension
Lisinopril	01 Jul 2001 (Study Day -7019) - Ongoing	Hypertension
Trazodone hydrochloride	08 Sep 2017 (Study Day -1106) - Ongoing	Anxiety/Insomnia
Codeine phosphate; paracetamol	01 Nov 2019 (Study Day -322) - Ongoing	Generalized Pain
Esomeprazole	07 Jul 2020 (Study Day -73) - Ongoing	Gerd
Hydrochlorothiazide	07 Jul 2020 (Study Day -73) - 04 Mar 2021 (Study Day 168)	Htn

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	17 Oct 2020 (Study Day 30) - 17 Oct 2020 (Study Day 30)	Arm Pain/Fever
Metformin	16 Nov 2020 (Study Day 60) - Ongoing	Pre-Diabetic
Bedside focused fast ultrasound*	11 Feb 2021 (Study Day 147) - 11 Feb 2021 (Study Day 147)	Diagnostic
Calcium chloride; potassium chloride; sodium lactate	11 Feb 2021 (Study Day 147) - 13 Feb 2021 (Study Day 149)	Small Bowel Obstruction
Ct angio abdomen pelvis with and/or without iv contrast*	11 Feb 2021 (Study Day 147) - 11 Feb 2021 (Study Day 147)	Diagnostic
Ct angio chest with and/or without*	11 Feb 2021 (Study Day 147) - 11 Feb 2021 (Study Day 147)	Diagnostic
Fentanyl	11 Feb 2021 (Study Day 147) - 11 Feb 2021 (Study Day 147)	Small Bowel Obstruction
Heparin	11 Feb 2021 (Study Day 147) - 16 Feb 2021 (Study Day 152)	Small Bowel Obstruction
Hydromorphone hydrochloride	11 Feb 2021 (Study Day 147) - 15 Feb 2021 (Study Day 151)	Small Bowel Obstruction
Iohexol	11 Feb 2021 (Study Day 147) - 11 Feb 2021 (Study Day 147)	Small Bowel Obstruction
Lidocaine hydrochloride	11 Feb 2021 (Study Day 147) - 12 Feb 2021 (Study Day 148)	Sore Throat Due To Ng Tube Placement
Meglumine amidotrizoate; sodium amidotrizoate	11 Feb 2021 (Study Day 147) - 11 Feb 2021 (Study Day 147)	Ng Tube Placement, Procedure
Meglumine amidotrizoate; sodium amidotrizoate	11 Feb 2021 (Study Day 147) - 12 Feb 2021 (Study Day 148)	Small Bowel Obstruction
Methocarbamol	11 Feb 2021 (Study Day 147) - 14 Feb 2021 (Study Day 150)	Small Bowel Obstruction
Morphine	11 Feb 2021 (Study Day 147) - 11 Feb 2021 (Study Day 147)	Small Bowel Obstruction
Ng tube placement*	11 Feb 2021 (Study Day 147) - 11 Feb 2021 (Study Day 147)	Adverse Event
Ondansetron	11 Feb 2021 (Study Day 147) - 11 Feb 2021 (Study Day 147)	Small Bowel Obstruction
Ondansetron	11 Feb 2021 (Study Day 147) - 16 Feb 2021 (Study Day 152)	Small Bowel Obstruction
Pantoprazole sodium sesquihydrate	11 Feb 2021 (Study Day 147) - 14 Feb 2021 (Study Day 150)	Small Bowel Obstruction
Xr portable feeding tube check*	11 Feb 2021 (Study Day 147) - 11 Feb 2021 (Study Day 147)	Diagnostic
Xray portable abdomen ap view*	11 Feb 2021 (Study Day 147) - 11 Feb 2021 (Study Day 147)	Diagnostic
Xray portable chest*	11 Feb 2021 (Study Day 147) - 11 Feb 2021 (Study Day 147)	Diagnostic
Ecg 12 lead*	12 Feb 2021 (Study Day 148) - 12 Feb 2021 (Study Day 148)	Adverse Event
Hydralazine hydrochloride	12 Feb 2021 (Study Day 148) - 15 Feb 2021 (Study Day 151)	Small Bowel Obstruction
Hydralazine hydrochloride	12 Feb 2021 (Study Day 148) - 15 Feb 2021 (Study Day 151)	Worsening Htn

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydromorphone hydrochloride	12 Feb 2021 (Study Day 148) - 13 Feb 2021 (Study Day 149)	Small Bowel Obstruction
Influenza vaccine inact split 4v	12 Feb 2021 (Study Day 148) - 12 Feb 2021 (Study Day 148)	Seasonal Flu Vaccine
Phenol	12 Feb 2021 (Study Day 148) - 16 Feb 2021 (Study Day 152)	Sore Throat Due To Ng Tube Placement
Picc placement*	12 Feb 2021 (Study Day 148) - 12 Feb 2021 (Study Day 148)	Adverse Event
Xray portable abdominal ap view*	12 Feb 2021 (Study Day 148) - 12 Feb 2021 (Study Day 148)	Adverse Event
Paracetamol	13 Feb 2021 (Study Day 149) - 15 Feb 2021 (Study Day 151)	Small Bowel Obstruction
Potassium chloride	13 Feb 2021 (Study Day 149) - 13 Feb 2021 (Study Day 149)	Hypokalemia
Macrogol 3350	14 Feb 2021 (Study Day 150) - Ongoing	Small Bowel Obstruction/ Prevention Of Reoccurrence
Melatonin	14 Feb 2021 (Study Day 150) - 15 Feb 2021 (Study Day 151)	Insomnia
Phenylephrine hydrochloride	14 Feb 2021 (Study Day 150) - 16 Feb 2021 (Study Day 152)	Sinusitis
Docusate; senna alexandrina	15 Feb 2021 (Study Day 151) - Ongoing	Small Bowel Obstruction/ Prevention Of Reoccurrence
Gabapentin	15 Feb 2021 (Study Day 151) - Ongoing	Small Bowel Obstruction/ Prevention Of Reoccurrence
Ondansetron	16 Feb 2021 (Study Day 152) - Ongoing	Nausea
Pantoprazole sodium sesquihydrate	16 Feb 2021 (Study Day 152) - 16 Feb 2021 (Study Day 152)	Small Bowel Obstruction
Hydrochlorothiazide	15 Mar 2021 (Study Day 179) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Oropharyngeal Pain	Grade 2/moderate	Not related	11 Feb 2021 (Study Day 147) - 16 Feb 2021 (Study Day 152)
Hypertension	Grade 2/moderate	Not related	12 Feb 2021 (Study Day 148) - 15 Feb 2021 (Study Day 151)
Hypokalaemia	Grade 2/moderate	Not related	13 Feb 2021 (Study Day 149) - 13 Feb 2021 (Study Day 149)
Insomnia	Grade 2/moderate	Not related	14 Feb 2021 (Study Day 150) - 15 Feb 2021 (Study Day 151)
Sinusitis	Grade 2/moderate	Not related	14 Feb 2021 (Study Day 150) - 16 Feb 2021 (Study Day 152)
Nausea	Grade 2/moderate	Not related	16 Feb 2021 (Study Day 152) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US367-2183 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 19 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 18 Sep 2020 (Study Day 31)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	08 Mar 2021 (Study Day 202) – 22 Mar 2021 (Study Day 216)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2183, a 39-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 20 Jan 2021. The participant was unblinded on 20 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 08 Mar 2021 (Study Day 202), 201 days after the first dose in Part A and 171 days after the second dose in Part A of the IP, the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. The IP dose was withdrawn due to the COVID-19. The event of COVID-19 lasted for 15 days, after which it was considered to be recovered/resolved on 22 Mar 2021 (Study Day 216). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1991 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2007 - Ongoing
Hypertension	Hypertension	2007 - Ongoing
Obesity	Obesity	2007 - Ongoing
Gastroesophageal reflux disease	Acid reflux	2009 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Azelastine	2007 - Ongoing	Seasonal Allergies
Fluticasone propionate	2007 - Ongoing	Seasonal Allergies
Pravastatin	2007 - Ongoing	High Cholesterol
Metformin	2010 - Ongoing	Diabetes Mellitus Type 2
Pantoprazole	2017 - Ongoing	Acid Reflux
Insulin	Apr 2020 - Ongoing	Diabetes Mellitus Type 2
Lisinopril	Apr 2020 - Ongoing	Hypertension
Ibuprofen	02 Sep 2020 (Study Day 15) - 05 Sep 2020 (Study Day 18)	Right Ear Pain
Ibuprofen	19 Sep 2020 (Study Day 32) - 19 Sep 2020 (Study Day 32)	Pain At Injection Site
Ibuprofen	20 Sep 2020 (Study Day 33) - 20 Sep 2020 (Study Day 33)	Pain At Injection Site
Influenza vaccine	11 Nov 2020 (Study Day 85) - 11 Nov 2020 (Study Day 85)	Influenza Prophylaxis
Prednisone	30 Nov 2020 (Study Day 104) - 02 Dec 2020 (Study Day 106)	Joint Pain Due To Obesity
Prednisone	03 Dec 2020 (Study Day 107) - 04 Dec 2020 (Study Day 108)	Joint Pain D/T Obesity
Paracetamol	06 Mar 2021 (Study Day 200) - Ongoing	COVID

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	08 Mar 2021 (Study Day 202) – 22 Mar 2021 (Study Day 216)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US367-2187 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 19 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: Not Administered
First Dose of Vaccine in Part B: 25 Jan 2021 (Study Day 160)
Second Dose of Vaccine in Part B: 05 Mar 2021 (Study Day 199)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia/Pneumonia Right Lung	SAE	Grade 3/ severe	Not related	06 Mar 2021 (Study Day 200) – 09 Mar 2021 (Study Day 203)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2187, a 72-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 25 Jan 2021. The participant was unblinded on 25 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 25 Jan 2021 (Study Day 160). The second dose was administered in the left arm on 05 Mar 2021 (Study Day 199).

Event Details

On 06 Mar 2021 (Study Day 200), 199 days after the first dose in Part A/40 days after the first dose in Part B and second dose Part A not applicable/1 day after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of pneumonia right lung lasted for 4 days, after which it was considered to be recovered/resolved on 09 Mar 2021 (Study Day 203). The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-045345	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2018 - Ongoing	Cardiac Prophylaxis
Atorvastatin	26 Sep 2020 (Study Day 39) - Ongoing	Hypertension
Cefdinir	06 Mar 2021 (Study Day 200) - 07 Mar 2021 (Study Day 201)	Pneumonia Right Lung

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US367-2255 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 21 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 22 Sep 2020 (Study Day 33)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Suicidal Ideation/ Suicidal Ideation	SAE	Grade 4	Not related	27 Mar 2021 (Study Day 219) – 02 Apr 2021 (Study Day 225)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2255, a 32-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 02 Feb 2021. The participant was unblinded on 02 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 27 Mar 2021 (Study Day 219), 218 days after the first dose in Part A and 186 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of suicidal ideation. Action taken with the IP was not applicable. The event of suicidal ideation lasted for 7 days, after which it was considered to be recovered/resolved on 02 Apr 2021 (Study Day 225). The investigator assessed the event of suicidal ideation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-067971	Suicidal ideation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	2000 - Ongoing
Generalised anxiety disorder	General anxiety disorder	2014 - Ongoing
Dyspepsia	Heartburn	2017 - Ongoing
Obesity	Severe obesity	2017 - Ongoing
Post-traumatic stress disorder	Post traumatic stress disorder	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluoxetine hydrochloride	2018 - 27 Mar 2021 (Study Day 219)	Depression
Amitriptyline	Apr 2020 - 27 Mar 2021 (Study Day 219)	Depression
Diazepam	Apr 2020 - 27 Mar 2021 (Study Day 219)	Anxiety
Ibuprofen	25 Aug 2020 (Study Day 5) - 25 Aug 2020 (Study Day 5)	Headache
Ibuprofen	27 Aug 2020 (Study Day 7) - 27 Aug 2020 (Study Day 7)	Headache
Ibuprofen	22 Sep 2020 (Study Day 33) - 28 Sep 2020 (Study Day 39)	Pain
Ibuprofen	30 Sep 2020 (Study Day 41) - Ongoing	Joint Aches
Omeprazole	02 Oct 2020 (Study Day 43) - Ongoing	Heartburn
Ibuprofen	17 Nov 2020 (Study Day 89) - 19 Nov 2020 (Study Day 91)	Groin Pain, Right Side
Anilides	26 Dec 2020 (Study Day 128) - 06 Jan 2021 (Study Day 139)	Upper Respiratory Infection
Cough and cold preparations	26 Dec 2020 (Study Day 128) - 06 Jan 2021 (Study Day 139)	Upper Respiratory Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US368-2134 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 17 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 15 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diabetic Ketoacidosis/ Diabetic Ketoacidosis	SAE	Grade 3/ severe	Not related	02 Mar 2021 (Study Day 167) – 09 Mar 2021 (Study Day 174)	Recovered/ resolved
Osteomyelitis/ Osteomyelitis Of Left Foot	SAE	Grade 3/ severe	Not related	02 Mar 2021 (Study Day 167) – 13 Apr 2021 (Study Day 209)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US368-2134, a 46-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 17 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 15 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 29 Jan 2021. The participant was unblinded on 29 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 02 Mar 2021 (Study Day 167), 166 days after the first dose in Part A and 138 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of diabetic ketoacidosis. Action taken with the IP was not applicable. The event of diabetic ketoacidosis lasted for 8 days, after which it was considered to be recovered/resolved on 09 Mar 2021 (Study Day 174). The investigator assessed the event of diabetic ketoacidosis to be not related to the IP.

On 02 Mar 2021 (Study Day 167), 166 days after the first dose in Part A and 138 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of osteomyelitis. Action taken with the IP was not applicable. The event of osteomyelitis of left foot lasted for 43 days, after which it was considered to be recovered/resolved on 13 Apr 2021 (Study Day 209). The investigator assessed the event of osteomyelitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-043436	Diabetic ketoacidosis
MOD-2021-043436	Osteomyelitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - Ongoing
Pain	Generalized chronic pain	2008 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus, type ii	2008 - Ongoing
Leg amputation	Right below knee amputation	2010 - 2010
Staphylococcal infection	Mrsa infection of right lower extremity	2010 - 2010
Hypertension	Hypertension	2011 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Syncope	Recurrent syncope	2018 - Ongoing
Skin ulcer	Left foot open ulcer	Mar 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amitriptyline	2008 - Ongoing	Chronic Pain - Generalized
Insulin glargine	2008 - Ongoing	Diabetes Mellitus Type II
Insulin lispro	2008 - Ongoing	Diabetes Mellitus Type II
Linagliptin	2008 - Ongoing	Diabetes Mellitus Type II
Liraglutide	2008 - Ongoing	Diabetes Mellitus Type II
Metformin	2008 - Ongoing	Diabetes Mellitus Type II
Tizanidine	2010 - Ongoing	Chronic Pain - Generalized
Tramadol	2010 - Ongoing	Generalized Chronic Pain
Carvedilol	2011 - Ongoing	Hypertension
Diltiazem	2011 - Ongoing	Hypertension
Omeprazole	2015 - Ongoing	Heartburn Prevention
Pravastatin	2015 - Ongoing	Hyperlipidemia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ct of the head and cervical spine*	21 Sep 2020 (Study Day 5) - 21 Sep 2020 (Study Day 5)	Adverse Event
Electrocardiogram*	21 Sep 2020 (Study Day 5) - 21 Sep 2020 (Study Day 5)	Adverse Event
Piperacillin sodium; tazobactam sodium	21 Sep 2020 (Study Day 5) - 24 Sep 2020 (Study Day 8)	Cellulitis/Osteomyelitis Of Left Foot
Vancomycin	21 Sep 2020 (Study Day 5) - 21 Sep 2020 (Study Day 5)	Cellulitis/Osteomyelitis Of Left Foot
X-ray of the chest, left shoulder, left foot*	21 Sep 2020 (Study Day 5) - 21 Sep 2020 (Study Day 5)	Adverse Event
Mri of the left foot*	22 Sep 2020 (Study Day 6) - 22 Sep 2020 (Study Day 6)	Adverse Event
Transthoracic echocardiogram*	22 Sep 2020 (Study Day 6) - 22 Sep 2020 (Study Day 6)	Adverse Event
Ibuprofen	24 Sep 2020 (Study Day 8) - 04 Oct 2020 (Study Day 18)	Headaches As A Result Of A Concussion
Sulfamethoxazole; trimethoprim	24 Sep 2020 (Study Day 8) - 06 Oct 2020 (Study Day 20)	Cellulitis/Osteomyelitis Of Left Foot
Angioplasty of left lower extremity*	22 Feb 2021 (Study Day 159) - 22 Feb 2021 (Study Day 159)	Adverse Event
Acetylsalicylic acid	02 Mar 2021 (Study Day 167) - Ongoing	Cardiovascular Health
Electrocardiogram*	02 Mar 2021 (Study Day 167) - 02 Mar 2021 (Study Day 167)	Adverse Event
Piperacillin sodium; tazobactam sodium	02 Mar 2021 (Study Day 167) - 06 Mar 2021 (Study Day 171)	Osteomyelitis Of Left Foot, Necrotizing Fasciitis Of Left Foot
Ultrasound of bilateral lower extremities*	02 Mar 2021 (Study Day 167) - 02 Mar 2021 (Study Day 167)	Adverse Event
Vancomycin	02 Mar 2021 (Study Day 167) - 06 Mar 2021 (Study Day 171)	Osteomyelitis Of Left Foot, Necrotizing Fasciitis Of Left Foot
X-ray of chest*	02 Mar 2021 (Study Day 167) - 02 Mar 2021 (Study Day 167)	Adverse Event
X-ray of left tibia/fibula*	02 Mar 2021 (Study Day 167) - 02 Mar 2021 (Study Day 167)	Adverse Event
Continuous cardiac monitor*	03 Mar 2021 (Study Day 168) - 03 Mar 2021 (Study Day 168)	Adverse Event
Insulin	03 Mar 2021 (Study Day 168) - 08 Mar 2021 (Study Day 173)	Diabetic Ketoacidosis
Magnesium oxide	03 Mar 2021 (Study Day 168) - 03 Mar 2021 (Study Day 168)	Diabetic Ketoacidosis
Magnesium sulfate	03 Mar 2021 (Study Day 168) - 03 Mar 2021 (Study Day 168)	Diabetic Ketoacidosis
Potassium chloride; sodium chloride	03 Mar 2021 (Study Day 168) - 09 Mar 2021 (Study Day 174)	Diabetic Ketoacidosis
Potassium phosphate dibasic	03 Mar 2021 (Study Day 168) - 03 Mar 2021 (Study Day 168)	Diabetic Ketoacidosis
Mri of left foot and left ankle*	04 Mar 2021 (Study Day 169) - 04 Mar 2021 (Study Day 169)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Staged deep incision and drainage with fasciotomy through multiple layers with excisional debridement of all non-viable tissue and 3rd metatarsal resection, left foot.*	04 Mar 2021 (Study Day 169) - 04 Mar 2021 (Study Day 169)	Adverse Event
X-ray of left foot and left ankle*	04 Mar 2021 (Study Day 169) - 04 Mar 2021 (Study Day 169)	Adverse Event
Ceftriaxone	06 Mar 2021 (Study Day 171) - 09 Mar 2021 (Study Day 174)	Osteomyelitis Of Left Foot, Necrotizing Fasciitis Of Left Foot
Clindamycin	06 Mar 2021 (Study Day 171) - 09 Mar 2021 (Study Day 174)	Osteomyelitis Of Left Foot, Necrotizing Fasciitis Of Left Foot
Ciprofloxacin	08 Mar 2021 (Study Day 173) - 07 Apr 2021 (Study Day 203)	Osteomyelitis Of Left Foot, Necrotizing Fasciitis Of Left Foot
Cefazolin	09 Mar 2021 (Study Day 174) - 13 Apr 2021 (Study Day 209)	Osteomyelitis Of The Left Foot, Necrotizing Fasciitis Of Left Foot
Insertion of left peripherally inserted central catheter*	09 Mar 2021 (Study Day 174) - 09 Mar 2021 (Study Day 174)	Adverse Event
Clopidogrel	10 Mar 2021 (Study Day 175) - Ongoing	Peripheral Vascular Disease

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Necrotizing Fasciitis	Grade 2/moderate	Not related	02 Mar 2021 (Study Day 167) - Ongoing
Peripheral Vascular Disorder	Grade 2/moderate	Not related	02 Mar 2021 (Study Day 167) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US368-2163 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 24 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 22 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nephritis/Right Nephritis	SAE	Grade 3/severe	Not related	02 Feb 2021 (Study Day 132) – 11 Feb 2021 (Study Day 141)	Recovered/resolved
Ureterolithiasis/Right Ureteral Stones	SAE	Grade 3/severe	Not related	02 Feb 2021 (Study Day 132) – 22 Mar 2021 (Study Day 180)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US368-2163, a 60-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 24 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 22 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 13 Jan 2021. The participant was unblinded on 13 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 02 Feb 2021 (Study Day 132), 131 days after the first dose in Part A and 103 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of nephritis. Action taken with the IP was not applicable. The event of right nephritis lasted for 10 days, after which it was considered to be recovered/resolved on 11 Feb 2021 (Study Day 141). The investigator assessed the event of nephritis to be not related to the IP.

On 02 Feb 2021 (Study Day 132), 131 days after the first dose in Part A and 103 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of ureterolithiasis. Action taken with the IP was not applicable. The event of right ureteral stones lasted for 49 days, after which it was considered to be recovered/resolved on 22 Mar 2021 (Study Day 180). The investigator assessed the event of ureterolithiasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010765	Nephritis
MOD-2021-010765	Ureterolithiasis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - Ongoing
Osteoarthritis	Left knee degeneration	Not reported - 2009
Osteoarthritis	Rt knee degeneration	Not reported - 2008
Asthma	Asthma, mild	1995 - Ongoing
Diabetes mellitus	Diabetes mellitus	01 Sep 2001 (Study Day -6963) - Ongoing
Dyslipidaemia	Dyslipidemia	Sep 2002 - Ongoing
Knee arthroplasty	Rt knee replacement	2008 - 2008
Knee arthroplasty	Lft knee replacement	2009 - 2009
Postmenopause	Post menopausal	01 Jun 2009 (Study Day -4133) - Ongoing
Drug eruption	Allergy: morphine, rash	2010 - Ongoing
Drug hypersensitivity	Allergy: sulfa, rash	2010 - Ongoing
Iodine allergy	Allergy: iodine, rash	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	01 Sep 2001 (Study Day -6963) - Ongoing	Diabetes Mellitus
Atorvastatin	17 Sep 2002 (Study Day -6582) - 11 Jan 2021 (Study Day 110)	Dyslipidemia
Insulin aspart	15 Sep 2020 (Study Day -9) - Ongoing	Diabetes Mellitus
Ibuprofen	23 Oct 2020 (Study Day 30) - 24 Oct 2020 (Study Day 31)	Inj Arm Pain
Atorvastatin	12 Jan 2021 (Study Day 111) - Ongoing	Hyperlipidemia
Ibuprofen	24 Jan 2021 (Study Day 123) - Ongoing	Body Aches And Headache

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone propionate; salmeterol xinafoate	29 Jan 2021 (Study Day 128) - Ongoing	Worsened Asthma
Salbutamol	29 Jan 2021 (Study Day 128) - Ongoing	Worsened Asthma
Chest x-ray*	02 Feb 2021 (Study Day 132) - 02 Feb 2021 (Study Day 132)	Adverse Event
Ct of the abdomen*	02 Feb 2021 (Study Day 132) - 02 Feb 2021 (Study Day 132)	Adverse Event
Electrocardiogram*	02 Feb 2021 (Study Day 132) - 02 Feb 2021 (Study Day 132)	Adverse Event
Cytoscopy right ureteral stent insertion*	03 Feb 2021 (Study Day 133) - 03 Feb 2021 (Study Day 133)	Adverse Event
Ciprofloxacin	04 Feb 2021 (Study Day 134) - 11 Feb 2021 (Study Day 141)	Right Nephritis
Hydrocodone bitartrate; paracetamol	04 Feb 2021 (Study Day 134) - 22 Mar 2021 (Study Day 180)	Right Flank And Abdominal Pain
Tamsulosin hydrochloride	04 Feb 2021 (Study Day 134) - 22 Mar 2021 (Study Day 180)	Right Ureteral Stones
Cefazolin	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Right Ureteral Stones
Cytoscopy right ureteral stent re-insertion*	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Adverse Event
Dexamethasone	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Right Ureteral Stones
Famotidine	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Right Ureteral Stones
Fentanyl	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Right Ureteral Stones
Lidocaine	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Right Ureteral Stones
Metoclopramide	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Right Ureteral Stones
Midazolam	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Right Ureteral Stones
Ondansetron	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Right Ureteral Stones
Paracetamol	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Right Ureteral Stones
Phenylephrine	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Right Ureteral Stones
Propofol	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Right Ureteral Stones
Right lithotripsy*	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Adverse Event
Right ureteral stent replacement*	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Adverse Event
Salbutamol	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Right Ureteral Stones
Right ureteral stent removal*	22 Mar 2021 (Study Day 180) - 22 Mar 2021 (Study Day 180)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Suspected COVID-19	Grade 2/moderate	Not related	23 Jan 2021 (Study Day 122) - 28 Jan 2021 (Study Day 127)
Asthma	Grade 2/moderate	Not related	29 Jan 2021 (Study Day 128) - Ongoing
Abdominal Pain	Grade 2/moderate	Not related	04 Feb 2021 (Study Day 134) - 22 Mar 2021 (Study Day 180)
Flank Pain	Grade 2/moderate	Not related	04 Feb 2021 (Study Day 134) - 22 Mar 2021 (Study Day 180)
Non-Cardiac Chest Pain	Grade 2/moderate	Not related	15 Mar 2021 (Study Day 173) - 17 Mar 2021 (Study Day 175)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US368-2211 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 23 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 20 Nov 2020 (Study Day 29)
First Dose of Vaccine in Part B: 15 Jan 2021 (Study Day 85)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Suspected COVID-19/ COVID-Like Illness	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	17 Jan 2021 (Study Day 87) – 01 Feb 2021 (Study Day 102)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US368-2211, a 56-year-old not Hispanic or Latino female, received the first dose of Placebo in the right arm on 23 Oct 2020 (Study Day 1). The second dose was administered in the right arm on 20 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 15 Jan 2021 (Study Day 85). The second dose was not administered.

Event Details

On 17 Jan 2021 (Study Day 87), 86 days after the first dose in Part A/2 days after the first dose in Part B and 58 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of suspected COVID-19. The IP dose was withdrawn due to the COVID-like illness. The event of COVID-like illness lasted for 16 days, after which it was considered to be recovered/resolved on 01 Feb 2021 (Study Day 102). The investigator assessed the event of suspected COVID-19 to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post menopause	2015 - Ongoing
Dyslipidaemia	Dyslipidemia	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

No prior or concomitant medications or procedures were reported.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 1/mild	Related	16 Jan 2021 (Study Day 86) - Ongoing
Suspected COVID-19	Grade 2/moderate	Not related	17 Jan 2021 (Study Day 87) - 01 Feb 2021 (Study Day 102)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US370-2040 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 21 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 20 Oct 2020 (Study Day 30)
First Dose of Vaccine in Part B: 11 Jan 2021 (Study Day 113)
Second Dose of Vaccine in Part B: 08 Feb 2021 (Study Day 141)
Reason for Narrative: SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Prostate Cancer/Prostate Cancer	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	26 Jan 2021 (Study Day 128) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US370-2040, a 58-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 21 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 20 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 11 Jan 2021 (Study Day 113). The second dose was administered in the left arm on 08 Feb 2021 (Study Day 141).

Event Details

On 26 Jan 2021 (Study Day 128), 127 days after the first dose in Part A/15 days after the first dose in Part B and 98 days after the second dose in Part A/13 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of prostate cancer. The IP dose was withdrawn due to the prostate cancer. The event of prostate cancer was considered to be ongoing. The investigator assessed the event of prostate cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-037620	Prostate cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gun shot wound	Gun shot wound of chest cavity	1967 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2011 - Ongoing
Depression	Depression	2019 - Ongoing
Obesity	Obesity	2019 - Ongoing
Dermal filler injection	Botox (forehead)	Jan 2020 - Not reported
Facial pain	Facial pain	31 Aug 2020 (Study Day -21) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colecalciferol	01 Jan 2019 (Study Day -629) - Ongoing	Vitamin Deficiency
Vilazodone hydrochloride	01 Jan 2019 (Study Day -629) - Ongoing	Depression
Semaglutide	01 Jan 2020 (Study Day -264) - Ongoing	Obesity
Tadalafil	01 Nov 2020 (Study Day 42) - Ongoing	Urinary Hesitancy
Amoxicillin	09 Jan 2021 (Study Day 111) - Ongoing	Oral Surgery Prophylaxis
Degarelix acetate	05 Feb 2021 (Study Day 138) - 05 Feb 2021 (Study Day 138)	Prostate Cancer
Ibuprofen	09 Feb 2021 (Study Day 142) - 09 Feb 2021 (Study Day 142)	Fever
Leuporelin acetate	05 Mar 2021 (Study Day 166) - Ongoing	Prostate Cancer

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pyrexia	Grade 1/mild	Related	09 Feb 2021 (Study Day 142) - 09 Feb 2021 (Study Day 142)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US371-2096 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 17 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 15 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 26 Feb 2021 (Study Day 163)
Second Dose of Vaccine in Part B: 22 Mar 2021 (Study Day 187)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Oesophageal Adenocarcinoma/ Esophageal Adenocarcinoma	SAE	Grade 3/ severe	Not related	20 Mar 2021 (Study Day 185) – Ongoing	Not recovered/not resolved
Pulmonary Embolism/ Pulmonary Emboli	SAE	Grade 3/ severe	Not related	15 Apr 2021 (Study Day 211) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US371-2096, a 58-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 17 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 15 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 26 Feb 2021. The participant was unblinded on 26 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 26 Feb 2021 (Study Day 163). The second dose was administered in the left arm on 22 Mar 2021 (Study Day 187).

Event Details

On 20 Mar 2021 (Study Day 185), 184 days after the first dose in Part A/22 days after the first dose in Part B and 156 days after the second dose in Part A/2 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of oesophageal adenocarcinoma. Action taken with the IP was not applicable. The event of oesophageal adenocarcinoma was considered to be ongoing. The investigator assessed the event of oesophageal adenocarcinoma to be not related to the IP.

On 15 Apr 2021 (Study Day 211), 210 days after the first dose in Part A/48 days after the first dose in Part B and 182 days after the second dose in Part A/24 days after the second dose in Part B of

the IP, the participant experienced a Grade 3/severe serious adverse event of pulmonary embolism. The IP dose was not changed due to the pulmonary emboli. The event of pulmonary emboli was considered to be ongoing. The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-084406	Oesophageal adenocarcinoma
MOD-2021-084406	Pulmonary embolism

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy to sulfa	1967 - Ongoing
Tonsillectomy	Tonsillectomy	1968 - 1968
Tonsillitis	Tonsillitis	1968 - 1968
Female sterilisation	Tubal ligation	20 Mar 1989 (Study Day -11504) - 20 Mar 1989 (Study Day -11504)
Cholecystectomy	Cholecystectomy	1998 - 1998
Cholecystitis	Cholecystitis	1998 - 1998
Drug hypersensitivity	Allergy to penicillin	1999 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2000 - Ongoing
Seasonal allergy	Seasonal allergic rhinitis	2000 - Ongoing
Stress urinary incontinence	Stress incontinence	2005 - 2005
Hypoacusis	Hard of hearing	2006 - Ongoing
Osteoarthritis	Osteoarthritis bilateral knees	2007 - Ongoing
Osteoarthritis	Osteoarthritis bilateral thumbs	2007 - Ongoing
Postmenopause	Post menopausal	2013 - Ongoing
Myopia	Myopia	2018 - Ongoing
Obesity	Obesity	14 Sep 2020 (Study Day -3) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol	Not reported - Ongoing	Abnormal Heart Rhythms
Omeprazole	2000 - Ongoing	Gastroesophageal Reflux Disease
Ibuprofen	2007 - Ongoing	Osteoarthritis
Paracetamol	02 Jan 2020 (Study Day -259) - Ongoing	Osteoarthritis
Fluticasone propionate	17 Jun 2020 (Study Day -92) - Ongoing	Seasonal Allergic Rhinitis
Levocetirizine	17 Aug 2020 (Study Day -31) - Ongoing	Seasonal Allergic Rhinitis
Pantoprazole sodium sesquihydrate	16 Oct 2020 (Study Day 30) - Ongoing	Acid Reflux
Meloxicam	21 Oct 2020 (Study Day 35) - Ongoing	Osteoarthritis (Bilateral Hands)
Prednisone	08 Dec 2020 (Study Day 83) - 12 Dec 2020 (Study Day 87)	COVID-19
Apixaban	04 Jan 2021 (Study Day 110) - Ongoing	Atrial Fibrillation
Nebivolol hydrochloride	04 Jan 2021 (Study Day 110) - Ongoing	Atrial Fibrillation
Paracetamol	06 Mar 2021 (Study Day 171) - 07 Mar 2021 (Study Day 172)	Fever

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Chills	Grade 1/mild	Related	06 Mar 2021 (Study Day 171) - 07 Mar 2021 (Study Day 172)
Cough	Grade 1/mild	Related	06 Mar 2021 (Study Day 171) - 07 Mar 2021 (Study Day 172)
Fatigue	Grade 1/mild	Related	06 Mar 2021 (Study Day 171) - 07 Mar 2021 (Study Day 172)
Headache	Grade 1/mild	Related	06 Mar 2021 (Study Day 171) - 07 Mar 2021 (Study Day 172)
Myalgia	Grade 1/mild	Related	06 Mar 2021 (Study Day 171) - 07 Mar 2021 (Study Day 172)
Nasal Congestion	Grade 1/mild	Related	06 Mar 2021 (Study Day 171) - 07 Mar 2021 (Study Day 172)
Oropharyngeal Pain	Grade 1/mild	Related	06 Mar 2021 (Study Day 171) - 07 Mar 2021 (Study Day 172)
Pain	Grade 1/mild	Related	06 Mar 2021 (Study Day 171) - 07 Mar 2021 (Study Day 172)
Pyrexia	Grade 1/mild	Related	06 Mar 2021 (Study Day 171) - 07 Mar 2021 (Study Day 172)
Vomiting	Grade 2/moderate	Not related	20 Mar 2021 (Study Day 185) - 20 Mar 2021 (Study Day 185)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US371-2174 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 15 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 11 Nov 2020 (Study Day 28)
First Dose of Vaccine in Part B: 26 Jan 2021 (Study Day 104)
Second Dose of Vaccine in Part B: 01 Mar 2021 (Study Day 138)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intervertebral Disc Degeneration/Worsening Of Degenerative Disc Disease	SAE	Grade 3/ severe	Not related	11 Feb 2021 (Study Day 120) – 13 Feb 2021 (Study Day 122)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US371-2174, a 53-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 15 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 11 Nov 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 26 Jan 2021. The participant was unblinded on 26 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 26 Jan 2021 (Study Day 104). The second dose was administered in the left arm on 01 Mar 2021 (Study Day 138).

Event Details

On 11 Feb 2021 (Study Day 120), 119 days after the first dose in Part A/16 days after the first dose in Part B and 92 days after the second dose in Part A/18 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of intervertebral disc degeneration. The IP dose was not changed due to the worsening of degenerative disc disease. The event of worsening of degenerative disc disease lasted for 3 days, after which it was considered to be recovered/resolved on 13 Feb 2021 (Study Day 122). The investigator assessed the event of intervertebral disc degeneration to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-027995	Invertebral disc degeneration

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Haemorrhoid operation	Hemorrhoidectomy	1999 - 1999
Haemorrhoids	Hemorrhoids	1999 - 1999
Myopia	Myopia	2000 - Ongoing
Fracture treatment	Left knee fracture repair	2003 - 2003
Hypertension	Hypertension	2003 - Ongoing
Ligament operation	Bilateral anterior cruciate ligament repair	2003 - 2003
Ligament operation	Bilateral medial collateral ligament repair	2003 - 2003
Ligament rupture	Bilateral anterior cruciate ligament tear	2003 - 2003
Ligament rupture	Bilateral medial collateral ligament tear	2003 - 2003
Lower limb fracture	Left knee fracture	2003 - 2003
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2005 - Ongoing
Haemorrhoid operation	Hemorrhoidectomy	2005 - 2005
Haemorrhoids	Hemorrhoids	2005 - 2005
Cholecystectomy	Cholecystectomy	2007 - 2007
Cholecystitis	Cholecystitis	2007 - 2007
Intervertebral disc degeneration	Degenerative disc disease	2010 - Ongoing
Seasonal allergy	Seasonal allergies	2012 - Ongoing
Gout	Gout (diet controlled)	2013 - Ongoing
Foot fracture	Left foot break	2015 - 2015
Foot operation	Left foot repair	2015 - 2015
Haemorrhoid operation	Hemorrhoidectomy	2015 - 2015
Haemorrhoids	Hemorrhoids	2015 - 2015

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Losartan	2003 - Ongoing	Hypertension
Metoprolol	2003 - Ongoing	Hypertension
Pantoprazole	2010 - Ongoing	Gastroesophageal Reflux Disease
Cetirizine hydrochloride	2012 - Ongoing	Seasonal Allergies
Influenza vaccine	28 Nov 2020 (Study Day 45) - 28 Nov 2020 (Study Day 45)	Flu Prevention
Allopurinol	28 Dec 2020 (Study Day 75) - Ongoing	Gout
Indometacin	28 Dec 2020 (Study Day 75) - Ongoing	Gout
Anterior discectomy cervical fusion of c4, c5, c6, c7*	11 Feb 2021 (Study Day 120) - 11 Feb 2021 (Study Day 120)	Adverse Event
Hydrocodone	12 Feb 2021 (Study Day 121) - 13 Feb 2021 (Study Day 122)	Quadruple Cervical Fusion With Bone Graft

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US372-2158 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 07 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 33)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Perirectal Abscess/ Perirectal Abscess	SAE	Grade 3/ severe	Not related	25 Feb 2021 (Study Day 203) – 05 Mar 2021 (Study Day 211)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US372-2158, a 45-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 18 Jan 2021. The participant was unblinded on 18 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 25 Feb 2021 (Study Day 203), 202 days after the first dose in Part A and 170 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of perirectal abscess. Action taken with the IP was not applicable. The event of perirectal abscess lasted for 9 days, after which it was considered to be recovered/resolved on 05 Mar 2021 (Study Day 211). The investigator assessed the event of perirectal abscess to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-026822	Perirectal abscess

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1976 - Ongoing
Cardiac murmur	Grade 2 heart murmur	2000 - Ongoing
Oedema peripheral	Lower extremity edema	2004 - Ongoing
Hysterectomy	Hysterectomy	2010 - Ongoing
Vaginal haemorrhage	Vaginal excessive bleeding	2010 - 2010

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone propionate	2017 - Ongoing	Seasonal Allergies
Paracetamol	09 Aug 2020 (Study Day 3) - Ongoing	Headache
Cefalexin	02 Feb 2021 (Study Day 180) - 09 Feb 2021 (Study Day 187)	Acute Sinusitis
Clindamycin	25 Feb 2021 (Study Day 203) - 25 Feb 2021 (Study Day 203)	Perirectal Abscess
Clindamycin	25 Feb 2021 (Study Day 203) - 28 Feb 2021 (Study Day 206)	Perirectal Abscess
Desmopressin acetate	25 Feb 2021 (Study Day 203) - 25 Feb 2021 (Study Day 203)	Perirectal Abscess
Famotidine	25 Feb 2021 (Study Day 203) - 28 Feb 2021 (Study Day 206)	Perirectal Abscess
Fentanyl citrate	25 Feb 2021 (Study Day 203) - 25 Feb 2021 (Study Day 203)	Perirectal Abscess
Incision and drainage of perirectal abscess*	25 Feb 2021 (Study Day 203) - 25 Feb 2021 (Study Day 203)	Adverse Event
Lithotomy*	25 Feb 2021 (Study Day 203) - 25 Feb 2021 (Study Day 203)	Adverse Event
Meglumine amidotrizoate; sodium amidotrizoate	25 Feb 2021 (Study Day 203) - 25 Feb 2021 (Study Day 203)	Perirectal Abscess
Placement of seton*	25 Feb 2021 (Study Day 203) - 25 Feb 2021 (Study Day 203)	Adverse Event
Paracetamol	26 Feb 2021 (Study Day 204) - 28 Feb 2021 (Study Day 206)	Perirectal Abscess
Desmopressin acetate	28 Feb 2021 (Study Day 206) - 28 Feb 2021 (Study Day 206)	Perirectal Abscess

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anal Fistula	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 179) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US372-2215 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 12 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 28)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Spondylolisthesis/L3-L4 Spondylolisthesis	SAE	Grade 3/ severe	Not related	11 Mar 2021 (Study Day 212) – 14 Mar 2021 (Study Day 215)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US372-2215, a 63-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 08 Jan 2021. The participant was unblinded on 08 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 11 Mar 2021 (Study Day 212), 211 days after the first dose in Part A and 184 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of spondylolisthesis. Action taken with the IP was not applicable. The event of l3-l4 spondylolisthesis lasted for 4 days, after which it was considered to be recovered/resolved on 14 Mar 2021 (Study Day 215). The investigator assessed the event of spondylolisthesis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-055277	Spondylolisthesis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillitis	Tonsillitis	1963 - 1963
Endometriosis	Endometriosis	1995 - 1995
Scoliosis	Scoliosis	2000 - Ongoing
Hot flush	Hot flashes	2003 - Ongoing
Postmenopause	Post menopausal	2003 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2005 - Ongoing
Back pain	Chronic back pain	2008 - Ongoing
Insomnia	Insomnia	2008 - Ongoing
Osteoarthritis	Osteoarthritis	2008 - Ongoing
Anxiety	Anxiety	2010 - Ongoing
Depression	Depression	2010 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2010 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	2010 - Ongoing
Migraine	Migraines	2010 - Ongoing
Hypertension	Hypertension	2013 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Estradiol	2004 - Ongoing	Hot Flashes
Calcium	2005 - Ongoing	Supplement
Probiotics nos	2010 - Ongoing	Irritable Bowl Syndrome
Losartan potassium	2013 - Ongoing	Hypertension
Chondroitin; glucosamine	2015 - Ongoing	Osteoarthritis
Cyclobenzaprine hydrochloride	2015 - Ongoing	Back Pain
Botulinum toxin type a	10 Jan 2017 (Study Day -1310) - Ongoing	Cosmetic
Hyaluronic acid	10 Jan 2017 (Study Day -1310) - Ongoing	Cosmetic
Rosuvastatin calcium	Jan 2020 - Ongoing	Hypercholesteremia
Diclofenac	Apr 2020 - Ongoing	Back Pain
L4-L5 lumbar infusion*	11 Mar 2021 (Study Day 212) - 11 Mar 2021 (Study Day 212)	Medical History
Paracetamol	11 Mar 2021 (Study Day 212) - 14 Mar 2021 (Study Day 215)	Worsening Osteoarthritis (Lumbar)
Oxygen	13 Mar 2021 (Study Day 214) - 13 Mar 2021 (Study Day 214)	L2-L4 Spondylolisthesis
Paracetamol	13 Mar 2021 (Study Day 214) - 13 Mar 2021 (Study Day 214)	L3-L4 Spondylolisthesis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US373-2023 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 07 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hip Fracture/ Broken Hip	SAE	Grade 3/ severe	Not applicable	22 Apr 2021 (Study Day 259) – Ongoing	Not reported

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US373-2023, a 71-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 26 Jan 2021. The participant was unblinded on 26 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 22 Apr 2021 (Study Day 259), 258 days after the first dose in Part A and 230 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of hip fracture. Action taken with the IP was not applicable. The outcome of the event was unknown. The investigator assessed the event of hip fracture to be not applicable to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-090663	Hip fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Mycobacterium tuberculosis complex test positive	Positive tuberculosis test	1960 - Ongoing
Myopia	Myopia - bilateral	1960 - Ongoing
Alcohol use	Alcohol use	1969 - Ongoing
Constipation	Constipation	1970 - Ongoing
Allergy to chemicals	Wine allergy	1980 - Ongoing
Rubber sensitivity	Latex allergy	1980 - Ongoing
Hysterectomy	Hysterectomy	1990 - 1990
Menopause	Menopause	1990 - 1990
Osteoarthritis	Bilateral osteoarthritis in knees	1990 - 2019
Polyarthritis	General arthritis	1990 - Ongoing
Postmenopause	Post-menopausal	1990 - Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Allergic reaction to excipient	Gel capsule allergy	2005 - Ongoing
Lyme disease	Lyme disease	2015 - 2015
Deafness bilateral	Bilateral hearing loss	2019 - Ongoing
Drug hypersensitivity	Steroids allergy	2019 - Ongoing
Insomnia	Insomnia	2019 - Ongoing
Knee arthroplasty	Bilateral knee replacement	Aug 2019 - Aug 2019
Back pain	Back pain	2020 - Ongoing
Food allergy	Avocado allergy	2020 - Ongoing
Food allergy	Mango allergy	2020 - Ongoing
Food allergy	Pineapple allergy	2020 - Ongoing
Food allergy	Swiss cheese allergy	2020 - Ongoing
Headache	Non-migraine headaches	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	2015 - Ongoing	Non-Migraine Headaches And Back Pain
Fluticasone propionate	2018 - Ongoing	Seasonal Allergies
Melatonin	2019 - Ongoing	Insomnia
Acetylsalicylic acid	2020 - Ongoing	Non-Migraine Headaches, And Back Pain
Herbal extract nos; homeopathics nos	2020 - Ongoing	Seasonal Allergies

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	05 Nov 2020 (Study Day 91) - 05 Nov 2020 (Study Day 91)	Influenza
Ofloxacin	10 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 133)	Right Eye Cataract Surgery
Prednisone acetate	10 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 133)	Right Eye Cataract Surgery
Right cataract surgery*	10 Dec 2020 (Study Day 126) - 10 Dec 2020 (Study Day 126)	Adverse Event
Prednisone acetate	17 Dec 2020 (Study Day 133) - Ongoing	Right Eye Cataract Surgery
Calcium levomefolate	20 Dec 2020 (Study Day 136) - Ongoing	Vitamin Deficiency
Magnesium	20 Dec 2020 (Study Day 136) - Ongoing	Magnesium Deficiency
Pyridoxine hydrochloride	20 Dec 2020 (Study Day 136) - Ongoing	Vitamin Deficiency
Vitamin b12 nos	20 Dec 2020 (Study Day 136) - Ongoing	Vitamin Deficiency
Left cataract surgery*	25 Feb 2021 (Study Day 203) - 25 Feb 2021 (Study Day 203)	Adverse Event
Prednisone acetate	25 Feb 2021 (Study Day 203) - Ongoing	Left Eye Cataract Surgery
Mammogram*	01 Mar 2021 (Study Day 207) - 01 Mar 2021 (Study Day 207)	Diagnostic
Ultrasound*	23 Mar 2021 (Study Day 229) - 23 Mar 2021 (Study Day 229)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US374-2034 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 25 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 22 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis Perforated/Ruptured Appendix	SAE	Grade 4	Not related	09 Feb 2021 (Study Day 169) – 26 Feb 2021 (Study Day 186)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2034, a 49-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 07 Jan 2021. The participant was unblinded on 07 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 09 Feb 2021 (Study Day 169), 168 days after the first dose in Part A and 140 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of appendicitis perforated. Action taken with the IP was not applicable. The event of ruptured appendix lasted for 18 days, after which it was considered to be recovered/resolved on 26 Feb 2021 (Study Day 186). The investigator assessed the event of appendicitis perforated to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014670	Appendicitis perforated

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	High blood pressure	Oct 2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fish oil	2010 - Ongoing	Supplement General Health
Iron	2010 - Ongoing	Supplement
Vitamins nos	2010 - Ongoing	Supplement
Colecalciferol	2019 - Ongoing	Supplement/General Wellness
Hydrochlorothiazide; lisinopril	2019 - Ongoing	High Blood Pressure
Influenza vaccine	06 Oct 2020 (Study Day 43) - 06 Oct 2020 (Study Day 43)	Influenza
Ibuprofen	07 Oct 2020 (Study Day 44) - 08 Oct 2020 (Study Day 45)	Headache
Paracetamol	07 Oct 2020 (Study Day 44) - 08 Oct 2020 (Study Day 45)	Headache
Ceftriaxone	11 Feb 2021 (Study Day 171) - 13 Feb 2021 (Study Day 173)	Ruptured Appendix
Laparoscopic appendectomy*	11 Feb 2021 (Study Day 171) - 11 Feb 2021 (Study Day 171)	Other, Appendicitis
Piperacillin sodium; tazobactam sodium	11 Feb 2021 (Study Day 171) - 13 Feb 2021 (Study Day 173)	Ruptured Appendix
Metronidazole	13 Feb 2021 (Study Day 173) - 23 Feb 2021 (Study Day 183)	Ruptured Appendix
Ceftriaxone	23 Feb 2021 (Study Day 183) - 01 Mar 2021 (Study Day 189)	Ruptured Appendix
Metronidazole	23 Feb 2021 (Study Day 183) - 01 Mar 2021 (Study Day 189)	Ruptured Appendix

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US374-2137 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 28 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 25 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Anaphylactic Reaction/A naphylaxis	SAE	Grade 3/ severe	Not related	09 Feb 2021 (Study Day 166) – 09 Feb 2021 (Study Day 166)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2137, a 40-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 27 Jan 2021. The participant was unblinded on 27 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 09 Feb 2021 (Study Day 166), 165 days after the first dose in Part A and 137 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of anaphylactic reaction. Action taken with the IP was not applicable. The event of anaphylaxis lasted for 1 days, after which it was considered to be recovered/resolved on 09 Feb 2021 (Study Day 166). The investigator assessed the event of anaphylactic reaction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-026408	Anaphylactic reaction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1988 - Ongoing
Dyspepsia	Indigestion	1998 - Ongoing
Pain	Generalized pain	1998 - Ongoing
Migraine	Migraines headaches	2001 - Ongoing
Endometriosis	Endometriosis	Jan 2001 - Jan 2001
Laparoscopy	Abdominal laparoscopy	Jan 2001 - Jan 2001
Genital herpes	Genital herpes	2008 - Ongoing
Anxiety	Anxiety	14 Dec 2010 (Study Day -3545) - Ongoing
Contrast media allergy	Allergy to contrast dye (sneezing)	22 Nov 2013 (Study Day -2471) - Ongoing
Food allergy	Allergy to avocodo	2015 - Ongoing
Insomnia	Insomnia	2015 - Ongoing
Bunion operation	Bunionectomy	01 Jun 2015 (Study Day -1915) - 01 Jun 2015 (Study Day -1915)
Hypertension	Hypertension	Sep 2019 - Ongoing
Hysterectomy	Hysterectomy	04 Oct 2019 (Study Day -329) - 05 Oct 2019 (Study Day -328)
Menometrorrhagia	Menometrorrhagia	04 Oct 2019 (Study Day -329) - 05 Oct 2019 (Study Day -328)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium carbonate	1998 - Ongoing	Indigestion
Paracetamol	1998 - Ongoing	Generalized Pain
Salbutamol	1998 - Ongoing	Asthma
Valaciclovir hydrochloride	Dec 2008 - Ongoing	Genital Herpes
Alprazolam	14 Dec 2010 (Study Day -3545) - Ongoing	Anxiety
Ondansetron	14 Dec 2010 (Study Day -3545) - Ongoing	Nausea
Melatonin	2015 - Ongoing	Insomnia
Ibuprofen	2019 - Ongoing	Generalized Pain
Loratadine	Oct 2019 - Ongoing	Asthma
Montelukast sodium	Oct 2019 - Ongoing	Asthma
Ibuprofen	28 Aug 2020 (Study Day 1) - 28 Aug 2020 (Study Day 1)	Pain At Injection Site

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pseudoephedrine hydrochloride	22 Sep 2020 (Study Day 26) - 23 Sep 2020 (Study Day 27)	Otalgia
Ibuprofen	25 Sep 2020 (Study Day 29) - 27 Sep 2020 (Study Day 31)	Headache
Paracetamol	25 Sep 2020 (Study Day 29) - 27 Sep 2020 (Study Day 31)	Fever
Influenza vaccine	27 Nov 2020 (Study Day 92) - 27 Nov 2020 (Study Day 92)	Flu Influenza
Lisinopril	31 Dec 2020 (Study Day 126) - Ongoing	Hypertension
Trazodone	31 Dec 2020 (Study Day 126) - Ongoing	Insomnia
Allergy testing due to asthma*	09 Feb 2021 (Study Day 166) - 09 Feb 2021 (Study Day 166)	Medical History
Diphenhydramine hydrochloride	09 Feb 2021 (Study Day 166) - 09 Feb 2021 (Study Day 166)	Anaphylaxis
Epinephrine	09 Feb 2021 (Study Day 166) - 09 Feb 2021 (Study Day 166)	Anaphylaxis
Sumatriptan succinate	17 Mar 2021 (Study Day 202) - Ongoing	Migraine Headaches

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US374-2153 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 29 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 26 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cholelithiasis Obstructive/ Cholelithiasis With Obstruction	SAE	Grade 3/ severe	Not related	16 Apr 2021 (Study Day 231) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2153, a 51-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 29 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 26 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 28 Jan 2021. The participant was unblinded on 28 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 16 Apr 2021 (Study Day 231), 230 days after the first dose in Part A and 202 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of cholelithiasis obstructive. Action taken with the IP was not applicable. The event of cholelithiasis with obstruction was considered to be ongoing. The investigator assessed the event of cholelithiasis obstructive to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-087107	Cholelithiasis obstructive

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Food allergy	Allergy, shellfish	2016 - Ongoing
Food allergy	Allergy, tree nuts	2016 - Ongoing
Hypersensitivity	Allergy, environmental	2016 - Ongoing
Cervical radiculopathy	Cervical radiculopathy	24 Jun 2020 (Study Day -66) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	2016 - Ongoing	Environmental Allergies
Gabapentin	24 Jun 2020 (Study Day -66) - Ongoing	Cervical Radiculopathy
Ibuprofen	27 Sep 2020 (Study Day 30) - 27 Sep 2020 (Study Day 30)	Pain At Injection Site
Influenza vaccine	14 Oct 2020 (Study Day 47) - 14 Oct 2020 (Study Day 47)	Influenza Prevention
Adjustments by chiropractor for cervical radiculopathy*	15 Jan 2021 (Study Day 140) - 15 Jan 2021 (Study Day 140)	Medical History
Laser therapy by chiropractor for cervical radiculopathy*	15 Jan 2021 (Study Day 140) - 15 Jan 2021 (Study Day 140)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US374-2225 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 30 Sep 2020 (Study Day 28)
First Dose of Vaccine in Part B: 14 Jan 2021 (Study Day 134)
Second Dose of Vaccine in Part B: 09 Feb 2021 (Study Day 160)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arnold-Chiari Malformation/ Arnold Chiari Syndrome	SAE	Grade 2/ moderate	Not related	14 Apr 2021 (Study Day 224) – 17 Apr 2021 (Study Day 227)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2225, a 22-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 14 Jan 2021 (Study Day 134). The second dose was administered in the left arm on 09 Feb 2021 (Study Day 160).

Event Details

On 14 Apr 2021 (Study Day 224), 223 days after the first dose in Part A/90 days after the first dose in Part B and 196 days after the second dose in Part A/64 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of arnold-chiari malformation. Action taken with the IP was not applicable. The event of arnold chiari syndrome lasted for 4 days, after which it was considered to be recovered/resolved on 17 Apr 2021 (Study Day 227). The investigator assessed the event of arnold-chiari malformation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-097314	Arnold-Chiari malformation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma [mild]	1999 - Ongoing
Hypersensitivity	Allergies environmental	1999 - Ongoing
Postural orthostatic tachycardia syndrome	Postural orthostatic tachycardia syndrome	2011 - Ongoing
Drug hypersensitivity	Codene allergy	2013 - Ongoing
Rubber sensitivity	Allergy latex	2014 - Ongoing
Temporomandibular joint syndrome	Temporomandibular joint disorder	2015 - Ongoing
Anxiety	Anxiety	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1999 - Ongoing	Asthma
Cetirizine hydrochloride	2016 - Ongoing	Allergies Environmental
Montelukast	2016 - Ongoing	Allergies Environmental
Levonorgestrel	Aug 2017 - Ongoing	Contraception
Duloxetine	May 2020 - 28 Jan 2021 (Study Day 148)	Anxiety
Influenza vaccine	22 Oct 2020 (Study Day 50) - 22 Oct 2020 (Study Day 50)	Influenza Prophylaxis
Duloxetine	28 Jan 2021 (Study Day 148) - Ongoing	Anxiety
Temporomandibular joint surgery*	15 Feb 2021 (Study Day 166) - 15 Feb 2021 (Study Day 166)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US374-2229 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 30 Sep 2020 (Study Day 28)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Major Depression/ Severe Major Depression With Psychotic Features	SAE	Grade 3/ severe	Not related	04 Apr 2021 (Study Day 214) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2229, a 71-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 27 Jan 2021. The participant was unblinded on 27 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 04 Apr 2021 (Study Day 214), 213 days after the first dose in Part A and 186 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of major depression. Action taken with the IP was not applicable. The event of severe major depression with psychotic features was considered to be ongoing. The investigator assessed the event of major depression to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-074459	Major depression

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Colitis ulcerative	History of ulcerative colitis	1970 - Ongoing
Gastroesophageal reflux disease	Acid reflux	2010 - Ongoing
Anxiety	Anxiety	2015 - Ongoing
Depression	Depression	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole	2010 - Ongoing	Acid Reflux
Mesalazine	2018 - Ongoing	Ulcerative Colitis Prophylaxis
Atorvastatin	2019 - Ongoing	Cardiac Protection
Colonoscopy*	29 Sep 2020 (Study Day 27) - 29 Sep 2020 (Study Day 27)	Diagnostic
Fentanyl	29 Sep 2020 (Study Day 27) - 29 Sep 2020 (Study Day 27)	Sedation For Colonoscopy
Midazolam	29 Sep 2020 (Study Day 27) - 29 Sep 2020 (Study Day 27)	Sedation For Colonoscopy
Ibuprofen	30 Sep 2020 (Study Day 28) - 01 Oct 2020 (Study Day 29)	Generalized Pain Fever
Ibuprofen	30 Sep 2020 (Study Day 28) - 06 Oct 2020 (Study Day 34)	Generalized Pain And Fever
Influenza vaccine	16 Oct 2020 (Study Day 44) - 16 Oct 2020 (Study Day 44)	Influenza Prophylaxis
Vitamin d nos	27 Oct 2020 (Study Day 55) - Ongoing	General Health Prophylaxis
Ibuprofen	11 Dec 2020 (Study Day 100) - 24 Dec 2020 (Study Day 113)	Broken Tooth
Oral surgery*	11 Dec 2020 (Study Day 100) - 11 Dec 2020 (Study Day 100)	Adverse Event
Paracetamol	11 Dec 2020 (Study Day 100) - 24 Dec 2020 (Study Day 113)	Broken Tooth
Amoxicillin	14 Dec 2020 (Study Day 103) - 24 Dec 2020 (Study Day 113)	Post Extraction Dental Infection
Quetiapine	08 Feb 2021 (Study Day 159) - Ongoing	Anxiety
Mirtazapine	24 Feb 2021 (Study Day 175) - Ongoing	Worsening Depression
Lorazepam	03 Mar 2021 (Study Day 182) - Ongoing	Worsening Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anxiety	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 152) - Ongoing
Depression	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 152) - Ongoing
Constipation	Grade 2/moderate	Not related	03 Mar 2021 (Study Day 182) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US374-2301 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Oct 2020 (Study Day 30)
First Dose of Vaccine in Part B: 14 Jan 2021 (Study Day 128)
Second Dose of Vaccine in Part B: 11 Feb 2021 (Study Day 156)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Internal Hernia/Internal Hernia	SAE	Grade 3/ severe	Not related	16 Jan 2021 (Study Day 130) – 22 Jan 2021 (Study Day 136)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2301, a 45-year-old Hispanic or Latino female, received the first dose of Placebo in the left arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 14 Jan 2021 (Study Day 128). The second dose was administered in the left arm on 11 Feb 2021 (Study Day 156).

Event Details

On 16 Jan 2021 (Study Day 130), 129 days after the first dose in Part A/2 days after the first dose in Part B and 100 days after the second dose in Part A/26 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of internal hernia. The IP dose was not changed due to the internal hernia. The event of internal hernia lasted for 7 days, after which it was considered to be recovered/resolved on 22 Jan 2021 (Study Day 136). The investigator assessed the event of internal hernia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010625	Internal hernia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - Ongoing
Menorrhagia	Menorrhagia	2010 - Ongoing
Hypertension	Hypertension	May 2019 - Ongoing
Gastric bypass	Gastric bypass	05 Aug 2019 (Study Day -401) - 05 Aug 2019 (Study Day -401)
Endometrial ablation	Endometrialablation	Oct 2019 - Oct 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Iron	2017 - Ongoing	Menorrhagia
Lisinopril	May 2019 - Ongoing	Hypertension
Hydrochlorothiazide	Jul 2019 - Ongoing	Hypertension
Laparoscopy internal hernia repair*	18 Jan 2021 (Study Day 132) - 18 Jan 2021 (Study Day 132)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US374-2384 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 16 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 13 Oct 2020 (Study Day 28)
First Dose of Vaccine in Part B: 16 Jan 2021 (Study Day 123)
Second Dose of Vaccine in Part B: 15 Feb 2021 (Study Day 153)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Colostomy/Reversal Of Ostomy - S/P Hartmann's Procedure	SAE	Grade 3/ severe	Not related	05 Apr 2021 (Study Day 202) – Ongoing	Recovering / resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The MedDRA Preferred Term/ Verbatim Term of Colostomy/Reversal Of Ostomy - S/P Hartmann's Procedure was updated to Diverticulitis Intestinal Perforated/Complications of Perforation after the database lock.

Participant US374-2384, a 40-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 16 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 13 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 16 Jan 2021. The participant was unblinded on 16 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 16 Jan 2021 (Study Day 123). The second dose was administered in the left arm on 15 Feb 2021 (Study Day 153).

Event Details

On 05 Apr 2021 (Study Day 202), 201 days after the first dose in Part A/79 days after the first dose in Part B and 174 days after the second dose in Part A/49 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of colostomy. Action taken with the IP was not applicable. The event of reversal of ostomy - s/p hartmann's procedure was considered to be ongoing. The investigator assessed the event of colostomy to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-073416	Diverticulitis intestinal perforated

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - Ongoing
Pneumonia	Pneumonia	Not reported
Vitamin D deficiency	Vitamin d deficiency	2015 - Ongoing
Hypertension	Hypertension	30 Jun 2017 (Study Day -1174) - Ongoing
Sarcoidosis	Sarcoidosis	2019 - Ongoing
Pneumonia	Pneumonia	Apr 2019 - Apr 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colecalciferol	2015 - Ongoing	Vitamin D Deficiency
Varenicline tartrate	12 Dec 2016 (Study Day -1374) - Ongoing	Smoking Cessation
Hydrochlorothiazide	30 Jun 2017 (Study Day -1174) - Ongoing	Hypertension
Losartan	30 Jun 2017 (Study Day -1174) - Ongoing	Hypertension
Chromium nicotinate; nicotinic acid	Jan 2018 - Ongoing	Supplement Prophylaxis
Fluticasone furoate; umeclidinium bromide; vilanterol trifenate	2019 - Ongoing	Sarcoidosis
Prednisone	Jul 2019 - Ongoing	Sarcoidosis
Choline; inositol; methionine	02 Oct 2020 (Study Day 17) - Ongoing	Obesity
Vitamin b12 nos	02 Oct 2020 (Study Day 17) - Ongoing	Obesity
Metronidazole	08 Oct 2020 (Study Day 23) - 15 Oct 2020 (Study Day 30)	Bacterial Vaginosis
Acetylsalicylic acid; caffeine	13 Oct 2020 (Study Day 28) - 13 Oct 2020 (Study Day 28)	Headache
Ibuprofen	13 Oct 2020 (Study Day 28) - 17 Oct 2020 (Study Day 32)	Headache
Influenza vaccine	28 Oct 2020 (Study Day 43) - 28 Oct 2020 (Study Day 43)	Influenza Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levofloxacin	01 Nov 2020 (Study Day 47) - 09 Nov 2020 (Study Day 55)	Thrombus Prophylaxis
Ondansetron	01 Nov 2020 (Study Day 47) - 09 Nov 2020 (Study Day 55)	Nausea/Diverticulitis
Piperacillin; tazobactam	01 Nov 2020 (Study Day 47) - 09 Nov 2020 (Study Day 55)	Diverticulitis
Ketorolac	02 Nov 2020 (Study Day 48) - 09 Nov 2020 (Study Day 55)	Diverticulitis
Labetalol	02 Nov 2020 (Study Day 48) - 09 Nov 2020 (Study Day 55)	Hypertension
Hartman's procedure*	05 Nov 2020 (Study Day 51) - 05 Nov 2020 (Study Day 51)	Adverse Event
Levofloxacin	10 Nov 2020 (Study Day 56) - 17 Nov 2020 (Study Day 63)	Pneumonia
Metronidazole	10 Nov 2020 (Study Day 56) - 17 Nov 2020 (Study Day 63)	Diverticulitis
Oxycodone hydrochloride; paracetamol	10 Nov 2020 (Study Day 56) - 25 Nov 2020 (Study Day 71)	Post-Op Pain
Potassium chloride	10 Nov 2020 (Study Day 56) - 13 Nov 2020 (Study Day 59)	Hypokalemia
Hydrocodone bitartrate; paracetamol	27 Nov 2020 (Study Day 73) - 15 Dec 2020 (Study Day 91)	Post-Op Pain
Cyclobenzaprine hydrochloride	15 Dec 2020 (Study Day 91) - 30 Dec 2020 (Study Day 106)	Lower Back Muscle Strain
Zolpidem tartrate	15 Dec 2020 (Study Day 91) - 04 Jan 2021 (Study Day 111)	Insomnia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US375-2010 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 07 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 33)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cholecystitis/Cholecystitis	SAE	Grade 2/ moderate	Not related	21 Jan 2021 (Study Day 168) – 23 Jan 2021 (Study Day 170)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US375-2010, a 67-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 18 Jan 2021. The participant was unblinded on 18 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 21 Jan 2021 (Study Day 168), 167 days after the first dose in Part A and 135 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of cholecystitis. Action taken with the IP was not applicable. The event of cholecystitis lasted for 3 days, after which it was considered to be recovered/resolved on 23 Jan 2021 (Study Day 170). The investigator assessed the event of cholecystitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-008903	Cholecystitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Alopecia	Alopecia	Not reported - Ongoing
Atrial fibrillation	Atrial fibrillation	Not reported - Ongoing
Cardiac murmur	Cardiac murmur (final diagnosis unknown)	Not reported - Ongoing
Carpal tunnel syndrome	Carpal tunnel syndrome	Not reported - 2014
Coronary artery disease	Coronary artery disease	Not reported - Ongoing
Diabetes mellitus	Diabetes	Not reported - Feb 2020
Drug hypersensitivity	Topical benzoyl peroxide allergy	Not reported - Ongoing
Nasal septum deviation	Nasal deviation right	Not reported - 1970
Seasonal allergy	Seasonal allergies	1960 - Ongoing
Nasal septal operation	Nasal deviation surgery right	1970 - 1970
Nephrolithiasis	Renal stones	1972 - 1982
Renal stone removal	Laparotomy for renal stones	1972 - 1972
Renal stone removal	Laparotomy for renal stones	1973 - 1973
Delivery	Childbirth	1977 - 1977
Renal stone removal	Renal stone manipulation	1982 - 1982
Lower limb fracture	Left tibia/fibula fracture	1995 - 1995
Hysterectomy	Complete hysterectomy (associated condition unknown)	1996 - 1996
Squamous cell carcinoma	Right hand squamous cell cancer	1996 - 1996
Menopause	Menopause after hysterectomy	1997 - 1998
Depression	Depression after husband's death	2009 - 2011
Gastroesophageal reflux disease	Gastroesophageal reflux disease (resolved after vertical sleeve)	2010 - Feb 2020
Carpal tunnel decompression	Carpal tunnel surgery bilaterally	2014 - 2014
Cardiac ablation	Coronary artery ablation (unknown associated condition)	2015 - 2015
Coronary arterial stent insertion	2 coronary stents	2015 - 2015
Myocardial infarction	Myocardial infarction	2015 - 2015
Gout	Gout	2018 - 2019
Gastroesophageal reflux disease	Gastroesophageal reflux	2019 - 02 Feb 2020 (Study Day -187)
Gastrectomy	Vertical sleeve gastrectomy	Feb 2020 - Feb 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fexofenadine hydrochloride	2000 - Ongoing	Seasonal Allergies

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Rivaroxaban	2015 - Ongoing	Atrial Fibrillation
Carvedilol	May 2015 - Ongoing	Atrial Fibrillation
Escitalopram oxalate	2018 - Ongoing	Depression
Omeprazole	2019 - Ongoing	Gastroesophageal Reflux
Allopurinol	2020 - Ongoing	Gout
Biotin	2020 - Ongoing	Alopecia
Calcium citrate	2020 - Ongoing	Multi Supplement
Vitamins nos	2020 - Ongoing	Supplement
Paracetamol	09 Sep 2020 (Study Day 34) - Ongoing	Migraine Headaches
Influenza vaccine	15 Sep 2020 (Study Day 40) - 15 Sep 2020 (Study Day 40)	Prophylaxis For Influenza
Abdominal ultrasound*	20 Jan 2021 (Study Day 167) - 20 Jan 2021 (Study Day 167)	Adverse Event
Electrocardiogram*	20 Jan 2021 (Study Day 167) - 20 Jan 2021 (Study Day 167)	Adverse Event
Cholecystectomy*	22 Jan 2021 (Study Day 169) - 22 Jan 2021 (Study Day 169)	Adverse Event
Cyanocobalamin	22 Jan 2021 (Study Day 169) - 23 Jan 2021 (Study Day 170)	Cholecystectomy Post Op
Electrocardiogram*	22 Jan 2021 (Study Day 169) - 22 Jan 2021 (Study Day 169)	Adverse Event
Gabapentin	22 Jan 2021 (Study Day 169) - 23 Jan 2021 (Study Day 170)	Cholecystectomy Post Op
Pantoprazole sodium sesquihydrate	22 Jan 2021 (Study Day 169) - 23 Jan 2021 (Study Day 170)	Cholecystectomy Pre And Post Op
Paracetamol	22 Jan 2021 (Study Day 169) - 23 Jan 2021 (Study Day 170)	Cholecystectomy Pre And Post Op
Piperacillin sodium; tazobactam sodium	22 Jan 2021 (Study Day 169) - 22 Jan 2021 (Study Day 169)	Cholecystectomy Pre Op
Folic acid	23 Jan 2021 (Study Day 170) - 23 Jan 2021 (Study Day 170)	Cholecystectomy Post Op
Hydrocodone bitartrate; paracetamol	23 Jan 2021 (Study Day 170) - 04 Feb 2021 (Study Day 182)	Pain Post Op Cholecystectomy
Lactobacillus acidophilus	23 Jan 2021 (Study Day 170) - 23 Jan 2021 (Study Day 170)	Cholecystectomy Post Op
Thiamine	23 Jan 2021 (Study Day 170) - 23 Jan 2021 (Study Day 170)	Cholecystectomy Post Op

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US375-2088 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 14 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 12 Jan 2021 (Study Day 152)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Deafness Unilateral/ Right Ear Hearing Loss	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	17 Jan 2021 (Study Day 157) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US375-2088, a 64-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 12 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 12 Jan 2021 (Study Day 152). The second dose was not administered.

Event Details

On 17 Jan 2021 (Study Day 157), 156 days after the first dose in Part A/5 days after the first dose in Part B and 128 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of deafness unilateral. The IP dose was withdrawn due to the right ear hearing loss. The event of right ear hearing loss was considered to be ongoing. The investigator assessed the event of deafness unilateral to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Contrast media allergy	Ivp dye allergy	Not reported - Ongoing
Drug hypersensitivity	Ibuprofen allergy	Not reported - Ongoing
Elbow operation	Right elbow reconstruction	Not reported
Hip surgery	Right total hip surgery	Not reported
Meniscus operation	Right knee meniscus repair	Not reported
Parathyroidectomy	Parathyroidectomy	Not reported
Nasal septal operation	Deviated septum repair	1995 - 1995
Headache	Intermittent headaches	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	2020 - Ongoing	Intermittent Headache
Influenza vaccine	23 Oct 2020 (Study Day 71) - 23 Oct 2020 (Study Day 71)	Prevention Of Seasonal Influenza
Pneumococcal vaccine polysacch 23v	23 Oct 2020 (Study Day 71) - 23 Oct 2020 (Study Day 71)	Prevention Of Pneumonia
Hyperbaric chamber- 38 hours of treatment*	22 Jan 2021 (Study Day 162) - 22 Jan 2021 (Study Day 162)	Adverse Event
Lisinopril	01 Feb 2021 (Study Day 172) - Ongoing	Hypertension
Dexamethasone	03 Feb 2021 (Study Day 174) - 03 Feb 2021 (Study Day 174)	Right Ear Hearing Loss
Dexamethasone perfusion right ear*	03 Feb 2021 (Study Day 174) - 03 Feb 2021 (Study Day 174)	Adverse Event
Dexamethasone	10 Feb 2021 (Study Day 181) - 10 Feb 2021 (Study Day 181)	Right Ear Hearing Loss
Dexamethasone perfusion right ear*	10 Feb 2021 (Study Day 181) - 10 Feb 2021 (Study Day 181)	Adverse Event
Prednisone	10 Feb 2021 (Study Day 181) - 17 Feb 2021 (Study Day 188)	Right Ear Hearing Loss
Prednisone	18 Feb 2021 (Study Day 189) - 20 Feb 2021 (Study Day 191)	Right Ear Hearing Loss
Prednisone	21 Feb 2021 (Study Day 192) - 23 Feb 2021 (Study Day 194)	Right Ear Hearing Loss
Covid-19 pcr test- negative*	12 Mar 2021 (Study Day 211) - 12 Mar 2021 (Study Day 211)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Deafness Unilateral	Grade 2/moderate	Related	17 Jan 2021 (Study Day 157) - Ongoing
Hypertension	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 172) - Ongoing
Chills	Grade 2/moderate	Not related	12 Mar 2021 (Study Day 211) - 14 Mar 2021 (Study Day 213)
Diarrhoea	Grade 2/moderate	Not related	12 Mar 2021 (Study Day 211) - 14 Mar 2021 (Study Day 213)
Nausea	Grade 2/moderate	Not related	12 Mar 2021 (Study Day 211) - 14 Mar 2021 (Study Day 213)
Pain	Grade 2/moderate	Not related	12 Mar 2021 (Study Day 211) - 14 Mar 2021 (Study Day 213)
Pyrexia	Grade 2/moderate	Not related	12 Mar 2021 (Study Day 211) - 14 Mar 2021 (Study Day 213)
Vomiting	Grade 2/moderate	Not related	12 Mar 2021 (Study Day 211) - 14 Mar 2021 (Study Day 213)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US375-2184 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 20 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 21 Sep 2020 (Study Day 33)
First Dose of Vaccine in Part B: 25 Jan 2021 (Study Day 159)
Second Dose of Vaccine in Part B: 26 Feb 2021 (Study Day 191)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diverticulitis/Acute Diverticulitis	SAE	Grade 3/severe	Not related	31 Mar 2021 (Study Day 224) – 10 Apr 2021 (Study Day 234)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US375-2184, a 81-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 25 Jan 2021. The participant was unblinded on 25 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 25 Jan 2021 (Study Day 159). The second dose was administered in the left arm on 26 Feb 2021 (Study Day 191).

Event Details

On 31 Mar 2021 (Study Day 224), 223 days after the first dose in Part A/65 days after the first dose in Part B and 191 days after the second dose in Part A/33 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of diverticulitis. Action taken with the IP was not applicable. The event of acute diverticulitis lasted for 11 days, after which it was considered to be recovered/resolved on 10 Apr 2021 (Study Day 234). The investigator assessed the event of diverticulitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-065723	Diverticulitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2005 - Ongoing
Prostate cancer	Prostate cancer	2012 - 2012
Prostatic operation	Prostate surgery for prostate cancer	2012 - 2012
Depression	Depression	2015 - Ongoing
Neuropathy peripheral	Neuropathy (unknown type & unknown location)	2017 - Ongoing
Malignant melanoma	Melanoma	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Duloxetine	2015 - Ongoing	Depression
Gabapentin	2017 - Ongoing	Neuropathy
Fluticasone furoate; umeclidinium bromide; vilanterol trifenate	2018 - Ongoing	Chronic Obstructive Pulmonary Disease
Influenza vaccine	29 Oct 2020 (Study Day 71) - 29 Oct 2020 (Study Day 71)	Prevention Of Seasonal Influenza
Pneumococcal vaccine	29 Oct 2020 (Study Day 71) - 29 Oct 2020 (Study Day 71)	Prevention Of Pneumonia
Acetylsalicylic acid	25 Feb 2021 (Study Day 190) - Ongoing	Thrombosis Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US375-2402 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 01 Oct 2020 (Study Day 28)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
High-Grade B-Cell Lymphoma/High Grade B-Cell Lymphoma	SAE	Grade 4	Not related	05 Feb 2021 (Study Day 155) – 26 Feb 2021 (Study Day 176)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US375-2402, a 70-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 19 Jan 2021. The participant was unblinded on 19 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 05 Feb 2021 (Study Day 155), 154 days after the first dose in Part A and 127 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of high-grade b-cell lymphoma. Action taken with the IP was not applicable. The event of high grade b-cell lymphoma lasted for 22 days, after which it was considered to be recovered/resolved with sequelae on 26 Feb 2021 (Study Day 176). The investigator assessed the event of high-grade b-cell lymphoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-023297	High-grade B-cell lymphoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cataract	Bilateral cataracts	Not reported - Ongoing
Tonsillectomy	Tonsillectomy	1958 - 1958
Migraine	Migraine headaches	2005 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Insomnia	Insomnia	Aug 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sumatriptan	2005 - Ongoing	Migraine Headaches
Atorvastatin	2010 - Ongoing	Hyperlipidemia
Melatonin	Aug 2020 - Ongoing	Insomnia
Ibuprofen	01 Oct 2020 (Study Day 28) - 03 Oct 2020 (Study Day 30)	Fever, Chills
Influenza vaccine	20 Oct 2020 (Study Day 47) - 20 Oct 2020 (Study Day 47)	Prophylaxis For Seasonal Influenza
Bromfenac sodium	23 Dec 2020 (Study Day 111) - Ongoing	Postprocedure Inflammation
Cataract removal, right*	23 Dec 2020 (Study Day 111) - 23 Dec 2020 (Study Day 111)	Medical History
Moxifloxacin	23 Dec 2020 (Study Day 111) - 30 Dec 2020 (Study Day 118)	Prevention Of Postprocedure Infection
Prednisolone acetate	23 Dec 2020 (Study Day 111) - Ongoing	Postprocedure Inflammation Prevention
Doxycycline	23 Feb 2021 (Study Day 173) - 25 Feb 2021 (Study Day 175)	High Grade B Cell Lymphoma
Hydrocodone bitartrate; paracetamol	23 Feb 2021 (Study Day 173) - 26 Feb 2021 (Study Day 176)	High-Grade B-Cell Lymphoma
Calcium chloride; potassium chloride; sodium lactate	25 Feb 2021 (Study Day 175) - 25 Feb 2021 (Study Day 175)	Routine Hydration
Ceftriaxone; sodium chloride	25 Feb 2021 (Study Day 175) - 25 Feb 2021 (Study Day 175)	High Grade B Cell Lymphoma
Chest radiograph*	25 Feb 2021 (Study Day 175) - 25 Feb 2021 (Study Day 175)	Adverse Event
Ct chest abdomen pelvis with iv contrast and oral contrast*	25 Feb 2021 (Study Day 175) - 25 Feb 2021 (Study Day 175)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dexamethasone	25 Feb 2021 (Study Day 175) - 25 Feb 2021 (Study Day 175)	High-Grade B-Cell Lymphoma
Iohexol	25 Feb 2021 (Study Day 175) - 25 Feb 2021 (Study Day 175)	High Grade B Cell Lymphoma
Morphine	25 Feb 2021 (Study Day 175) - 25 Feb 2021 (Study Day 175)	High Grade B Cell Lymphoma
Ondansetron hydrochloride	25 Feb 2021 (Study Day 175) - 26 Feb 2021 (Study Day 176)	Postprocedure Prevention Of Nausea, Vomiting
Sodium chloride	25 Feb 2021 (Study Day 175) - 26 Feb 2021 (Study Day 176)	Routine Hydration
Sodium chloride	25 Feb 2021 (Study Day 175) - 26 Feb 2021 (Study Day 176)	Routine Iv Flush
Allopurinol	26 Feb 2021 (Study Day 176) - Ongoing	High Grade B Cell Lymphoma
Bupivacaine; epinephrine	26 Feb 2021 (Study Day 176) - 26 Feb 2021 (Study Day 176)	Procedure Anesthesia
Celecoxib	26 Feb 2021 (Study Day 176) - 26 Feb 2021 (Study Day 176)	High Grade B Cell Lymphoma
Cervical lymph node biopsy*	26 Feb 2021 (Study Day 176) - 26 Feb 2021 (Study Day 176)	Diagnostic
Electrolytes nos	26 Feb 2021 (Study Day 176) - 26 Feb 2021 (Study Day 176)	Routine Pre-Procedure Medication
Famotidine	26 Feb 2021 (Study Day 176) - 26 Feb 2021 (Study Day 176)	Routine Pre-Procedure Medication
Midazolam	26 Feb 2021 (Study Day 176) - 26 Feb 2021 (Study Day 176)	Routine Preprocedure Medication
Oxycodone; paracetamol	26 Feb 2021 (Study Day 176) - Ongoing	High Grade B Cell Lymphoma
Paracetamol	26 Feb 2021 (Study Day 176) - 26 Feb 2021 (Study Day 176)	High Grade B Cell Lymphoma
Tramadol	26 Feb 2021 (Study Day 176) - 26 Feb 2021 (Study Day 176)	High Grade B Cell Lymphoma
Trazodone	26 Feb 2021 (Study Day 176) - Ongoing	Insomnia
Ondansetron	09 Mar 2021 (Study Day 187) - Ongoing	Nausea And Vomiting Post Chemotherapy
Promethazine	09 Mar 2021 (Study Day 187) - Ongoing	Nausea And Vomiting Post Chemotherapy
Cyclophosphamide	11 Mar 2021 (Study Day 189) - Ongoing	High Grade B Cell Lymphoma
Doxorubicin	11 Mar 2021 (Study Day 189) - Ongoing	High Grade B Cell Lymphoma
Pegfilgrastim	11 Mar 2021 (Study Day 189) - Ongoing	High Grade B Cell Lymphoma
Prednisone	11 Mar 2021 (Study Day 189) - Ongoing	High Grade B-Cell Lymphoma
Rituximab	11 Mar 2021 (Study Day 189) - Ongoing	High Grade B Cell Lymphoma
Vincristine	11 Mar 2021 (Study Day 189) - Ongoing	High Grade B Cell Lymphoma

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US376-2023 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 21 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 17 Sep 2020 (Study Day 28)
First Dose of Vaccine in Part B: 11 Jan 2021 (Study Day 144)
Second Dose of Vaccine in Part B: 08 Feb 2021 (Study Day 172)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Aortic Valve Incompetence/ Aortic Valve Failure	SAE	Grade 4	Not related	26 Jan 2021 (Study Day 159) – 30 Jan 2021 (Study Day 163)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US376-2023, a 66-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 11 Jan 2021 (Study Day 144). The second dose was administered in the left arm on 08 Feb 2021 (Study Day 172).

Event Details

On 26 Jan 2021 (Study Day 159), 158 days after the first dose in Part A/15 days after the first dose in Part B and 131 days after the second dose in Part A/13 days before the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of aortic valve incompetence. The IP dose was not changed due to the aortic valve failure. The event of aortic valve failure lasted for 5 days, after which it was considered to be recovered/resolved on 30 Jan 2021 (Study Day 163). The investigator assessed the event of aortic valve incompetence to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009904	Aortic valve incompetence

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myopia	Nearsighted	1958 - Ongoing
Deafness	Hearing loss	1971 - Ongoing
Tinnitus	Tinnitus	1971 - Ongoing
Tuberculosis	Tuberculosis	1976 - 1976
Allergy to chemicals	Rat powder allergy	1983 - Ongoing
Meniere's disease	Meniere's disease	1994 - 1994
Herpes zoster	Shingles	1998 - 1998
Intervertebral disc operation	Discectomy	2002 - 2002
Intervertebral disc protrusion	Herniated disc	2002 - 2002
Blood cholesterol increased	High cholesterol	2006 - Ongoing
Hypertension	High blood pressure	2006 - Ongoing
Paralysis	Paralysis	2006 - 2006
Spinal cord abscess	Spinal lumbar abscess	2006 - 2006
Aortic aneurysm	Aortic aneurysm	2007 - 2007
Arrhythmia	Arrhythmia	2014 - 2014
Benign prostatic hyperplasia	Benign hypertrophy prostate	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2006 - 30 Jan 2021 (Study Day 163)	Supplement For Heart Health
Lovastatin	2006 - Ongoing	High Cholesterol
Metoprolol	2006 - 30 Jan 2021 (Study Day 163)	Hypertension
Vitamins nos	2006 - Ongoing	Supplement
Hydrochlorothiazide	2018 - Ongoing	Hypertension
Losartan	2020 - Ongoing	Hypertension
Ct angiography of the heart*	28 Jan 2021 (Study Day 161) - 28 Jan 2021 (Study Day 161)	Adverse Event
Acetylsalicylic acid	30 Jan 2021 (Study Day 163) - Ongoing	Aortic Valve
Metoprolol	30 Jan 2021 (Study Day 163) - Ongoing	Hypertension
Clopidogrel bisulfate	31 Jan 2021 (Study Day 164) - Ongoing	Aortic Aneurysm

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US376-2120 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 31 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nephrolithiasis/ Nephrolithiasis	SAE	Grade 3/ severe	Not related	21 Feb 2021 (Study Day 175) – 16 Mar 2021 (Study Day 198)	Recovered/ resolved
Staphylococcal Bacteraemia/Methicillin- Susceptible Staphylococcus Aureus Bacteremia	SAE	Grade 2/ moderate	Not related	21 Feb 2021 (Study Day 175) – 25 Feb 2021 (Study Day 179)	Recovered/ resolved
Urinary Tract Infection/ Complicated Urinary Tract Infection	SAE	Grade 2/ moderate	Not related	21 Feb 2021 (Study Day 175) – 25 Feb 2021 (Study Day 179)	Recovered/ resolved
Staphylococcal Bacteraemia/Methicillin- Susceptible Staphylococcus Aureus Bacteremia	SAE	Grade 3/ severe	Not related	13 Mar 2021 (Study Day 195) – 17 Mar 2021 (Study Day 199)	Recovered/ resolved
Escherichia Urinary Tract Infection/E. Coli Uti	SAE	Grade 2/ moderate	Not related	14 Mar 2021 (Study Day 196) – 29 Mar 2021 (Study Day 211)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US376-2120, a 79-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 30 Dec 2020. The participant was unblinded on 30 Dec 2020 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 21 Feb 2021 (Study Day 175), 174 days after the first dose in Part A and 146 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of nephrolithiasis. Action taken with the IP was not applicable. The event of nephrolithiasis lasted for 24 days, after which it was considered to be recovered/resolved on 16 Mar 2021 (Study Day 198). The investigator assessed the event of nephrolithiasis to be not related to the IP.

On 21 Feb 2021 (Study Day 175), 174 days after the first dose in Part A and 146 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of staphylococcal bacteraemia. Action taken with the IP was not applicable. The event of methicillin-susceptible staphylococcus aureus bacteremia lasted for 5 days, after which it was considered to be recovered/resolved on 25 Feb 2021 (Study Day 179). The investigator assessed the event of staphylococcal bacteraemia to be not related to the IP.

On 21 Feb 2021 (Study Day 175), 174 days after the first dose in Part A and 146 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of urinary tract infection. Action taken with the IP was not applicable. The event of complicated urinary tract infection lasted for 5 days, after which it was considered to be recovered/resolved on 25 Feb 2021 (Study Day 179). The investigator assessed the event of urinary tract infection to be not related to the IP.

On 13 Mar 2021 (Study Day 195), 194 days after the first dose in Part A and 166 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of staphylococcal bacteraemia. Action taken with the IP was not applicable. The event of methicillin-susceptible staphylococcus aureus bacteremia lasted for 5 days, after which it was considered to be recovered/resolved on 17 Mar 2021 (Study Day 199). The investigator assessed the event of staphylococcal bacteraemia to be not related to the IP.

On 14 Mar 2021 (Study Day 196), 195 days after the first dose in Part A and 167 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of escherichia urinary tract infection. Action taken with the IP was not applicable. The event of e. coli uti lasted for 16 days, after which it was considered to be recovered/resolved on 29 Mar 2021 (Study Day 211). The investigator assessed the event of escherichia urinary tract infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-017224	Nephrolithiasis
MOD-2021-017224	Staphylococcal bacteraemia
MOD-2021-017224	Urinary tract infection
MOD-2021-017224	Staphylococcal bacteraemia
MOD-2021-017224	Escherichia urinary tract infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nephrolithiasis	Kidney stones	01 Jan 1967 (Study Day -19601) - 31 Dec 1967 (Study Day -19237)
Skin cancer	Skin cancer	01 Jan 1980 (Study Day -14853) - 31 Dec 2019 (Study Day -244)
Skin cancer	Some type of skin cancer	01 Jan 1980 (Study Day -14853) - 31 Dec 1980 (Study Day -14488)
Seminoma	Seminoma, left testicle	01 Jan 1989 (Study Day -11565) - 31 Dec 1989 (Study Day -11201)
Corrective lens user	Glasses/contacts	01 Jan 1990 (Study Day -11200) - Ongoing
Actinic keratosis	Actinic kertatosis	01 Jan 2000 (Study Day -7548) - Ongoing
Aortic aneurysm	Aortic aneurism	01 Jan 2000 (Study Day -7548) - Ongoing
Cataract	Cataracts	2010 - 2018
Eczema	Exzema	01 Jan 2010 (Study Day -3895) - Ongoing
Tinnitus	Tinnitus	01 Jan 2010 (Study Day -3895) - Ongoing
Dyspepsia	Heartburn	01 Jan 2015 (Study Day -2069) - Ongoing
Benign prostatic hyperplasia	Prostate issues (bph, enlarged)	01 Jan 2016 (Study Day -1704) - Ongoing
Blood donor	Frequent blood/plasma donor	01 Jan 2016 (Study Day -1704) - Ongoing
Deafness	Hearing loss	01 Jan 2016 (Study Day -1704) - Ongoing
Cataract operation	Cataract removal	2018 - 2018
Atrial fibrillation	Proximal atrial fibrillation	2019 - Ongoing
Atrial fibrillation	Proximal atrial fibrillation	01 Jan 2019 (Study Day -608) - 31 Dec 2019 (Study Day -244)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	01 Jan 1995 (Study Day -9374) - Ongoing	Cholesterol Management
Losartan	01 Jan 2000 (Study Day -7548) - Ongoing	Thoracic Aneurism Prophylaxis
Metoprolol	01 Jan 2000 (Study Day -7548) - Ongoing	Thoracic Aneurism Prophylaxis
Tadalafil	01 Jan 2016 (Study Day -1704) - Ongoing	Bph
Terazosin	01 Jan 2016 (Study Day -1704) - Ongoing	Bph
Vitamin b12 nos	01 Jan 2016 (Study Day -1704) - Ongoing	Prevention
Vitamin d nos	01 Jan 2016 (Study Day -1704) - Ongoing	Prevention
Apixaban	01 Jan 2019 (Study Day -608) - Ongoing	Paroxysmal Atrial Fibrillation
Influenza vaccine	14 Oct 2020 (Study Day 45) - 14 Oct 2020 (Study Day 45)	Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ceftriaxone	21 Feb 2021 (Study Day 175) - 21 Feb 2021 (Study Day 175)	Nephrolithiasis
Paracetamol	21 Feb 2021 (Study Day 175) - 22 Feb 2021 (Study Day 176)	Nephrolithiasis
Cystoscopy with stent in right ureter*	22 Feb 2021 (Study Day 176) - 22 Feb 2021 (Study Day 176)	Adverse Event
Daptomycin	25 Feb 2021 (Study Day 179) - 28 Feb 2021 (Study Day 182)	Mssa Bacteremia
Sulfamethoxazole; trimethoprim	25 Feb 2021 (Study Day 179) - 27 Mar 2021 (Study Day 209)	E. Coli Uti
Tamsulosin	25 Feb 2021 (Study Day 179) - 07 Mar 2021 (Study Day 189)	Bph
Linezolid	01 Mar 2021 (Study Day 183) - 07 Mar 2021 (Study Day 189)	Mssa Bacteremia
Cefepime hydrochloride	14 Mar 2021 (Study Day 196) - 14 Mar 2021 (Study Day 196)	E. Coli Uti
Ceftriaxone	18 Mar 2021 (Study Day 200) - 29 Mar 2021 (Study Day 211)	E. Coli Uti

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US376-2131 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 29 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Fibula Fracture/ Comminuted Distal Fibular Fracture	SAE	Grade 3/ severe	Not related	20 Mar 2021 (Study Day 201) – 23 Mar 2021 (Study Day 204)	Recovered/ resolved
Fracture Displacement/ Closed Displaced Pilon Fracture Of Right Tibia	SAE	Grade 3/ severe	Not related	20 Mar 2021 (Study Day 201) – 23 Mar 2021 (Study Day 204)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US376-2131, a 48-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 20 Mar 2021 (Study Day 201), 200 days after the first dose in Part A and 172 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of fibula fracture. Action taken with the IP was not applicable. The event of comminuted distal fibular fracture lasted for 4 days, after which it was considered to be recovered/resolved on 23 Mar 2021 (Study Day 204). The investigator assessed the event of fibula fracture to be not related to the IP.

On 20 Mar 2021 (Study Day 201), 200 days after the first dose in Part A and 172 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of fracture displacement. Action taken with the IP was not applicable. The event of closed displaced pilon fracture of right tibia lasted for 4 days, after which it was considered to be

recovered/resolved on 23 Mar 2021 (Study Day 204). The investigator assessed the event of fracture displacement to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-055359	Fibula fracture
MOD-2021-055359	Fracture displacement

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1995 - Ongoing
Rotator cuff syndrome	Tendinitis right shoulder	2003 - Ongoing
Asthma	Asthma	2005 - Ongoing
Tinnitus	Tinnitus	2005 - Ongoing
Anxiety	Anxiety	2009 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2014 - Ongoing
Joint swelling	Inflammation of knees	2015 - Ongoing
Menstruation irregular	Irregular periods	2019 - Ongoing
Herpes zoster	Shingles	2020 - 2020
Muscle spasms	Leg cramps	2020 - Ongoing
Dermatitis contact	Mild contact dermatitis on leg	31 Aug 2020 (Study Day -1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium	Not reported - Ongoing	Supplement
Calcium carbonate; sodium fluorophosphate	Not reported - Ongoing	Tinnitus
Montelukast	Not reported - Ongoing	Asthma
Omega-3 nos	Not reported - Ongoing	Supplement
Vitamin d nos	Not reported - Ongoing	Deficiency
Vitamins nos	Not reported - Ongoing	Supplement
Magnesium	2020 - Ongoing	Legs Cramping

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Prednisone	09 Sep 2020 (Study Day 9) - Ongoing	Dermatitis
Ibuprofen	30 Sep 2020 (Study Day 30) - 02 Oct 2020 (Study Day 32)	Injection Site Pain
Curcuma longa	24 Nov 2020 (Study Day 85) - Ongoing	Inflammation Of The Knees
Closed reduction and lower extremity external fixator application right tibia*	20 Mar 2021 (Study Day 201) - 20 Mar 2021 (Study Day 201)	Adverse Event
Fentanyl citrate	20 Mar 2021 (Study Day 201) - 20 Mar 2021 (Study Day 201)	Leg Fracture Pain
Hydromorphone	20 Mar 2021 (Study Day 201) - 20 Mar 2021 (Study Day 201)	Leg Fracture Pain
Remove external fixator, remove ankle screws, orif fibula and tibia with insertion im nail*	22 Mar 2021 (Study Day 203) - 22 Mar 2021 (Study Day 203)	Adverse Event
Acetylsalicylic acid	23 Mar 2021 (Study Day 204) - Ongoing	Post Operative Blood Clot Prevention
Paracetamol	23 Mar 2021 (Study Day 204) - Ongoing	Right Tibia Fracture Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US377-2007 (Part B)
Vaccination Group: Placebo in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 05 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 35)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Invasive Ductal Breast Carcinoma/Left Breast Ductal Cell Carcinoma	SAE	Grade 4	Not related	05 Feb 2021 (Study Day 185) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US377-2007, a 33-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and consented to receive 2 doses of mRNA-1273. The first dose was not administered. The second dose was not administered.

Event Details

On 05 Feb 2021 (Study Day 185), Not reported the participant experienced a Grade 4 serious adverse event of invasive ductal breast carcinoma. Action taken with the IP was not applicable. The event of left breast ductal cell carcinoma was considered to be ongoing. The investigator assessed the event of invasive ductal breast carcinoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014155	Invasive ductal breast carcinoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nicotine dependence	Nicotine addiction (1 pack per day)	2006 - Ongoing
Caesarean section	Cesarean section	2007 - 2007
Caesarean section	Cesarean section	2011 - 2011
Salpingectomy	Bilateral salpingectomy	2013 - 2013

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amoxicillin; clavulanic acid	25 Sep 2020 (Study Day 52) - 06 Oct 2020 (Study Day 63)	Dental Abscess
Tramadol	25 Sep 2020 (Study Day 52) - 06 Oct 2020 (Study Day 63)	Dental Abscess
Varenicline tartrate	25 Feb 2021 (Study Day 205) - Ongoing	Smoking Cessation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US377-2041 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 11 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypertension/Exacerbation Of Hypertension	SAE	Grade 3/severe	Not related	15 Feb 2021 (Study Day 189) – 16 Feb 2021 (Study Day 190)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US377-2041, a 87-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 15 Feb 2021 (Study Day 189), 188 days after the first dose in Part A and 160 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of hypertension. Action taken with the IP was not applicable. The event of exacerbation of hypertension lasted for 2 days, after which it was considered to be recovered/resolved on 16 Feb 2021 (Study Day 190). The investigator assessed the event of hypertension to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-015200	Hypertension

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hysterectomy	Complete hysterectomy	1995 - 1995
Hypothyroidism	Hypothyroidism	2015 - Ongoing
Thyroidectomy	Thyroidectomy	2015 - 2015
Hypertension	Hypertension	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Timolol maleate	1990 - Ongoing	Glaucoma Right Eye
Levothyroxine sodium	2015 - Ongoing	Hypothyroidism
Metoprolol	2017 - 15 Feb 2021 (Study Day 189)	Hypertension
Prednisolone sodium phosphate	Jan 2020 - Ongoing	Cornea Transplant . Right Eye.
Influenza vaccine	13 Oct 2020 (Study Day 64) - 13 Oct 2020 (Study Day 64)	Influenza Prophylaxis
Atorvastatin	16 Feb 2021 (Study Day 190) - 16 Mar 2021 (Study Day 218)	Hyperlipidemia
Lisinopril	16 Feb 2021 (Study Day 190) - 10 Mar 2021 (Study Day 212)	Hypertension
Lisinopril	10 Mar 2021 (Study Day 212) - Ongoing	Exacerbation Of Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Grade 1/mild	Not related	15 Feb 2021 (Study Day 189) - 16 Mar 2021 (Study Day 218)
Hypertension	Grade 2/moderate	Not related	08 Mar 2021 (Study Day 210) - 10 Mar 2021 (Study Day 212)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US377-2252 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 21 Oct 2020 (Study Day 41)
First Dose of Vaccine in Part B: 13 Jan 2021 (Study Day 125)
Second Dose of Vaccine in Part B: 24 Feb 2021 (Study Day 167)
Reason for Narrative: Severe COVID-19, SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 1/ mild	Not related	23 Jan 2021 (Study Day 135) – 07 Feb 2021 (Study Day 150)	Recovered/ resolved
COVID-19 Pneumonia/ COVID-19 Pneumonia	SAE	Grade 3/ severe	Not related	02 Feb 2021 (Study Day 145) – 07 Feb 2021 (Study Day 150)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US377-2252, a 73-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 21 Oct 2020 (Study Day 41). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 13 Jan 2021 (Study Day 125). The second dose was administered in the left arm on 24 Feb 2021 (Study Day 167).

Severe COVID-19 Details

On 23 Jan 2021 (Study Day 135), 134 days after the first dose in Part A/10 days after the first dose in Part B and 94 days after the second dose in Part A/32 days before the second dose in Part B of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID-19.

On 02 Feb 2021 (Study Day 145), 144 days after the first dose in Part A/20 days after the first dose in Part B and 104 days after the second dose in Part A/22 days before the second dose in Part B of the IP, the participant experienced a Grade 3/Severe serious adverse event of COVID-19 pneumonia.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 41, 21 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 25 Jan 2021 (Study Day 137), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
06 Oct 2020 (Study Day 26)	Cough	Mild
06 Oct 2020 (Study Day 26)	Nasal Congestion	Mild
06 Oct 2020 (Study Day 26)	Runny Nose (Rhinorrhea)	Mild
07 Oct 2020 (Study Day 27)	Runny Nose (Rhinorrhea)	Mild
25 Jan 2021 (Study Day 137)	Cough	Mild
25 Jan 2021 (Study Day 137)	Headache	Mild
25 Jan 2021 (Study Day 137)	Nasal Congestion	Mild
26 Jan 2021 (Study Day 138)	Chills	Mild
26 Jan 2021 (Study Day 138)	Nasal Congestion	Mild
27 Jan 2021 (Study Day 139)	Nasal Congestion	Mild
28 Jan 2021 (Study Day 140)	Nasal Congestion	Mild
29 Jan 2021 (Study Day 141)	Headache	Mild
30 Jan 2021 (Study Day 142)	Chills	Mild
30 Jan 2021 (Study Day 142)	Headache	Mild
30 Jan 2021 (Study Day 142)	Nausea	Mild
30 Jan 2021 (Study Day 142)	Temperature (°F)	101.3
31 Jan 2021 (Study Day 143)	Chills	Mild
31 Jan 2021 (Study Day 143)	Headache	Mild
31 Jan 2021 (Study Day 143)	O2 Saturation (%)	92
31 Jan 2021 (Study Day 143)	Temperature (°F)	100.4
01 Feb 2021 (Study Day 144)	Chills	Mild
01 Feb 2021 (Study Day 144)	Headache	Mild
01 Feb 2021 (Study Day 144)	O2 Saturation (%)	93
03 Feb 2021 (Study Day 146)	Fatigue	Mild
04 Feb 2021 (Study Day 147)	Diarrhea	Mild
05 Feb 2021 (Study Day 148)	Difficulty Breathing	Moderate
06 Feb 2021 (Study Day 149)	Difficulty Breathing	Moderate

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
31 Jan 2021 (Study Day 143)	Oxygen Saturation	92%
31 Jan 2021 - 01 Feb 2021 (Study Day 143-144)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Dates	Severity Indication	Result
01 Feb 2021 - 01 Feb 2021 (Study Day 144-144)	Respiratory Failure	Yes
02 Feb 2021 - 02 Feb 2021 (Study Day 145-145)	Clinical Evidence of Pneumonia	Yes
02 Feb 2021 - 02 Feb 2021 (Study Day 145-145)	Radiographical Evidence of Pneumonia	Yes

The IP dose was not changed due to the COVID-19. The event of COVID-19 lasted for 16 days, after which it was considered to be recovered/resolved on 07 Feb 2021 (Study Day 150). The investigator assessed the event of COVID-19 to be not related to the IP.

The IP dose was not changed due to the COVID-19 pneumonia. The event of COVID-19 pneumonia lasted for 6 days, after which it was considered to be recovered/resolved on 07 Feb 2021 (Study Day 150). The investigator assessed the event of COVID-19 pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010718	COVID-19
MOD-2021-010718	COVID-19 pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cardiac failure congestive	Congestive heart failure	1995 - Ongoing
Pollakiuria	Frequency of micturition	2004 - Ongoing
Prostate cancer	Prostate cancer	2009 - Ongoing
Transurethral prostatectomy	Trans urethral resection of prostate	2009 - 2009

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Furosemide	2010 - Ongoing	Congestive Heart Failure
Tamsulosin hydrochloride	2018 - Ongoing	Frequency Of Micturition

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Spironolactone	2019 - Ongoing	Congestive Heart Failure
Influenza vaccine	19 Aug 2020 (Study Day -23) - 19 Aug 2020 (Study Day -23)	Influenza Prophylaxis
Lisinopril	03 Nov 2020 (Study Day 54) - Ongoing	Congestive Heart Failure
Apixaban	04 Jan 2021 (Study Day 116) - Ongoing	Atrial Fibrillation
Fenofibrate	04 Jan 2021 (Study Day 116) - Ongoing	Hyperlipidemia
Sotalol	04 Jan 2021 (Study Day 116) - Ongoing	Atrial Fibrillation
Fluticasone; salmeterol	05 Feb 2021 (Study Day 148) - Ongoing	Chronic Obstructive Pulmonary Disease
Levofloxacin	05 Feb 2021 (Study Day 148) - 19 Feb 2021 (Study Day 162)	COVID-19 Pneumonia
Salbutamol sulfate	05 Feb 2021 (Study Day 148) - Ongoing	Chronic Obstructive Pulmonary Disease

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	23 Jan 2021 (Study Day 135) - 07 Feb 2021 (Study Day 150)
Acute Respiratory Failure	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 144) - 04 Feb 2021 (Study Day 147)
Chronic Obstructive Pulmonary Disease	Grade 2/moderate	Not related	04 Feb 2021 (Study Day 147) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US378-2014 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 13 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 08 Jan 2021 (Study Day 149)
Second Dose of Vaccine in Part B: 05 Feb 2021 (Study Day 177)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug Eruption/Drug Rash	SAE	Grade 4	Not related	06 Mar 2021 (Study Day 206) – 18 Mar 2021 (Study Day 218)	Recovered/resolved
Duodenal Ulcer Perforation/Perforated Duodenal Ulcer	SAE	Grade 4	Not related	17 Mar 2021 (Study Day 217) – 30 Mar 2021 (Study Day 230)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US378-2014, a 64-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 08 Jan 2021. The participant was unblinded on 08 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 08 Jan 2021 (Study Day 149). The second dose was administered in the left arm on 05 Feb 2021 (Study Day 177).

Event Details

On 06 Mar 2021 (Study Day 206), 205 days after the first dose in Part A/57 days after the first dose in Part B and 177 days after the second dose in Part A/29 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of drug eruption. Action taken with the IP was not applicable. The event of drug rash lasted for 13 days, after which it was considered to be recovered/resolved on 18 Mar 2021 (Study Day 218). The investigator assessed the event of drug eruption to be not related to the IP.

On 17 Mar 2021 (Study Day 217), 216 days after the first dose in Part A/68 days after the first dose in Part B and 188 days after the second dose in Part A/40 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of duodenal ulcer perforation. Action taken with the IP was not applicable. The event of perforated duodenal ulcer lasted for

14 days, after which it was considered to be recovered/resolved on 30 Mar 2021 (Study Day 230). The investigator assessed the event of duodenal ulcer perforation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-043837	Drug eruption
MOD-2021-043837	Duodenal ulcer perforation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1970 - Ongoing
Hypertension	Hypertension	1975 - Ongoing
Obesity	Obesity	2000 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2005 - Ongoing
Transient ischaemic attack	Transient ischemic attack	02 Feb 2005 (Study Day -5671) - 02 Feb 2005 (Study Day -5671)
Sinus headache	Occasional sinus headache	2006 - Ongoing
Osteoarthritis	Osteoarthritis	2015 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2015 - Ongoing
Panic disorder	Panic disorder	2018 - Ongoing
Asthma	Asthma	01 Feb 2020 (Study Day -194) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	2006 - Ongoing	Sinus Headache
Amlodipine; benazepril	2008 - 17 Mar 2021 (Study Day 217)	Hypertension
Atenolol	2008 - Ongoing	Hypertension
Vitamins nos	2010 - Ongoing	General Health
Celecoxib	2015 - 18 Dec 2020 (Study Day 128)	Osteoarthritis
Vitamin d nos	2015 - Oct 2020	Vitamin D Deficiency
Citalopram	2018 - 26 Mar 2021 (Study Day 226)	Panic Disorder
Rosuvastatin	2018 - Ongoing	Hyperlipidemia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sitosterol	2018 - Ongoing	Hyperlipidemia
Acetylsalicylic acid	2019 - 23 Feb 2021 (Study Day 195)	Cv Prophylaxis
Fluticasone propionate; salmeterol xinafoate	01 Feb 2020 (Study Day -194) - Ongoing	Asthma
Salbutamol	01 Feb 2020 (Study Day -194) - Ongoing	Asthma
Azelastine	12 Aug 2020 (Study Day -1) - Ongoing	Occ Sinus Headache
Fluticasone	12 Aug 2020 (Study Day -1) - Ongoing	Occ Sinus Headache
Guaifenesin	29 Aug 2020 (Study Day 17) - Ongoing	Seasonal Allergies
Vitamin d nos	Oct 2020 - Ongoing	Vitamin D Deficiency
Influenza vaccine	02 Oct 2020 (Study Day 51) - 02 Oct 2020 (Study Day 51)	Influenza Prophylaxis
Alprazolam	22 Feb 2021 (Study Day 194) - 22 Feb 2021 (Study Day 194)	Pre-Operative Sedation
Arthroplasty total knee - right*	22 Feb 2021 (Study Day 194) - 22 Feb 2021 (Study Day 194)	Medical History
Cefazolin	22 Feb 2021 (Study Day 194) - 23 Feb 2021 (Study Day 195)	Peri-Operative Infection Prophylaxis
Dexamethasone	22 Feb 2021 (Study Day 194) - 22 Feb 2021 (Study Day 194)	Peri-Operative Inflammation Prophylaxis
Docusate sodium; sennoside a+b	22 Feb 2021 (Study Day 194) - 08 Mar 2021 (Study Day 208)	Constipation Prophylaxis
Epinephrine	22 Feb 2021 (Study Day 194) - 22 Feb 2021 (Study Day 194)	Operative Anesthesia
Gluconate sodium; magnesium chloride hexahydrate; potassium chloride; sodium acetate trihydrate; sodium chloride	22 Feb 2021 (Study Day 194) - 22 Feb 2021 (Study Day 194)	Intra-Operative Fluid Replacement
Ketamine	22 Feb 2021 (Study Day 194) - 22 Feb 2021 (Study Day 194)	Operative Anesthesia
Oxycodone hydrochloride	22 Feb 2021 (Study Day 194) - 22 Feb 2021 (Study Day 194)	Pre-Operative Sedation
Ropivacaine	22 Feb 2021 (Study Day 194) - 22 Feb 2021 (Study Day 194)	Operative Anesthesia
Tranexamic acid	22 Feb 2021 (Study Day 194) - 22 Feb 2021 (Study Day 194)	Intraoperative Blood Loss Prevention
Vancomycin	22 Feb 2021 (Study Day 194) - 22 Feb 2021 (Study Day 194)	Pre-Operative Infection Prophylaxis
Acetylsalicylic acid	23 Feb 2021 (Study Day 195) - 07 Mar 2021 (Study Day 207)	Post-Operative Embolic Prophylaxis
Cefadroxil	23 Feb 2021 (Study Day 195) - 05 Mar 2021 (Study Day 205)	Infection Prophylaxis
Oxycodone	23 Feb 2021 (Study Day 195) - 02 Mar 2021 (Study Day 202)	Post-Operative Pain
Oxycodone	04 Mar 2021 (Study Day 204) - 17 Mar 2021 (Study Day 217)	R Knee Replacement Post-Operative Pain
Diphenhydramine hydrochloride	06 Mar 2021 (Study Day 206) - 18 Mar 2021 (Study Day 218)	Drug Rash
Famotidine	06 Mar 2021 (Study Day 206) - 18 Mar 2021 (Study Day 218)	Drug Rash

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrocortisone sodium succinate	06 Mar 2021 (Study Day 206) - 06 Mar 2021 (Study Day 206)	Drug Rash
Ketorolac	07 Mar 2021 (Study Day 207) - 07 Mar 2021 (Study Day 207)	Post-Operative Pain
Prednisone	07 Mar 2021 (Study Day 207) - 07 Mar 2021 (Study Day 207)	Drug Rash
Cetirizine	08 Mar 2021 (Study Day 208) - 18 Mar 2021 (Study Day 218)	Drug Rash
Enoxaparin sodium	08 Mar 2021 (Study Day 208) - 12 Mar 2021 (Study Day 212)	Embolic Prophylaxis
Methylprednisolone sodium succinate	08 Mar 2021 (Study Day 208) - 08 Mar 2021 (Study Day 208)	Drug Rash
Ondansetron	08 Mar 2021 (Study Day 208) - 08 Mar 2021 (Study Day 208)	Nausea Related To Drug Rash
Triamcinolone	08 Mar 2021 (Study Day 208) - 18 Mar 2021 (Study Day 218)	Drug Rash
Prednisone	09 Mar 2021 (Study Day 209) - 10 Mar 2021 (Study Day 210)	Drug Rash
Insulin lispro	10 Mar 2021 (Study Day 210) - 11 Mar 2021 (Study Day 211)	Hyperglycemia
Simeticone	10 Mar 2021 (Study Day 210) - 12 Mar 2021 (Study Day 212)	Flatulence
Prednisone	11 Mar 2021 (Study Day 211) - 14 Mar 2021 (Study Day 214)	Drug Rash
Acetylsalicylic acid	12 Mar 2021 (Study Day 212) - 17 Mar 2021 (Study Day 217)	Cardiovascular Prophylaxis
Prednisone	15 Mar 2021 (Study Day 215) - 17 Mar 2021 (Study Day 217)	Drug Rash
Pantoprazole sodium sesquihydrate	17 Mar 2021 (Study Day 217) - 30 Mar 2021 (Study Day 230)	Perforated Duodenal Ulcer
Dexmedetomidine hydrochloride	18 Mar 2021 (Study Day 218) - 18 Mar 2021 (Study Day 218)	Perforated Duodenal Ulcer
Ephedrine	18 Mar 2021 (Study Day 218) - 19 Mar 2021 (Study Day 219)	Perforated Duodenal Ulcer
Epinephrine	18 Mar 2021 (Study Day 218) - 18 Mar 2021 (Study Day 218)	Perforated Duodenal Ulcer
Exploratory laparotomy with duodenal ulcer cauterization*	18 Mar 2021 (Study Day 218) - 18 Mar 2021 (Study Day 218)	Adverse Event
Fentanyl	18 Mar 2021 (Study Day 218) - 19 Mar 2021 (Study Day 219)	Perforated Duodenal Ulcer
Gluconate sodium; magnesium chloride hexahydrate; potassium chloride; sodium acetate trihydrate; sodium chloride	18 Mar 2021 (Study Day 218) - 20 Mar 2021 (Study Day 220)	Perforated Duodenal Ulcer
Iohexol	18 Mar 2021 (Study Day 218) - 18 Mar 2021 (Study Day 218)	Perforated Duodenal Ulcer
Ketamine	18 Mar 2021 (Study Day 218) - 18 Mar 2021 (Study Day 218)	Perforated Duodenal Ulcer
Midazolam hydrochloride	18 Mar 2021 (Study Day 218) - 18 Mar 2021 (Study Day 218)	Perforated Duodenal Ulcer

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Norepinephrine	18 Mar 2021 (Study Day 218) - 19 Mar 2021 (Study Day 219)	Perforated Duodenal Ulcer
Ondansetron	18 Mar 2021 (Study Day 218) - 19 Mar 2021 (Study Day 219)	Perforated Duodenal Ulcer
Prednisone	18 Mar 2021 (Study Day 218) - 18 Mar 2021 (Study Day 218)	Drug Rash
Propofol	18 Mar 2021 (Study Day 218) - 18 Mar 2021 (Study Day 218)	Perforated Duodenal Ulcer
Red blood cells, concentrated	18 Mar 2021 (Study Day 218) - Ongoing	Perforated Duodenal Ulcer
Rocuronium	18 Mar 2021 (Study Day 218) - 19 Mar 2021 (Study Day 219)	Perforated Duodenal Ulcer
Vancomycin	18 Mar 2021 (Study Day 218) - 18 Mar 2021 (Study Day 218)	Perforated Duodenal Ulcer
Albumin human	19 Mar 2021 (Study Day 219) - 19 Mar 2021 (Study Day 219)	Perforated Duodenal Ulcer
Calcium chloride	19 Mar 2021 (Study Day 219) - 19 Mar 2021 (Study Day 219)	Perforated Duodenal Ulcer
Calcium gluconate	19 Mar 2021 (Study Day 219) - 19 Mar 2021 (Study Day 219)	Perforated Duodenal Ulcer
Fluconazole	19 Mar 2021 (Study Day 219) - 21 Mar 2021 (Study Day 221)	Perforated Duodenal Ulcer
Glucose	19 Mar 2021 (Study Day 219) - 19 Mar 2021 (Study Day 219)	Perforated Duodenal Ulcer
Heparin	19 Mar 2021 (Study Day 219) - 19 Mar 2021 (Study Day 219)	Perforated Duodenal Ulcer
Hydrocortisone sodium succinate	19 Mar 2021 (Study Day 219) - 21 Mar 2021 (Study Day 221)	Perforated Duodenal Ulcer
Hydromorphone hydrochloride	19 Mar 2021 (Study Day 219) - 19 Mar 2021 (Study Day 219)	Perforated Duodenal Ulcer
Hydromorphone hydrochloride	19 Mar 2021 (Study Day 219) - 24 Mar 2021 (Study Day 224)	Perforated Duodenal Ulcer
Insulin	19 Mar 2021 (Study Day 219) - 21 Mar 2021 (Study Day 221)	Perforated Duodenal Ulcer
Phenylephrine	19 Mar 2021 (Study Day 219) - 19 Mar 2021 (Study Day 219)	Perforated Duodenal Ulcer
Piperacillin sodium; tazobactam sodium	19 Mar 2021 (Study Day 219) - 22 Mar 2021 (Study Day 222)	Perforated Duodenal Ulcer
Propofol	19 Mar 2021 (Study Day 219) - 19 Mar 2021 (Study Day 219)	Perforated Duodenal Ulcer
Vancomycin	19 Mar 2021 (Study Day 219) - 19 Mar 2021 (Study Day 219)	Perforated Duodenal Ulcer
Vancomycin	19 Mar 2021 (Study Day 219) - 21 Mar 2021 (Study Day 221)	Perforated Duodenal Ulcer
Vasopressin	19 Mar 2021 (Study Day 219) - 19 Mar 2021 (Study Day 219)	Perforated Duodenal Ulcer
Insulin glargine	20 Mar 2021 (Study Day 220) - 29 Mar 2021 (Study Day 229)	Perforated Duodenal Ulcer
Labetalol	20 Mar 2021 (Study Day 220) - 20 Mar 2021 (Study Day 220)	Perforated Duodenal Ulcer

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Phytomenadione	20 Mar 2021 (Study Day 220) - 20 Mar 2021 (Study Day 220)	Perforated Duodenal Ulcer
Plasma	20 Mar 2021 (Study Day 220) - 21 Mar 2021 (Study Day 221)	Perforated Duodenal Ulcer
Sucralfate	20 Mar 2021 (Study Day 220) - Ongoing	Perforated Duodenal Ulcer
Amlodipine	21 Mar 2021 (Study Day 221) - 21 Mar 2021 (Study Day 221)	Hypertension
Furosemide	21 Mar 2021 (Study Day 221) - 24 Mar 2021 (Study Day 224)	Perforated Duodenal Ulcer
Gabapentin	21 Mar 2021 (Study Day 221) - 01 Apr 2021 (Study Day 232)	Perforated Duodenal Ulcer
Insulin lispro	21 Mar 2021 (Study Day 221) - 21 Mar 2021 (Study Day 221)	Perforated Duodenal Ulcer
Iohexol	21 Mar 2021 (Study Day 221) - 21 Mar 2021 (Study Day 221)	Perforated Duodenal Ulcer
Potassium	21 Mar 2021 (Study Day 221) - 21 Mar 2021 (Study Day 221)	Perforated Duodenal Ulcer
Solutions for parenteral nutrition	21 Mar 2021 (Study Day 221) - 24 Mar 2021 (Study Day 224)	Perforated Duodenal Ulcer
Lipids nos	22 Mar 2021 (Study Day 222) - 24 Mar 2021 (Study Day 224)	Perforated Duodenal Ulcer
Nifedipine	22 Mar 2021 (Study Day 222) - 01 Apr 2021 (Study Day 232)	Perforated Duodenal Ulcer
Vancomycin	22 Mar 2021 (Study Day 222) - 22 Mar 2021 (Study Day 222)	Perforated Duodenal Ulcer
Bisacodyl	23 Mar 2021 (Study Day 223) - 23 Mar 2021 (Study Day 223)	Perforated Duodenal Ulcer
Potassium	23 Mar 2021 (Study Day 223) - 24 Mar 2021 (Study Day 224)	Perforated Duodenal Ulcer
Macrogol 3350	24 Mar 2021 (Study Day 224) - 24 Mar 2021 (Study Day 224)	Perforated Duodenal Ulcer
Oxycodone	24 Mar 2021 (Study Day 224) - 29 Mar 2021 (Study Day 229)	Perforated Duodenal Ulcer
Furosemide	25 Mar 2021 (Study Day 225) - 26 Mar 2021 (Study Day 226)	Perforated Duodenal Ulcer
Alprazolam	26 Mar 2021 (Study Day 226) - Ongoing	Perforated Duodenal Ulcer
Iohexol	26 Mar 2021 (Study Day 226) - 27 Mar 2021 (Study Day 227)	Perforated Duodenal Ulcer
Magnesium sulfate	26 Mar 2021 (Study Day 226) - 26 Mar 2021 (Study Day 226)	Perforated Duodenal Ulcer
Potassium chloride	26 Mar 2021 (Study Day 226) - 26 Mar 2021 (Study Day 226)	Perforated Duodenal Ulcer
Sodium phosphate	26 Mar 2021 (Study Day 226) - 26 Mar 2021 (Study Day 226)	Perforated Duodenal Ulcer

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Flatulence	Grade 2/moderate	Not related	10 Mar 2021 (Study Day 210) - 12 Mar 2021 (Study Day 212)
Hyperglycaemia	Grade 2/moderate	Not related	10 Mar 2021 (Study Day 210) - 11 Mar 2021 (Study Day 211)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US378-2028 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 19 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pulmonary Embolism/ Bilateral Pulmonary Embolus	SAE	Grade 4	Not related	21 Feb 2021 (Study Day 187) – 25 Feb 2021 (Study Day 191)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US378-2028, a 66-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Jan 2021. The participant was unblinded on 04 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 21 Feb 2021 (Study Day 187), 186 days after the first dose in Part A and 158 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of pulmonary embolism. Action taken with the IP was not applicable. The event of bilateral pulmonary embolus lasted for 5 days, after which it was considered to be recovered/resolved with sequelae on 25 Feb 2021 (Study Day 191). The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-026309	Pulmonary embolism

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hysterectomy	Hysterectomy	1984 - 1984
Hypothyroidism	Hypothyroidism	1990 - Ongoing
Osteoarthritis	Osteoarthritis	2010 - Ongoing
Osteoarthritis	Unilateral primary osteoarthritis right hip	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine sodium	1990 - Ongoing	Hypothyroidism
Naproxen sodium	2019 - Ongoing	Osteoarthritis
Influenza vaccine	07 Oct 2020 (Study Day 50) - 07 Oct 2020 (Study Day 50)	Influenza Prophylaxis
Acetylsalicylic acid	16 Dec 2020 (Study Day 120) - 22 Feb 2021 (Study Day 188)	Right Hip Replacement (Post-Op Anticoagulation)
Anesthetics, local	16 Dec 2020 (Study Day 120) - 16 Dec 2020 (Study Day 120)	Right Hip Replacement
Celecoxib	16 Dec 2020 (Study Day 120) - 09 Jan 2021 (Study Day 144)	Right Hip Replacement (Post-Op Pain)
Cyclobenzaprine hydrochloride	16 Dec 2020 (Study Day 120) - 30 Dec 2020 (Study Day 134)	Right Hip Replacement (Post-Op Pain)
Omeprazole	16 Dec 2020 (Study Day 120) - 28 Jan 2021 (Study Day 163)	Right Hip Replacement (Gi Prophylaxis)
Oxycodone	16 Dec 2020 (Study Day 120) - 23 Dec 2020 (Study Day 127)	Right Hip Replacement Post Op Pain
Paracetamol	16 Dec 2020 (Study Day 120) - Ongoing	Right Hip Replacement (Post-Op Pain)
Right hip replacement*	16 Dec 2020 (Study Day 120) - 16 Dec 2020 (Study Day 120)	Medical History
Sennoside a+b	16 Dec 2020 (Study Day 120) - 02 Jan 2021 (Study Day 137)	Right Hip Replacement (Prophylaxis Post Op Constipation)
Alteplase	22 Feb 2021 (Study Day 188) - 22 Feb 2021 (Study Day 188)	Ekos Catheter Procedure
Azithromycin	22 Feb 2021 (Study Day 188) - 22 Feb 2021 (Study Day 188)	Presumptive Sepsis
Ceftriaxone	22 Feb 2021 (Study Day 188) - 22 Feb 2021 (Study Day 188)	Presumptive Sepsis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ct angiogram chest*	22 Feb 2021 (Study Day 188) - 22 Feb 2021 (Study Day 188)	Adverse Event
Ekos catheter*	22 Feb 2021 (Study Day 188) - 22 Feb 2021 (Study Day 188)	Adverse Event
Fentanyl	22 Feb 2021 (Study Day 188) - 22 Feb 2021 (Study Day 188)	Ekos Catheter Procedure
Heparin	22 Feb 2021 (Study Day 188) - 23 Feb 2021 (Study Day 189)	Bilateral Pulmonary Embolus
Lidocaine	22 Feb 2021 (Study Day 188) - 22 Feb 2021 (Study Day 188)	Ekos Catheter Procedure
Midazolam	22 Feb 2021 (Study Day 188) - 22 Feb 2021 (Study Day 188)	Ekos Catheter Procedure
Apixaban	23 Feb 2021 (Study Day 189) - 01 Mar 2021 (Study Day 195)	Bilateral Pulmonary Embolus
Perflutren	23 Feb 2021 (Study Day 189) - 23 Feb 2021 (Study Day 189)	Transthoracic Echocardiogram
Vascular duplex studies*	25 Feb 2021 (Study Day 191) - 25 Feb 2021 (Study Day 191)	Adverse Event
Apixaban	02 Mar 2021 (Study Day 196) - Ongoing	Bilateral Pulmonary Embolus

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US378-2162 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Oct 2020 (Study Day 32)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Angina Pectoris/ Cardiac Chest Pain	SAE	Grade 4	Not related	21 Jan 2021 (Study Day 136) – 21 Jan 2021 (Study Day 136)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US378-2162, a 78-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 08 Jan 2021. The participant was unblinded on 08 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 21 Jan 2021 (Study Day 136), 135 days after the first dose in Part A and 104 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of angina pectoris. Action taken with the IP was not applicable. The event of cardiac chest pain lasted for 1 days, after which it was considered to be recovered/resolved on 21 Jan 2021 (Study Day 136). The investigator assessed the event of angina pectoris to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-006669	Angina pectoris

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Constipation	Constipation	Not reported - Ongoing
Coronary artery disease	Coronary artery disease	Not reported - Ongoing
Deafness neurosensory	Sensory hearing loss	Not reported - Ongoing
Essential tremor	Essential tremor	Not reported - Ongoing
Gastroesophageal reflux disease	Gerd	Not reported - Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Benign prostatic hyperplasia	Bph	2015 - Ongoing
Back pain	Back pain	2017 - Ongoing
Angina pectoris	Angina	30 Oct 2017 (Study Day -1044) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Not reported - Ongoing	Cad
Atorvastatin	Not reported - Ongoing	Hyperlipidemia
Carbidopa; levodopa	Not reported - Ongoing	Tremors
Losartan	Not reported - Ongoing	Hypertension
Macrogol 3350	Not reported - Ongoing	Constipation
Omeprazole	Not reported - Ongoing	Gerd
Primidone	Not reported - Ongoing	Tremor
Tamsulosin hydrochloride	Not reported - Ongoing	Bph
Vitamins nos	2000 - Ongoing	General Health
Finasteride	2015 - Ongoing	Bph
Gabapentin	2017 - 22 Oct 2020 (Study Day 45)	Back Pain
Paracetamol	2017 - Ongoing	Back Pain
Vitamin d nos	08 Sep 2020 (Study Day 1) - Ongoing	General Health
Nuclear stress test*	22 Sep 2020 (Study Day 15) - 22 Sep 2020 (Study Day 15)	Adverse Event
Left heart catheterization*	23 Sep 2020 (Study Day 16) - 23 Sep 2020 (Study Day 16)	Adverse Event
Metoprolol	24 Sep 2020 (Study Day 17) - 27 Oct 2020 (Study Day 50)	Coronary Artery Disease
Paracetamol	09 Oct 2020 (Study Day 32) - 09 Oct 2020 (Study Day 32)	Post-Vaccination Symptom Prophylaxis
Glyceryl trinitrate	14 Oct 2020 (Study Day 37) - 14 Oct 2020 (Study Day 37)	Cardiac Chest Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colonoscopy*	22 Oct 2020 (Study Day 45) - 22 Oct 2020 (Study Day 45)	Other, Routine
Influenza vaccine	26 Oct 2020 (Study Day 49) - 26 Oct 2020 (Study Day 49)	Influenza Prophylaxis
Metoprolol	28 Oct 2020 (Study Day 51) - Ongoing	Cornary Artery Disease
Investigational drug	20 Jan 2021 (Study Day 135) - 20 Jan 2021 (Study Day 135)	Fracture Prophylaxis
Glyceryl trinitrate	21 Jan 2021 (Study Day 136) - Ongoing	Chest Pain (Cardiac)
Isosorbide mononitrate	23 Jan 2021 (Study Day 138) - Ongoing	Angina
Ranolazine	23 Jan 2021 (Study Day 138) - Ongoing	Angina
Skin biopsy right arm*	12 Mar 2021 (Study Day 186) - 12 Mar 2021 (Study Day 186)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Malignant Melanoma	Grade 3/severe	Not related	12 Mar 2021 (Study Day 186) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US379-2012 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 12 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Back Pain/ Worsening Of Chronic Back Pain	SAE	Grade 3/ severe	Not related	10 Jan 2021 (Study Day 152) – 19 Feb 2021 (Study Day 192)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US379-2012, a 71-year-old race unknown male, received the first dose of mRNA-1273 in the left arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 10 Jan 2021 (Study Day 152), 151 days after the first dose in Part A and 123 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of back pain. Action taken with the IP was not applicable. The event of worsening of chronic back pain lasted for 41 days, after which it was considered to be recovered/resolved on 19 Feb 2021 (Study Day 192). The investigator assessed the event of back pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-056820	Back pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Herpes simplex	Herpes simplex type i	1997 - Ongoing
Tinnitus	Tinnitus bilateral ears	2005 - Ongoing
Skin papilloma	Wart left arm	2010 - Jul 2020
Skin papilloma	Wart right arm	2010 - Jul 2020
Back pain	Chronic back pain	2011 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2015 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Hypothyroidism	Hypothyroidism	2015 - Ongoing
Polyuria	Polyuria	2015 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2017 - Ongoing
Osteoarthritis	Left hand osteoarthritis	2018 - Ongoing
Pain in extremity	Left hand pain	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2000 - Ongoing	Nutritional Supplement
Levothyroxine sodium	2015 - Ongoing	Hypothyroidism
Lisinopril	2015 - Ongoing	Hypertension
Apoaequorin	2017 - Ongoing	Nutritional Supplement
Ascorbic acid	2017 - Ongoing	Nutritional Supplement
Pantoprazole sodium sesquihydrate	2017 - Ongoing	Gastroesophageal Reflux Disease
Diclofenac	2018 - Ongoing	Left Hand Pain
Valaciclovir hydrochloride	2018 - Ongoing	Herpes Symplex Type I
Influenza vaccine	25 Sep 2020 (Study Day 45) - 25 Sep 2020 (Study Day 45)	Flu Prophylaxis
L4-15 fusion*	17 Feb 2021 (Study Day 190) - 17 Feb 2021 (Study Day 190)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US379-2016 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 12 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pancreatitis/Pancreatitis	SAE	Grade 3/ severe	Not related	10 Apr 2021 (Study Day 242) – 19 Apr 2021 (Study Day 251)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US379-2016, a 64-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 07 Jan 2021. The participant was unblinded on 07 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 10 Apr 2021 (Study Day 242), 241 days after the first dose in Part A and 213 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of pancreatitis. Action taken with the IP was not applicable. The event of pancreatitis lasted for 10 days, after which it was considered to be recovered/resolved on 19 Apr 2021 (Study Day 251). The investigator assessed the event of pancreatitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-080962	Pancreatitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Endometriosis	Endometriosis	1986 - 1992
Fibromyalgia	Fibromyalgia	1992 - Ongoing
Hysterectomy	Hysterectomy	1992 - 1992
Migraine	Migraine headaches	1992 - Ongoing
Nausea	Nausea, intermittent	1992 - Ongoing
Osteoarthritis	Osteoarthritis, bilateral knees	2000 - 2013
Gastroesophageal reflux disease	Acid reflux	Jan 2008 - Ongoing
Intervertebral disc degeneration	Degenerative disc disease, cervical, lumbar, thoracic	2012 - Ongoing
Knee arthroplasty	Bilateral knee replacement	2013 - 2013
Hypertension	Hypertension	01 Feb 2020 (Study Day -193) - Ongoing
Cataract	Cataracts, bilateral eyes	01 Jul 2020 (Study Day -42) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Guaifenesin	2000 - Ongoing	Fibromyalgia
Promethazine	Jan 2000 - Ongoing	Intermittent Nausea
Omeprazole	2008 - Ongoing	Acid Reflux
Magnesium oxide	2010 - Ongoing	Fibromyalgia
Paracetamol	Jan 2012 - Ongoing	Degenerative Disc Disease
Celecoxib	Jan 2014 - Ongoing	Degenerative Disc Disease
Methocarbamol	20 Jan 2016 (Study Day -1666) - Ongoing	Fibromyalgia
Oxycodone	20 Jan 2016 (Study Day -1666) - Ongoing	Fibromyalgia
Tapentadol hydrochloride	20 Jan 2017 (Study Day -1300) - Ongoing	Fibromyalgia
Doxazosin mesilate	01 Jul 2020 (Study Day -42) - Ongoing	Hypertension
Hydrochlorothiazide	01 Jul 2020 (Study Day -42) - Ongoing	Hypertension
Right cataract removal*	07 Oct 2020 (Study Day 57) - 07 Oct 2020 (Study Day 57)	Medical History
Influenza vaccine	10 Oct 2020 (Study Day 60) - 10 Oct 2020 (Study Day 60)	Influenza Prophylaxis
Left cataract removal*	21 Oct 2020 (Study Day 71) - 21 Oct 2020 (Study Day 71)	Medical History
Amoxicillin; clavulanic acid	17 Dec 2020 (Study Day 128) - 24 Dec 2020 (Study Day 135)	Sinus Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US380-2074 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 31 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cholecystitis Acute/Acute Cholecystitis	SAE	Grade 3/severe	Not related	27 Mar 2021 (Study Day 209) – 29 Mar 2021 (Study Day 211)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US380-2074, a 69-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 13 Jan 2021. The participant was unblinded on 13 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 27 Mar 2021 (Study Day 209), 208 days after the first dose in Part A and 180 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of cholecystitis acute. Action taken with the IP was not applicable. The event of acute cholecystitis lasted for 3 days, after which it was considered to be recovered/resolved on 29 Mar 2021 (Study Day 211). The investigator assessed the event of cholecystitis acute to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-064835	Cholecystitis acute

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Blood cholesterol increased	High cholesterol	1990 - Ongoing
Hypertension	Hypertension	1990 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pseudoephedrine hydrochloride	Not reported - Ongoing	Seasonal Allergies
Atenolol	2005 - Ongoing	Hypertension
Simvastatin	2005 - Ongoing	High Cholesterol
Ibuprofen	01 Sep 2020 (Study Day 2) - 06 Sep 2020 (Study Day 7)	Pain At Injection Site
Loratadine	01 Sep 2020 (Study Day 2) - 06 Sep 2020 (Study Day 7)	Sinus Headache Related To Seasonal Allergies
Ibuprofen	29 Sep 2020 (Study Day 30) - 01 Oct 2020 (Study Day 32)	Arm Pain At Injection Site Headache
Hydrochlorothiazide; losartan potassium	01 Mar 2021 (Study Day 183) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 2/moderate	Not related	01 Mar 2021 (Study Day 183) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US380-2120 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 02 Oct 2020 (Study Day 30)
First Dose of Vaccine in Part B: 07 Jan 2021 (Study Day 127)
Second Dose of Vaccine in Part B: 17 Feb 2021 (Study Day 168)
Reason for Narrative: Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	COVID-19	Grade 1/ mild	Not related	15 Jan 2021 (Study Day 135) – 20 Jan 2021 (Study Day 140)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US380-2120, a 76-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 07 Jan 2021. The participant was unblinded on 07 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 07 Jan 2021 (Study Day 127). The second dose was administered in the left arm on 17 Feb 2021 (Study Day 168).

Severe COVID-19 Details

On 15 Jan 2021 (Study Day 135), 134 days after the first dose in Part A/8 days after the first dose in Part B and 105 days after the second dose in Part A/33 days before the second dose in Part B of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 30, 02 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 15 Jan 2021 (Study Day 135), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
15 Jan 2021 (Study Day 135)	Chills	Mild
15 Jan 2021 (Study Day 135)	Cough	Mild
15 Jan 2021 (Study Day 135)	Fatigue	Mild
15 Jan 2021 (Study Day 135)	Runny Nose (Rhinorrhea)	Moderate
15 Jan 2021 (Study Day 135)	Sore Throat	Mild
16 Jan 2021 (Study Day 136)	Cough	Mild
16 Jan 2021 (Study Day 136)	Nasal Congestion	Mild
16 Jan 2021 (Study Day 136)	Runny Nose (Rhinorrhea)	Mild
16 Jan 2021 (Study Day 136)	Sore Throat	Mild
17 Jan 2021 (Study Day 137)	Cough	Mild
17 Jan 2021 (Study Day 137)	Nasal Congestion	Mild
17 Jan 2021 (Study Day 137)	Runny Nose (Rhinorrhea)	Mild
18 Jan 2021 (Study Day 138)	Cough	Moderate
18 Jan 2021 (Study Day 138)	Diarrhea	Mild
19 Jan 2021 (Study Day 139)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Date	Severity Indication	Result
16 Jan 2021 - 16 Jan 2021 (Study Day 136-136)	Systolic Blood Pressure < 90 mm Hg, Diastolic Blood Pressure < 60 mm Hg	Yes

The IP dose was not changed due to the symptomatic COVID-19. The event of symptomatic COVID-19 lasted for 6 days, after which it was considered to be recovered/resolved on 20 Jan 2021 (Study Day 140). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-023550	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Menopause	Menopause	Not reported - Ongoing
Hypothyroidism	Under active thyroid	1985 - Ongoing
Blood triglycerides increased	Elevated triglycerides	2008 - Ongoing
Cataract operation	Cataracts surgery	2015 - Not reported
Ankle fracture	R ankle fracture	2018 - Not reported
Gastroesophageal reflux disease	Gerd	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	1985 - Ongoing	Hypothyroidism
Fenofibrate	2008 - Ongoing	Elevated Triglycerides
Pantoprazole	2019 - Ongoing	Gerd
Ibuprofen	15 Jan 2021 (Study Day 135) - 23 Jan 2021 (Study Day 143)	Fever Due To Symptomatic COVID

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	15 Jan 2021 (Study Day 135) - 20 Jan 2021 (Study Day 140)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US380-2168 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Oct 2020 (Study Day 32)
First Dose of Vaccine in Part B: 05 Jan 2021 (Study Day 120)
Second Dose of Vaccine in Part B: 01 Feb 2021 (Study Day 147)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Castleman's Disease/Excision Of Perihepatic Mass, Castleman's Disease	SAE	Grade 3/ severe	Not related	30 Mar 2021 (Study Day 204) – 30 Mar 2021 (Study Day 204)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US380-2168, a 41-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 05 Jan 2021. The participant was unblinded on 05 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 05 Jan 2021 (Study Day 120). The second dose was administered in the left arm on 01 Feb 2021 (Study Day 147).

Event Details

On 30 Mar 2021 (Study Day 204), 203 days after the first dose in Part A/84 days after the first dose in Part B and 172 days after the second dose in Part A/57 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of castleman's disease. Action taken with the IP was not applicable. The event of excision of perihepatic mass, castleman's disease lasted for 1 day, after which it was considered to be recovered/resolved on 30 Mar 2021 (Study Day 204). The investigator assessed the event of castleman's disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-071929	Castleman's disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dry skin	Chronic dry feet	Not reported - Ongoing
Dry skin	Chronic dry skin	Not reported - Ongoing
Multiple allergies	Allergies to dust, mold, and cats	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Chronic sinusitis	Chronic sinusitis	2000 - Ongoing
Hepatic lesion	Benign liver lesion	2008 - Ongoing
Colitis ulcerative	Ulcerative colitis	2010 - Ongoing
Dyspepsia	Frequent heart burn	2010 - Ongoing
Anxiety	Anxiety	2014 - Ongoing
Intervertebral disc operation	Herniated disc surgery	2019 - 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	2004 - Ongoing	Seasonal Allergies
Fluticasone propionate	2004 - Ongoing	Seasonal Allergies
Esomeprazole magnesium	2010 - Ongoing	Heart Burn
Mesalazine	2015 - Ongoing	Ulcerative Colitis
Sertraline hydrochloride	2015 - Ongoing	Anxiety
Vitamins nos	2015 - Ongoing	Supplement
Ammonium lactate	2016 - Ongoing	Dry Feet
Colecalciferol	2018 - Ongoing	Supplement
Azelastine	2020 - Ongoing	Seasonal Allergies
Budesonide	2020 - Ongoing	Chronic Sinusitis
Clobetasol propionate	2020 - Ongoing	Dry Skin
Sodium bicarbonate; sodium chloride	2020 - Ongoing	Chronic Sinusitis
Vitamin e nos	2020 - Ongoing	Supplement
Paracetamol	10 Sep 2020 (Study Day 3) - 17 Sep 2020 (Study Day 10)	Head Ache, Muscle Pain
Amoxicillin; clavulanic acid	07 Oct 2020 (Study Day 30) - Ongoing	Sinusitis
Influenza vaccine	31 Oct 2020 (Study Day 54) - 31 Oct 2020 (Study Day 54)	Prevent Influenza Infection
Famotidine	24 Nov 2020 (Study Day 78) - Ongoing	Seasonal Allergies

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Esophageal manometry*	03 Feb 2021 (Study Day 149) - 03 Feb 2021 (Study Day 149)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US381-2081 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 07 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 02 Sep 2020 (Study Day 27)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis/Acute Appendicitis	SAE	Grade 4	Not related	29 Mar 2021 (Study Day 235) – 01 Apr 2021 (Study Day 238)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2081, a 47-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 02 Sep 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 03 Mar 2021. The participant was unblinded on 03 Mar 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 29 Mar 2021 (Study Day 235), 234 days after the first dose in Part A and 208 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of appendicitis. Action taken with the IP was not applicable. The event of acute appendicitis lasted for 4 days, after which it was considered to be recovered/resolved on 01 Apr 2021 (Study Day 238). The investigator assessed the event of appendicitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-066930	Appendicitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Visual impairment	Bilateral visual impairment	1987 - Ongoing
Seasonal allergy	Seasonal allergies	1995 - Ongoing
Hyperlipidaemia	Hyperlipidemia	18 Oct 2017 (Study Day -1024) - Ongoing
Lipoprotein deficiency	Lipoprotein deficiency disorder	18 Oct 2017 (Study Day -1024) - Ongoing
Vitamin D deficiency	Vitamin d deficiency	18 Oct 2017 (Study Day -1024) - Ongoing
Dyspepsia	Frequent indigestion	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin d nos	04 Aug 2020 (Study Day -3) - Ongoing	General Health
Influenza vaccine	07 Oct 2020 (Study Day 62) - 07 Oct 2020 (Study Day 62)	Flu Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US381-2229 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 21 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 18 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 14 Jan 2021 (Study Day 147)
Second Dose of Vaccine in Part B: 11 Feb 2021 (Study Day 175)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/ Myocardial Infarction	SAE	Grade 4	Not related	25 Feb 2021 (Study Day 189) – 25 Feb 2021 (Study Day 189)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2229, an 81-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 14 Jan 2021 (Study Day 147). The second dose was administered in the left arm on 11 Feb 2021 (Study Day 175).

Event Details

On 25 Feb 2021 (Study Day 189), 188 days after the first dose in Part A/42 days after the first dose in Part B and 160 days after the second dose in Part A/14 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction lasted for 1 day, after which it was considered to be recovered/resolved on 25 Feb 2021 (Study Day 189). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-030118	Myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Constipation	Constipation	1945 - Ongoing
Drug hypersensitivity	Penicillin allergy	1960 - Ongoing
Alcohol use	Alcohol use 3-4 week	1966 - Ongoing
Female sterilisation	Tubal ligation-bilateral	1970 - 1970
Postmenopause	Post menopausal	1973 - Ongoing
Nerve injury	Nerve damage in neck	1995 - 1995
Spinal fusion surgery	Neck vertebrate infusion	1995 - 1995
Cholecystectomy	Gallbladder removed	1998 - 1998
Cholecystitis	Gallbladder inflamed	1998 - 1998
Arthroscopy	Left knee arthroscopy	2000 - 2000
Ligament rupture	Left knee acl tear x2	2000 - 2000
Hysterectomy	Hysterectomy	2002 - 2002
Uterine leiomyoma	Fibroids	2002 - 2002
Hypothyroidism	Hypothyroidism	2005 - Ongoing
Knee arthroplasty	Left knee replacement	2009 - 2009
Osteoarthritis	Degenerative joint disease	2009 - Ongoing
Osteoarthritis	Osteoarthritis bilateral knees	2009 - 2009
Osteopenia	Osteopenia	2010 - Ongoing
Spondylitis	Arthritis in lower back	2010 - Ongoing
Sciatica	Right left sciatica	Aug 2010 - Ongoing
Bunion operation	Bilateral bunionectomy	2013 - 2013
Foot deformity	Bilateral bunions	2013 - 2013
Asthma	Seasonal asthma	2015 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Restless legs syndrome	Restless leg syndrome	2015 - Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2017 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2017 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2017 - Ongoing
Chronic kidney disease	Benign hypertension with chronic kidney disease type 3	Jan 2017 - Ongoing
Barrett's oesophagus	Barrets esophagus	Aug 2017 - Ongoing
Cataract	Bilateral eyes cataracts	2018 - 2018
Cataract operation	Bilateral eyes cataract surgery	2018 - 2018
Deafness bilateral	Bilateral hearing loss	2018 - Ongoing
Glaucoma	Glaucoma	2018 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hearing aid user	Bilateral hearing aids	2018 - Ongoing
Insomnia	Insomnia	2018 - Jun 2020
Sleep apnoea syndrome	Obstructive sleep apnea	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Estradiol	2000 - 27 Feb 2021 (Study Day 191)	Hormone Replacement Therapy Due To Post-Menopausal
Levothyroxine	2005 - Ongoing	Hypothyroidism
Etodolac	2010 - 27 Feb 2021 (Study Day 191)	Osteoarthritis In Lower Back
Amlodipine	2015 - 27 Feb 2021 (Study Day 191)	Hypertension
Clonazepam	2015 - Ongoing	Restless Leg Syndrome
Fluticasone propionate	2016 - Ongoing	Seasonal Allergies
Botulinum toxin type a	2017 - 2017	Wrinkle Prevention
Minerals nos; vitamins nos	2018 - Ongoing	Glaucoma
Paracetamol	04 Sep 2020 (Study Day 15) - 04 Sep 2020 (Study Day 15)	Low Back Pain
Removal of foreign body*	07 Sep 2020 (Study Day 18) - 07 Sep 2020 (Study Day 18)	Adverse Event
Influenza vaccine	03 Nov 2020 (Study Day 75) - 03 Nov 2020 (Study Day 75)	Flu Preventative
Paracetamol	08 Nov 2020 (Study Day 80) - 08 Nov 2020 (Study Day 80)	COVID Like Illness
Sennoside a+b	08 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 90)	Constipation
Acetylsalicylic acid	25 Feb 2021 (Study Day 189) - 25 Feb 2021 (Study Day 189)	Myocardial Infarction
Balloon angioplasty*	25 Feb 2021 (Study Day 189) - 25 Feb 2021 (Study Day 189)	Adverse Event
Chest xray*	25 Feb 2021 (Study Day 189) - 25 Feb 2021 (Study Day 189)	Adverse Event
Computerized tomography angiography*	25 Feb 2021 (Study Day 189) - 25 Feb 2021 (Study Day 189)	Adverse Event
Ekg*	25 Feb 2021 (Study Day 189) - 25 Feb 2021 (Study Day 189)	Adverse Event
Glyceryl trinitrate	25 Feb 2021 (Study Day 189) - 25 Feb 2021 (Study Day 189)	Myocardial Infarction
Heparin	25 Feb 2021 (Study Day 189) - 25 Feb 2021 (Study Day 189)	Myocardial Infarction
Influenza a/b*	25 Feb 2021 (Study Day 189) - 25 Feb 2021 (Study Day 189)	Adverse Event
Pre surgical required covid pcr, negative.*	25 Feb 2021 (Study Day 189) - 25 Feb 2021 (Study Day 189)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Repeat ekg*	25 Feb 2021 (Study Day 189) - 25 Feb 2021 (Study Day 189)	Adverse Event
Rsv*	25 Feb 2021 (Study Day 189) - 25 Feb 2021 (Study Day 189)	Adverse Event
Cardiac echo*	26 Feb 2021 (Study Day 190) - 26 Feb 2021 (Study Day 190)	Adverse Event
Ekg*	26 Feb 2021 (Study Day 190) - 26 Feb 2021 (Study Day 190)	Adverse Event
Glyceryl trinitrate	26 Feb 2021 (Study Day 190) - 26 Feb 2021 (Study Day 190)	Cad
Famotidine	27 Feb 2021 (Study Day 191) - Ongoing	Gastroesophageal Reflux Disease
Acetylsalicylic acid	28 Feb 2021 (Study Day 192) - Ongoing	Coronary Artery Disease
Atorvastatin	28 Feb 2021 (Study Day 192) - Ongoing	Coronary Artery Disease
Ticagrelor	28 Feb 2021 (Study Day 192) - Ongoing	Coronary Artery Disease

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cardiac Murmur	Grade 2/moderate	Not related	14 Jan 2021 (Study Day 147) - Ongoing
Dizziness	Grade 1/mild	Not related	14 Jan 2021 (Study Day 147) - 14 Jan 2021 (Study Day 147)
Coronary Artery Disease	Grade 3/severe	Not related	25 Feb 2021 (Study Day 189) - Ongoing
Type Iia Hyperlipidaemia	Grade 2/moderate	Not related	03 Mar 2021 (Study Day 195) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US382-2088 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 11 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Urinary Tract Infection/ Urinary Tract Infection	SAE	Grade 3/ severe	Not related	09 Mar 2021 (Study Day 211) – 05 Apr 2021 (Study Day 238)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US382-2088, a 74-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 09 Mar 2021 (Study Day 211), 210 days after the first dose in Part A and 181 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of urinary tract infection. Action taken with the IP was not applicable. The event of urinary tract infection lasted for 28 days, after which it was considered to be recovered/resolved on 05 Apr 2021 (Study Day 238). The investigator assessed the event of urinary tract infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-073251	Urinary tract infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1980 - Ongoing
Hypertension	Hypertension	1986 - Ongoing
Vasectomy	Vasectomy	2000 - Ongoing
Back pain	Back pain	2015 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2016 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2017 - Ongoing
Aortic valve disease	Aortic valve dysfunction	2019 - 2019
Aortic valve replacement	Aortic valve replacement	2019 - 2019
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2006 - Ongoing	Hypertension
Atenolol	2006 - Ongoing	Hypertension
Lisinopril	2006 - Ongoing	Hypertension
Atorvastatin	2016 - Ongoing	High Cholesterol
Diphtheria vaccine toxoid; tetanus vaccine toxoid	2017 - 2017	Vaccine
Tamsulosin hydrochloride	2017 - Ongoing	Bph
Influenza vaccine	2019 - 2019	Vaccine
Omeprazole	2019 - Ongoing	Gerd
Warfarin	2019 - Ongoing	Aortic Valve Replacement
Influenza vaccine	19 Oct 2020 (Study Day 70) - 19 Oct 2020 (Study Day 70)	Vaccine
Varicella zoster vaccine	02 Nov 2020 (Study Day 84) - 02 Nov 2020 (Study Day 84)	Vaccine

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US382-2181 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 19 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 24 Sep 2020 (Study Day 37)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis/Appendicitis	SAE	Grade 2/ moderate	Not related	03 Mar 2021 (Study Day 197) – 04 Mar 2021 (Study Day 198)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US382-2181, a 25-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 37). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 03 Mar 2021 (Study Day 197), 196 days after the first dose in Part A and 160 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of appendicitis. Action taken with the IP was not applicable. The event of appendicitis lasted for 2 days, after which it was considered to be recovered/resolved on 04 Mar 2021 (Study Day 198). The investigator assessed the event of appendicitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-033821	Appendicitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Eczema	Eczema	2018 - Ongoing
Erectile dysfunction	Erectile dysfunction	2020 - Ongoing
Haemorrhoids	Hemorrhoids	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	2019 - 2019	Influenza
Other agents for treatment of hemorrhoids and anal fissures for topical use	2020 - Ongoing	Hemorrhoids
Naproxen sodium	25 Sep 2020 (Study Day 38) - 25 Sep 2020 (Study Day 38)	Injection Site Pain
Guaifenesin	28 Sep 2020 (Study Day 41) - Ongoing	Cough
Appendectomy*	03 Mar 2021 (Study Day 197) - 03 Mar 2021 (Study Day 197)	Adverse Event
Ct scan of abdomen for appendicitis*	03 Mar 2021 (Study Day 197) - 03 Mar 2021 (Study Day 197)	Adverse Event
Oxycodone	03 Mar 2021 (Study Day 197) - 09 Mar 2021 (Study Day 203)	Post Appendectomy
Vancomycin hydrochloride	12 Mar 2021 (Study Day 206) - Ongoing	C Diff

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Clostridium Difficile Infection	Grade 1/mild	Not related	09 Mar 2021 (Study Day 203) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US382-2342 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Oct 2020 (Study Day 30)
First Dose of Vaccine in Part B: 05 Jan 2021 (Study Day 119)
Second Dose of Vaccine in Part B: 25 Feb 2021 (Study Day 170)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pleural Effusion/Right Pleural Effusion	SAE	Grade 3/severe	Not related	05 Feb 2021 (Study Day 150) – 08 Feb 2021 (Study Day 153)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US382-2342, a 77-year-old not Hispanic or Latino male, received the first dose of Placebo in the right arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 08 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Jan 2021. The participant was unblinded on 04 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 05 Jan 2021 (Study Day 119). The second dose was administered in the right arm on 25 Feb 2021 (Study Day 170).

Event Details

On 05 Feb 2021 (Study Day 150), 149 days after the first dose in Part A/31 days after the first dose in Part B and 120 days after the second dose in Part A/20 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of pleural effusion. The IP dose was not changed due to the right pleural effusion. The event of right pleural effusion lasted for 4 days, after which it was considered to be recovered/resolved with sequelae on 08 Feb 2021 (Study Day 153). The investigator assessed the event of pleural effusion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012131	Pleural effusion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Acne	Acne	Not reported - 1970
Gallbladder disorder	Gallbladder disease	Not reported - 2019
Dyspepsia	Heartburn	1970 - Ongoing
Gastroesophageal reflux disease	Gerd	1970 - Ongoing
Deafness	Hearing loss	1975 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Inguinal hernia	Inguinal hernias	2005 - 2005
Macular degeneration	Macular degeneration	2005 - Ongoing
Blood cholesterol increased	High cholesterol	2010 - Ongoing
Blood triglycerides increased	High triglycerides	2010 - Ongoing
Prostatic disorder	Prostate issues	2017 - Ongoing
Urinary incontinence	Urinary incontinence	2017 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2019 - Ongoing
Osteopenia	Osteopenia	Feb 2019 - Ongoing
Cardiomegaly	Enlarged heart	Aug 2019 - Ongoing
Mitral valve prolapse	Mitral valve prolapse	30 Aug 2019 (Study Day -376) - Ongoing
Skin cancer	Skin cancer on back	2020 - Ongoing
Oedema peripheral	Edema of the ankles	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole	1970 - Ongoing	Gerd
Amlodipine	2005 - Ongoing	Htn
Pneumococcal vaccine	22 Jun 2009 (Study Day -4097) - 22 Jun 2009 (Study Day -4097)	Vaccine
Hepatitis b vaccine	16 Sep 2011 (Study Day -3281) - 16 Sep 2011 (Study Day -3281)	Vaccine
Acetylsalicylic acid	2014 - Ongoing	Cardiac Supplement - Heart Issues Being Monitored
Diphtheria vaccine toxoid; pertussis vaccine; tetanus vaccine toxoid	21 Apr 2014 (Study Day -2333) - 21 Apr 2014 (Study Day -2333)	Vaccine
Rosuvastatin	2019 - Ongoing	Hcl

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Alendronate sodium	28 Feb 2019 (Study Day -559) - Ongoing	Osteopenia
Mirabegron	2020 - Ongoing	Overactive Bladder - Urinary Incontinence
Influenza vaccine	23 Aug 2020 (Study Day -17) - 23 Aug 2020 (Study Day -17)	Vaccine
Trospium	01 Oct 2020 (Study Day 23) - Ongoing	Urinary Incontinence
Amlodipine besilate	15 Dec 2020 (Study Day 98) - Ongoing	Hypertension
Chest x-ray pa and lateral*	05 Feb 2021 (Study Day 150) - 05 Feb 2021 (Study Day 150)	Diagnostic
Ct chest with iv contrast*	05 Feb 2021 (Study Day 150) - 05 Feb 2021 (Study Day 150)	Diagnostic
Chest x-ray*	06 Feb 2021 (Study Day 151) - 06 Feb 2021 (Study Day 151)	Diagnostic
Doxycycline hyclate	07 Feb 2021 (Study Day 152) - Ongoing	Right Pleural Effusion
Ultrasound guided right thoracentesis*	07 Feb 2021 (Study Day 152) - 07 Feb 2021 (Study Day 152)	Adverse Event
Chest x-ray*	22 Mar 2021 (Study Day 195) - 22 Mar 2021 (Study Day 195)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US382-2465 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 23 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 23 Nov 2020 (Study Day 32)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Sepsis/Sepsis	SAE	Grade 3/ severe	Not related	11 Apr 2021 (Study Day 171) – 14 Apr 2021 (Study Day 174)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The MedDRA Preferred Term/ Verbatim Term of Sepsis/Sepsis was updated to Systemic Inflammatory Response Syndrome/Systemic Inflammatory Response Syndrome after the database lock.

Participant US382-2465, a 41-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 23 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 23 Nov 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Jan 2021. The participant was unblinded on 04 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 11 Apr 2021 (Study Day 171), 170 days after the first dose in Part A and 139 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of sepsis. Action taken with the IP was not applicable. The event of sepsis lasted for 4 days, after which it was considered to be recovered/resolved on 14 Apr 2021 (Study Day 174). The investigator assessed the event of sepsis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-077386	Systemic inflammatory response syndrome

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Back pain	2004 - Ongoing
Intervertebral disc degeneration	Disc desiccation - lower spine	2004 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Gastrointestinal haemorrhage	Gi bleed	2016 - 2016
Seasonal allergy	Seasonal allergies	2018 - Ongoing
Thyroid mass	Thyroid nodule	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide; losartan potassium	Oct 2015 - Ongoing	Hypertension
Metoprolol	Oct 2015 - Ongoing	Hypertension
Naproxen sodium	24 Nov 2020 (Study Day 33) - 24 Nov 2020 (Study Day 33)	Fever, Headache
Paracetamol	24 Nov 2020 (Study Day 33) - 24 Nov 2020 (Study Day 33)	Fever, Headache
Paracetamol	14 Dec 2020 (Study Day 53) - 15 Dec 2020 (Study Day 54)	Sore Throat, Jaw Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US383-2071 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 04 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis Perforated/ Ruptured Appendix	SAE	Grade 4	Not related	21 Mar 2021 (Study Day 230) – 27 Mar 2021 (Study Day 236)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US383-2071, a 58-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 28 Jan 2021. The participant was unblinded on 28 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 21 Mar 2021 (Study Day 230), 229 days after the first dose in Part A and 201 days after the second dose in Part A of the IP, the participant experienced a Grade 4 serious adverse event of appendicitis perforated. Action taken with the IP was not applicable. The event of ruptured appendix lasted for 7 days, after which it was considered to be recovered/resolved on 27 Mar 2021 (Study Day 236). The investigator assessed the event of appendicitis perforated to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-065620	Appendicitis perforated

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Female sterilisation	Bilateral tubal ligation	1982 - 1982
Osteoarthritis	Osteoarthritis	1984 - Ongoing
Breast cancer	Breast cancer r breast	2000 - 2000
Depression	Depression	2000 - Ongoing
Fibromyalgia	Fibromyalgia	2000 - Ongoing
Breast cancer	Breast cancer left breast	2011 - 2011
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2015 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2016 - Ongoing
Hypothyroidism	Hypothyroidism	2016 - Ongoing
Vitamin D decreased	Low vitamin d	2017 - Ongoing
Intervertebral disc protrusion	L5 s1 herniated disc	2018 - Ongoing
Nausea	Chronic nausea	2018 - Ongoing
Eczema	Eczema (bilateral legs and arms)	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2015 - Ongoing	Chronic Obstructive Pulmonary Disease
Salbutamol sulfate	2015 - Ongoing	Chronic Obstructive Pulmonary Disease
Celecoxib	2016 - Ongoing	Osteoarthritis
Levothyroxine	2016 - Ongoing	Hypothyroidism
Pregabalin	2016 - Ongoing	Fibromyalgia
Pantoprazole	2017 - Ongoing	Gerd - Gastroesophageal Reflux Disease
Ondansetron	2019 - Ongoing	Chronic Nausea
Trazodone	2019 - Ongoing	Depression
Vortioxetine	2019 - Ongoing	Depression
Formoterol fumarate; glycopyrronium bromide	Apr 2020 - Ongoing	Copd - Chronic Obstructive Pulmonary Disease
Colecalciferol	May 2020 - Ongoing	Low Vitamin D
Clobetasol propionate	Jul 2020 - Ongoing	Eczema
L5 s1 herniated disc repair*	01 Dec 2020 (Study Day 120) - 01 Dec 2020 (Study Day 120)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US383-2176 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 12 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 04 Jan 2021 (Study Day 146)
Second Dose of Vaccine in Part B: 01 Feb 2021 (Study Day 174)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hiatus Hernia/Worsening Of Paraesophageal Hernia	SAE	Grade 4	Not related	02 Mar 2021 (Study Day 203) – 03 Mar 2021 (Study Day 204)	Recovered/resolved
Vertigo/Vertigo	SAE	Grade 4	Not related	22 Apr 2021 (Study Day 254) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US383-2176, a 74-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Jan 2021. The participant was unblinded on 04 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 04 Jan 2021 (Study Day 146). The second dose was administered in the left arm on 01 Feb 2021 (Study Day 174).

Event Details

On 02 Mar 2021 (Study Day 203), 202 days after the first dose in Part A/57 days after the first dose in Part B and 174 days after the second dose in Part A/29 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of hiatus hernia. Action taken with the IP was not applicable. The event of worsening of paraesophageal hernia lasted for 2 days, after which it was considered to be recovered/resolved on 03 Mar 2021 (Study Day 204). The investigator assessed the event of hiatus hernia to be not related to the IP.

On 22 Apr 2021 (Study Day 254), 253 days after the first dose in Part A/108 days after the first dose in Part B and 225 days after the second dose in Part A/80 days after the second dose in Part B of the IP, the participant experienced a Grade 4 serious adverse event of vertigo. Action taken with

the IP was not applicable. The event of vertigo was considered to be ongoing. The investigator assessed the event of vertigo to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-074057	Hiatus hernia
MOD-2021-090688	Vertigo

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1970 - Ongoing
Hypertension	Hypertension	1995 - Ongoing
Postmenopause	Post menopausal	1998 - Ongoing
Hiatus hernia	Hiatal hernia	2000 - Ongoing
Myalgia	General myalgia	2011 - Ongoing
Osteoarthritis	Bilateral knee osteoarthritis	2011 - Ongoing
Breast cancer	Breast cancer	2014 - 2014
Insomnia	Insomnia	2015 - Ongoing
Peripheral arterial occlusive disease	Peripheral arterial disease	2018 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2019 - Ongoing
Limb injury	Right shoulder injury	2019 - 2019
Cataract	Cataract (left eye)	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	1970 - Ongoing	Seasonal Allergies
Meclozine	1970 - Ongoing	Seasonal Allergies
Acetylsalicylic acid	2000 - Ongoing	Cardiac Prophylaxis
Hydrochlorothiazide	2000 - Ongoing	Hypertension
Paracetamol	2011 - Ongoing	General Myalgia
Escitalopram oxalate	2015 - Ongoing	Insomnia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Losartan	2015 - Ongoing	Hypertension
Amlodipine	2017 - Ongoing	Hypertension
Cilostazol	2018 - Ongoing	Peripheral Arterial Disease
Pantoprazole	2019 - Ongoing	Gastroesophageal Reflux Disease
Famotidine	2020 - Ongoing	Gastroesophageal Reflux Disease
Bromfenac	31 Aug 2020 (Study Day 20) - 10 Sep 2020 (Study Day 30)	Post Cataract Surgery Infection Preventive
Bromfenac sodium	31 Aug 2020 (Study Day 20) - 10 Sep 2020 (Study Day 30)	Post Cataract Surgery Infection Preventive
Cataract surgery - left eye*	31 Aug 2020 (Study Day 20) - 31 Aug 2020 (Study Day 20)	Medical History
Prednisone	31 Aug 2020 (Study Day 20) - 10 Sep 2020 (Study Day 30)	Left Eye Post Cataract Surgery Infection Preventive
Influenza vaccine	07 Oct 2020 (Study Day 57) - 07 Oct 2020 (Study Day 57)	Influenza Prophylactic
Apixaban	02 Mar 2021 (Study Day 203) - Ongoing	Atrial Fibrillation
Robotic assisted paraesophageal hernia repair*	03 Mar 2021 (Study Day 204) - 03 Mar 2021 (Study Day 204)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Atrial Fibrillation	Grade 2/moderate	Not applicable	02 Mar 2021 (Study Day 203) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US385-2015 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 24 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 21 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 19 Jan 2021 (Study Day 149)
Second Dose of Vaccine in Part B: 17 Feb 2021 (Study Day 178)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Back Pain/Worsening Back Pain	SAE	Grade 3/severe	Not related	28 Mar 2021 (Study Day 217) – 31 Mar 2021 (Study Day 220)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US385-2015, a 69-year-old not Hispanic or Latino female, received the first dose of Placebo in the right arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 21 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 19 Jan 2021. The participant was unblinded on 19 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 19 Jan 2021 (Study Day 149). The second dose was administered in the right arm on 17 Feb 2021 (Study Day 178).

Event Details

On 28 Mar 2021 (Study Day 217), 216 days after the first dose in Part A/68 days after the first dose in Part B and 188 days after the second dose in Part A/39 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of back pain. Action taken with the IP was not applicable. The event of worsening back pain lasted for 4 days, after which it was considered to be recovered/resolved on 31 Mar 2021 (Study Day 220). The investigator assessed the event of back pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-079771	Back pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Chronic back pain	Not reported - Ongoing
Hypothyroidism	Hypothyroidism	1990 - Ongoing
Blood oestrogen decreased	Low estrogen level	1995 - Ongoing
Hysterectomy	Hysterectomy	1995 - 1995
Oophorectomy	Oophorectomy	1995 - 1995
Asthma	Asthma	1996 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2005 - Ongoing
Insomnia	Insomnia	2010 - Ongoing
Botulinum toxin injection	Botox	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Estradiol	1997 - Ongoing	Low Estrogen Level
Zolpidem tartrate	2010 - Ongoing	Insomnia
Levothyroxine	2019 - Ongoing	Hypothyroidism
Pravastatin	2019 - Ongoing	Hyperlipidemia
Clindamycin	31 Aug 2020 (Study Day 8) - 06 Sep 2020 (Study Day 14)	Prophylaxis Tooth Extraction (Subject Has Prior Joint Replacement)
Ibuprofen	31 Aug 2020 (Study Day 8) - 06 Sep 2020 (Study Day 14)	Prophylaxis Tooth Extraction For Swelling
Tooth extraction*	31 Aug 2020 (Study Day 8) - 31 Aug 2020 (Study Day 8)	Other, Dental Work
Influenza vaccine	06 Oct 2020 (Study Day 44) - 06 Oct 2020 (Study Day 44)	Prophylaxis For Influenza
Guaifenesin	14 Dec 2020 (Study Day 113) - 30 Dec 2020 (Study Day 129)	Nasal Congestion Due To COVID-19
Methocarbamol	28 Dec 2020 (Study Day 127) - 08 Jan 2021 (Study Day 138)	Sciatica Left Leg
Ibuprofen	29 Dec 2020 (Study Day 128) - 08 Jan 2021 (Study Day 138)	Sciatica Left Leg

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US385-2177 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 11 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 06 Oct 2020 (Study Day 26)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia/Pneumonia	SAE	Grade 3/severe	Not related	13 Apr 2021 (Study Day 215) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US385-2177, a 53-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 06 Oct 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 10 Feb 2021. The participant was unblinded on 10 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 13 Apr 2021 (Study Day 215), 214 days after the first dose in Part A and 189 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of pneumonia was considered to be ongoing. The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-079910	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Insomnia	Insomnia	1995 - Ongoing
Hyperlipidaemia	Hyperlipidemia	1996 - Ongoing
Asthma	Asthma	2019 - Ongoing
Hypertension	Hypertension	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	Not reported - Ongoing	Hyperlipidemia
Losartan	Not reported - Ongoing	Hypertension
Montelukast	Not reported - Ongoing	Asthma
Zolpidem tartrate	Not reported - Ongoing	Insomnia
Triamcinolone	29 Sep 2020 (Study Day 19) - 13 Oct 2020 (Study Day 33)	Rash In Perineal Area-Non-Urticarial
Influenza vaccine	30 Nov 2020 (Study Day 81) - 30 Nov 2020 (Study Day 81)	Flu Shot
Acetylsalicylic acid	23 Feb 2021 (Study Day 166) - Ongoing	Blood Thinner

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US386-2007 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 13 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Kidney Injury/Acute Kidney Injury	SAE	Grade 3/severe	Not related	11 Mar 2021 (Study Day 211) – 14 Mar 2021 (Study Day 214)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2007, a 65-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 05 Jan 2021. The participant was unblinded on 05 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 11 Mar 2021 (Study Day 211), 210 days after the first dose in Part A and 182 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of acute kidney injury. Action taken with the IP was not applicable. The event of acute kidney injury lasted for 4 days, after which it was considered to be recovered/resolved on 14 Mar 2021 (Study Day 214). The investigator assessed the event of acute kidney injury to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-043395	Acute kidney injury

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gestational diabetes	Gestational diabetes	Jun 1983 - Dec 1983
Caesarean section	Cesarian section	Dec 1983 - Dec 1983
Obesity	Obesity	Jan 1984 - Ongoing
Hypothyroidism	Hypothyroidism	1985 - Ongoing
Papillary thyroid cancer	Papillary thyroid carcinoma	1985 - 1985
Thyroidectomy	Thyroidectomy	1985 - 1985
Genital herpes	Genital herpes	1987 - Ongoing
Osteoarthritis	Osteoarthritis	1990 - Ongoing
Caesarean section	Cesarian section	Dec 1995 - Dec 1995
Salpingo-oophorectomy bilateral	Bilateral salpingo-oophorectomy	2006 - 2006
Hysterectomy	Total abdominal hysterectomy	Sep 2006 - Sep 2006
Haemorrhoids thrombosed	External thrombosed hemorrhoids	Jun 2009 - Jul 2009
Sleep apnoea syndrome	Obstructive sleep apnea	Mar 2012 - Ongoing
Hip arthroplasty	Total hip replacement (right)	Jan 2013 - Jan 2013
Hyperlipidaemia	Hyperlipidemia	2014 - Ongoing
Narcolepsy	Narcolepsy	2015 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	2015 - Ongoing
Osteopenia	Osteopenia	01 Sep 2016 (Study Day -1442) - Ongoing
Constipation	Constipation	2017 - Ongoing
Iron deficiency anaemia	Iron deficiency anemia	Sep 2017 - Dec 2017
Seasonal allergy	Seasonal allergies	2018 - Ongoing
Knee arthroplasty	Knee replacement (left)	16 Dec 2019 (Study Day -241) - 16 Dec 2019 (Study Day -241)
Deep vein thrombosis	Anterior tibial vein thrombosis	20 Feb 2020 (Study Day -175) - Jun 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	1980 - 12 Mar 2021 (Study Day 212)	Osteoarthritis
Levothyroxine sodium	1985 - Ongoing	Hypothyroidism
Valaciclovir hydrochloride	2014 - Ongoing	Genital Herpes
Metformin	2015 - Ongoing	Type 2 Diabetes
Simvastatin	2015 - Ongoing	Hyperlipidemia
Vitamins nos	2015 - Ongoing	General Health
Docusate sodium	2017 - Ongoing	Constipation
Ferrous sulfate	2017 - Ongoing	Prophylaxis For Nutritional Deficiency

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Melatonin	2017 - Ongoing	Sleep Aide
Ascorbic acid	2018 - Ongoing	Prophylaxis For Nutritional Deficiency
Cetirizine hydrochloride	2018 - Ongoing	Seasonal Allergies
Colecalciferol	Mar 2020 - 12 Mar 2021 (Study Day 212)	General Health
Zinc	Mar 2020 - Ongoing	General Health
Acetylsalicylic acid	01 Jul 2020 (Study Day -43) - Ongoing	Superficial Thrombosis
Celecoxib	28 Sep 2020 (Study Day 47) - 05 Oct 2020 (Study Day 54)	Osteoarthritis
Diclofenac	28 Sep 2020 (Study Day 47) - 28 Sep 2020 (Study Day 47)	Osteoarthritis
Influenza vaccine	02 Oct 2020 (Study Day 51) - 02 Oct 2020 (Study Day 51)	Prevention Of Influenza
Celecoxib	06 Oct 2020 (Study Day 55) - 12 Mar 2021 (Study Day 212)	Osteoarthritis
Ibuprofen	08 Nov 2020 (Study Day 88) - 08 Nov 2020 (Study Day 88)	Neck Pain
Menthol	08 Nov 2020 (Study Day 88) - 10 Nov 2020 (Study Day 90)	Neck Pain
Ibuprofen	09 Nov 2020 (Study Day 89) - 09 Nov 2020 (Study Day 89)	Neck Pain
Chlorphenamine maleate; dextromethorphan hydrobromide; paracetamol	05 Dec 2020 (Study Day 115) - 07 Dec 2020 (Study Day 117)	Viral Upper Respiratory Symptoms
Acetylsalicylic acid	11 Mar 2021 (Study Day 211) - 11 Mar 2021 (Study Day 211)	Neurologic Issue Due To Acute Kidney Injury
Chest xray*	11 Mar 2021 (Study Day 211) - 11 Mar 2021 (Study Day 211)	Adverse Event
Ct scan of brain*	11 Mar 2021 (Study Day 211) - 11 Mar 2021 (Study Day 211)	Adverse Event
Ekg*	11 Mar 2021 (Study Day 211) - 11 Mar 2021 (Study Day 211)	Adverse Event
Lorazepam	11 Mar 2021 (Study Day 211) - 11 Mar 2021 (Study Day 211)	Mri
Mra head and neck*	11 Mar 2021 (Study Day 211) - 11 Mar 2021 (Study Day 211)	Adverse Event
Mri of brain*	11 Mar 2021 (Study Day 211) - 11 Mar 2021 (Study Day 211)	Adverse Event
Sodium chloride	11 Mar 2021 (Study Day 211) - 11 Mar 2021 (Study Day 211)	Acute Kidney Injury
Renal ultrasound*	12 Mar 2021 (Study Day 212) - 12 Mar 2021 (Study Day 212)	Adverse Event
Nitrofurantoin	16 Mar 2021 (Study Day 216) - 25 Mar 2021 (Study Day 225)	Urinary Tract Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Carotid Artery Aneurysm	Grade 2/moderate	Not related	11 Mar 2021 (Study Day 211) - Ongoing
Urinary Tract Infection	Grade 1/mild	Not applicable	11 Mar 2021 (Study Day 211) - 25 Mar 2021 (Study Day 225)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US386-2020 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 17 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Sep 2020 (Study Day 31)
First Dose of Vaccine in Part B: 02 Mar 2021 (Study Day 198)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Anaemia/Severe Anemia	SAE	Grade 3/severe	Not related	28 Apr 2021 (Study Day 255) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2020, a 61-year-old Hispanic or Latino male, received the first dose of Placebo in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 02 Mar 2021. The participant was unblinded on 02 Mar 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the right arm on 02 Mar 2021 (Study Day 198). The second dose was not administered.

Event Details

On 28 Apr 2021 (Study Day 255), 254 days after the first dose in Part A/57 days after the first dose in Part B and 224 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of anaemia. Action taken with the IP was not applicable. The event of severe anemia was considered to be ongoing. The investigator assessed the event of anaemia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-101188	Iron deficiency anaemia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	2010 - Ongoing
Hypertension	Hypertension	2018 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	Mar 2020 - Ongoing
Hyperlipidaemia	Hyperlipidemia	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	2018 - Ongoing	Diabetes Mellitus Type 2
Gabapentin	Jun 2019 - Jun 2019	Peripheral Neuropathy
Atorvastatin	Mar 2020 - 15 Feb 2021 (Study Day 183)	Hyperlipidemia
Glipizide	Mar 2020 - 12 Jan 2021 (Study Day 149)	Diabetes Mellitus Type 2
Lisinopril	Mar 2020 - 15 Feb 2021 (Study Day 183)	Hypertension
Tamsulosin hydrochloride	Mar 2020 - Ongoing	Benign Prostatic Hyperplasia
Iron	30 Oct 2020 (Study Day 75) - Ongoing	Iron Deficiency Anemia
Macrogol; potassium chloride; sodium bicarbonate; sodium chloride; sodium sulfate	03 Jan 2021 (Study Day 140) - 03 Jan 2021 (Study Day 140)	Colonoscopy
Colonoscopy with biopsy*	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Adverse Event
Esophagogastroduodenoscopy with biopsy*	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Adverse Event
Fentanyl	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Colonoscopy
Fentanyl	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Endoscopy
Midazolam hydrochloride	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Colonoscopy
Midazolam hydrochloride	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Endoscopy
Moderate sedation*	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Adverse Event
Ferric carboxymaltose	13 Jan 2021 (Study Day 150) - 13 Jan 2021 (Study Day 150)	Iron Deficiency Anemia
Glipizide	13 Jan 2021 (Study Day 150) - Ongoing	Uncontrolled Type 2 Diabetes Mellitus
Vitamins nos	13 Jan 2021 (Study Day 150) - Ongoing	Anemia
Red blood cells, concentrated	19 Jan 2021 (Study Day 156) - 19 Jan 2021 (Study Day 156)	Iron Deficiency Anemia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ct of chest, abdomen and pelvis*	22 Jan 2021 (Study Day 159) - 22 Jan 2021 (Study Day 159)	Adverse Event
Gastric biopsy*	04 Feb 2021 (Study Day 172) - 04 Feb 2021 (Study Day 172)	Adverse Event
Upper endoscopy*	04 Feb 2021 (Study Day 172) - 04 Feb 2021 (Study Day 172)	Adverse Event
Diagnostic laparoscopy*	19 Feb 2021 (Study Day 187) - 19 Feb 2021 (Study Day 187)	Adverse Event
Paracetamol	19 Feb 2021 (Study Day 187) - 23 Feb 2021 (Study Day 191)	Pain Post Portha Cath Insertion
Port placement*	19 Feb 2021 (Study Day 187) - 19 Feb 2021 (Study Day 187)	Adverse Event
Mri abdomen*	20 Feb 2021 (Study Day 188) - 20 Feb 2021 (Study Day 188)	Adverse Event
Lidocaine; prilocaine	22 Feb 2021 (Study Day 190) - 22 Feb 2021 (Study Day 190)	Porth-A-Cath Access
Ondansetron	22 Feb 2021 (Study Day 190) - Ongoing	Chemotherapy Induced-Nausea
Pet/ct scan skull base to mid thigh*	22 Feb 2021 (Study Day 190) - 22 Feb 2021 (Study Day 190)	Adverse Event
Prochlorperazine	22 Feb 2021 (Study Day 190) - Ongoing	Chemotherapy Induced-Nausea
Pantoprazole	17 Mar 2021 (Study Day 213) - Ongoing	Prophylaxis For Heartburn

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US386-2099 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 31 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 13 Jan 2021 (Study Day 136)
Second Dose of Vaccine in Part B: 12 Feb 2021 (Study Day 166)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nephrolithiasis/Non Obstructing Left Nephrolithiasis	SAE	Grade 3/ severe	Not related	13 Mar 2021 (Study Day 195) – 11 Apr 2021 (Study Day 224)	Recovered/ resolved
Ureterolithiasis/Left Proximal And Distal Ureteral Calculi	SAE	Grade 3/ severe	Not related	13 Mar 2021 (Study Day 195) – 14 Mar 2021 (Study Day 196)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2099, a 51-year-old Hispanic or Latino male, received the first dose of Placebo in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 13 Jan 2021. The participant was unblinded on 13 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 13 Jan 2021 (Study Day 136). The second dose was administered in the left arm on 12 Feb 2021 (Study Day 166).

Event Details

On 13 Mar 2021 (Study Day 195), 194 days after the first dose in Part A/59 days after the first dose in Part B and 166 days after the second dose in Part A/29 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of nephrolithiasis. Action taken with the IP was not applicable. The event of non obstructing left nephrolithiasis lasted for 30 days, after which it was considered to be recovered/resolved on 11 Apr 2021 (Study Day 224). The investigator assessed the event of nephrolithiasis to be not related to the IP.

On 13 Mar 2021 (Study Day 195), 194 days after the first dose in Part A/59 days after the first dose in Part B and 166 days after the second dose in Part A/29 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of ureterolithiasis. Action taken with the IP was not applicable. The event of left proximal and distal ureteral calculi

lasted for 2 days, after which it was considered to be recovered/resolved on 14 Mar 2021 (Study Day 196). The investigator assessed the event of ureterolithiasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-048696	Ureterolithiasis
MOD-2021-048696	Nephrolithiasis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Pain	General body aches	2000 - Ongoing
Chronic hepatitis B	Chronic hepatitis b	Feb 2005 - Ongoing
HIV infection	Hiv	Dec 2018 - Ongoing
Glucose tolerance impaired	Prediabetes	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Entecavir	Feb 2005 - Ongoing	Hepatitis B
Cobicistat; darunavir ethanolate	Dec 2018 - Ongoing	Hiv
Doravirine	Dec 2018 - Ongoing	Hiv
Ibuprofen	2020 - Ongoing	General Pain
Ibuprofen	04 Oct 2020 (Study Day 35) - 04 Oct 2020 (Study Day 35)	General Pain Post Vaccination Reactogenicity Symptoms
Camphor; eucalyptus spp. oil; menthol	19 Oct 2020 (Study Day 50) - 19 Oct 2020 (Study Day 50)	Forehead Pain
Influenza vaccine	21 Oct 2020 (Study Day 52) - 21 Oct 2020 (Study Day 52)	Influenza
Ibuprofen	12 Feb 2021 (Study Day 166) - 12 Feb 2021 (Study Day 166)	Prophylaxis Post Vaccine Reactogenicity Symptoms
Calcium chloride dihydrate; potassium chloride; sodium chloride; sodium lactate	13 Mar 2021 (Study Day 195) - 14 Mar 2021 (Study Day 196)	Left Proximal And Distal Ureteral Calculi Non Obstructing Left Nephrolithiasis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Docusate sodium; sennoside a+b	13 Mar 2021 (Study Day 195) - 14 Mar 2021 (Study Day 196)	Left Proximal And Distal Ureteral Calculi Non Obstructing Left Nephrolithiasis
Morphine	13 Mar 2021 (Study Day 195) - 14 Mar 2021 (Study Day 196)	Left Proximal And Distal Ureteral Calculi Non Obstructing Left Nephrolithiasis
Phenazopyridine hydrochloride	13 Mar 2021 (Study Day 195) - 14 Mar 2021 (Study Day 196)	Left Proximal And Distal Ureteral Calculi Non Obstructing Left Nephrolithiasis
Sodium chloride	13 Mar 2021 (Study Day 195) - 14 Mar 2021 (Study Day 196)	Left Proximal And Distal Ureteral Calculi Non Obstructing Left Nephrolithiasis
Cystoscopy*	14 Mar 2021 (Study Day 196) - 14 Mar 2021 (Study Day 196)	Adverse Event
Laser lithotripsy*	14 Mar 2021 (Study Day 196) - 14 Mar 2021 (Study Day 196)	Adverse Event
Macrogol 3350	14 Mar 2021 (Study Day 196) - 14 Mar 2021 (Study Day 196)	Left Proximal And Distal Ureteral Calculi Non Obstructing Left Nephrolithiasis
Tamsulosin	14 Mar 2021 (Study Day 196) - 14 Mar 2021 (Study Day 196)	Left Proximal And Distal Ureteral Calculi Non Obstructing Left Nephrolithiasis
Ureteral stent placement*	14 Mar 2021 (Study Day 196) - 14 Mar 2021 (Study Day 196)	Adverse Event
Ureteroscopy*	14 Mar 2021 (Study Day 196) - 14 Mar 2021 (Study Day 196)	Adverse Event
Azithromycin	15 Mar 2021 (Study Day 197) - Ongoing	Prophylaxis For Pain Post Laparoscopic Surgery (Due To Nephrolithiasis)
Cefuroxime axetil	15 Mar 2021 (Study Day 197) - 21 Mar 2021 (Study Day 203)	Prophylaxis For Infection Post Laparoscopic Surgery Due To Nephrolithiasis
Hydrocodone bitartrate; paracetamol	15 Mar 2021 (Study Day 197) - Ongoing	Prophylaxis For Pain Post Laparoscopic Surgery(Due To Nephrolithiasis)
Tolterodine	22 Mar 2021 (Study Day 204) - Ongoing	Prophylaxis For Urinary Spasm

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US386-2110 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 02 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 30 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cerebrovascular Accident/ Cerebrovascular Accident	SAE	Grade 3/ severe	Not related	29 Mar 2021 (Study Day 209) – 31 Mar 2021 (Study Day 211)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2110, a 60-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 30 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 22 Feb 2021. The participant was unblinded on 22 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 29 Mar 2021 (Study Day 209), 208 days after the first dose in Part A and 180 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of cerebrovascular accident. Action taken with the IP was not applicable. The event of cerebrovascular accident lasted for 3 days, after which it was considered to be recovered/resolved with sequelae on 31 Mar 2021 (Study Day 211). The investigator assessed the event of cerebrovascular accident to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-067762	Transient ischaemic attack

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Keratoconus	Keratoconus	1980 - Ongoing
Blindness unilateral	Blind left eye	1986 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	1995 - Ongoing
Hypertension	Hypertension	1995 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	1996 - Ongoing
Drug eruption	Drug allergy: bactrim (rash)	1998 - Ongoing
Pruritus allergic	Drug allergy: hydrocodone (itch)	1998 - Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2000 - Ongoing
Peripheral sensory neuropathy	Sensory neuropathy in both feet	2010 - Ongoing
Transurethral prostatectomy	Transurethral resection of the prostate	Mar 2010 - Mar 2010
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2014 - Ongoing
HIV infection	Human immunodeficiency virus	2014 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2014 - Ongoing
Dry skin	Dry skin	2018 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2018 - Ongoing
Anxiety	Anxiety	2020 - Ongoing
Obesity	Obesity	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Furosemide	2010 - 21 Oct 2020 (Study Day 50)	Hypertension
Gabapentin	2010 - Ongoing	Sensory Neuropathy In Both Feet
Dulaglutide	2014 - Ongoing	Diabetes Type Ii
Lisinopril	2014 - 26 Jan 2021 (Study Day 147)	Hypertension
Dapagliflozin propanediol monohydrate	2016 - Ongoing	Diabetes Type Ii
Esomeprazole magnesium	2016 - Ongoing	Gastroesophageal Reflux Disease
Evolocumab	2017 - Ongoing	Hypercholesterolemia
Ammonium lactate	2018 - Ongoing	Dry Skin

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ergocalciferol	2018 - Ongoing	Vitamin D Deficiency
Loratadine	2018 - Ongoing	Seasonal Allergies
Mirabegron	2018 - Ongoing	Benign Prostatic Hyperplasia
Clonidine	2019 - 21 Oct 2020 (Study Day 50)	Hypertension
Dolutegravir sodium; lamivudine	2020 - Ongoing	Human Immunodeficiency Virus
Phentermine	2020 - Ongoing	Obesity
Topiramate	2020 - Ongoing	Anxiety
Paracetamol	04 Sep 2020 (Study Day 3) - 04 Sep 2020 (Study Day 3)	Post Vaccination Reactogenicity Symptom: Headache
Bacitracin; neomycin sulfate; polymyxin b sulfate	02 Oct 2020 (Study Day 31) - 03 Oct 2020 (Study Day 32)	Mosquito Bites On Bilateral Arms And Legs
Bumetanide	24 Oct 2020 (Study Day 53) - Ongoing	Hypertension
Diltiazem	24 Oct 2020 (Study Day 53) - Ongoing	Hypertension
Influenza vaccine	26 Oct 2020 (Study Day 55) - 26 Oct 2020 (Study Day 55)	Influenza Prevention
Ct scan of abdomen and pelvis*	18 Nov 2020 (Study Day 78) - 18 Nov 2020 (Study Day 78)	Adverse Event
Colonoscopy*	30 Nov 2020 (Study Day 90) - 30 Nov 2020 (Study Day 90)	Adverse Event
Bupropion hydrochloride; naltrexone hydrochloride	14 Dec 2020 (Study Day 104) - 20 Dec 2020 (Study Day 110)	Uncontrolled Obesity
Bupropion hydrochloride; naltrexone hydrochloride	21 Dec 2020 (Study Day 111) - 27 Dec 2020 (Study Day 117)	Uncontrolled Obesity
Bupropion hydrochloride; naltrexone hydrochloride	28 Dec 2020 (Study Day 118) - 03 Jan 2021 (Study Day 124)	Uncontrolled Obesity
Bupropion hydrochloride; naltrexone hydrochloride	04 Jan 2021 (Study Day 125) - Ongoing	Uncontrolled Obesity
Hydralazine	19 Jan 2021 (Study Day 140) - 19 Jan 2021 (Study Day 140)	Uncontrolled Hypertension
Morphine	19 Jan 2021 (Study Day 140) - 19 Jan 2021 (Study Day 140)	Headache
Lisinopril	27 Jan 2021 (Study Day 148) - Ongoing	Uncontrolled Hypertension
Cynara cardunculus; malus spp. vinegar extract; taraxacum officinale	15 Feb 2021 (Study Day 167) - Ongoing	General Well Being

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dysphemia	Grade 1/mild	Not related	26 Feb 2021 (Study Day 178) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US386-2128 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 02 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diverticulitis/ Diverticulitis	SAE	Grade 3/ severe	Not related	25 Apr 2021 (Study Day 234) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2128, a 69-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 02 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 22 Feb 2021. The participant was unblinded on 22 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 25 Apr 2021 (Study Day 234), 233 days after the first dose in Part A and 205 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of diverticulitis. Action taken with the IP was not applicable. The event of diverticulitis was considered to be ongoing. The investigator assessed the event of diverticulitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-096980	Diverticulitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Thrombosis	Superficial leg blood clot	1985 - 1985
Autoimmune thyroiditis	Hashimoto's hypothyroidism	1987 - Ongoing
Seasonal allergy	Seasonal allergies	1995 - Ongoing
Postmenopause	Post menopausal	1999 - Ongoing
Osteopenia	Osteopenia	2005 - Ongoing
Hypobarism	Altitude sickness	2008 - Ongoing
Drug hypersensitivity	Allergy to anesthesia medication(transaminitis)	2013 - Ongoing
Blood cholesterol increased	Elevated cholesterol	2014 - Ongoing
Adverse drug reaction	Arthralgias as side effect of letrozole	2017 - Ongoing
Adverse drug reaction	Myalgia as side effect of letrozole	2017 - Ongoing
Gastroesophageal reflux disease	Acid reflux	2017 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	2017 - Ongoing
Invasive ductal breast carcinoma	Left breast cancer(invasive ductal carcinoma)	May 2017 - Jan 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine sodium	1987 - Ongoing	Hypothyroidism
Acetazolamide	2008 - Ongoing	Altitude Sickness
Rosuvastatin	2014 - Ongoing	Elevated Cholesterol
Calcium	2017 - Ongoing	Osteopenia
Colecalciferol	2017 - Ongoing	Osteopenia
Letrozole	2017 - Ongoing	Breast Cancer
Denosumab	2019 - Ongoing	Osteopenia
Psyllium hydrophilic mucilloid	2020 - Ongoing	Irritable Bowel Disease
Vitamin b12 nos	May 2020 - Ongoing	Prophylaxis For Good Health
Paracetamol	03 Oct 2020 (Study Day 30) - 03 Oct 2020 (Study Day 30)	Solicited Symptoms: Low Grade Fever, Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US386-2144 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 07 Oct 2020 (Study Day 30)
First Dose of Vaccine in Part B: 25 Jan 2021 (Study Day 140)
Second Dose of Vaccine in Part B: 01 Mar 2021 (Study Day 175)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intestinal Obstruction/Partial Bowel Obstruction	SAE	Grade 3/severe	Not related	19 Feb 2021 (Study Day 165) – 24 Feb 2021 (Study Day 170)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2144, a 53-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 25 Jan 2021. The participant was unblinded on 25 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 25 Jan 2021 (Study Day 140). The second dose was administered in the left arm on 01 Mar 2021 (Study Day 175).

Event Details

On 19 Feb 2021 (Study Day 165), 164 days after the first dose in Part A/25 days after the first dose in Part B and 135 days after the second dose in Part A/10 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of intestinal obstruction. The IP dose was not changed due to the partial bowel obstruction. The event of partial bowel obstruction lasted for 6 days, after which it was considered to be recovered/resolved on 24 Feb 2021 (Study Day 170). The investigator assessed the event of intestinal obstruction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-026301	Intestinal obstruction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
HIV infection	Human immunodeficiency virus	Aug 1999 - Ongoing
Pneumocystis jirovecii infection	S/p pneumocystis	Aug 1999 - Aug 2000
Hypertension	High blood pressure	2000 - Ongoing
Back pain	Chronic back pain	2010 - Ongoing
Neuropathy peripheral	Peripheal neuropathy	2010 - Ongoing
Osteoarthritis	Osteoarthritis	2010 - Ongoing
Oedema peripheral	Edema bilateral legs and ankles	2018 - Ongoing
Vitamin B12 deficiency	B12 deficiency	2018 - Ongoing
Anal abscess	Recurrent perianal abscess	May 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrocodone bitartrate; paracetamol	2010 - Ongoing	Chronic Back Pain
Pregabalin	2018 - Ongoing	Peripheral Neuropathy
Vitamin b12 nos	2018 - Ongoing	B12 Deficiency
Amlodipine	2019 - Ongoing	High Blood Pressure
Emtricitabine; rilpivirine hydrochloride; tenofovir alafenamide fumarate	2019 - Ongoing	Human Immunodeficiency Virus
Hydrochlorothiazide	2019 - Ongoing	High Blood Pressure
Influenza vaccine	23 Oct 2020 (Study Day 46) - 23 Oct 2020 (Study Day 46)	Influenza Prevention
Ciprofloxacin	06 Nov 2020 (Study Day 60) - 15 Nov 2020 (Study Day 69)	Perirectal Abscess
Doxycycline	06 Nov 2020 (Study Day 60) - 15 Nov 2020 (Study Day 69)	Perirectal Abscess
Metronidazole	06 Nov 2020 (Study Day 60) - 15 Nov 2020 (Study Day 69)	Perirectal Abscess
Colonoscopy*	02 Dec 2020 (Study Day 86) - 02 Dec 2020 (Study Day 86)	Adverse Event
Mri*	22 Jan 2021 (Study Day 137) - 22 Jan 2021 (Study Day 137)	Adverse Event
Gabapentin	03 Feb 2021 (Study Day 149) - 28 Feb 2021 (Study Day 174)	Prophylaxes For Rectal Pain For Seton Placement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	03 Feb 2021 (Study Day 149) - 28 Feb 2021 (Study Day 174)	Prophylaxes For Rectal Pain For Seton Placement
Macrogol 3350	03 Feb 2021 (Study Day 149) - 28 Feb 2021 (Study Day 174)	Prophylaxes For Rectal Pain For Seton Placement
Seton placement*	03 Feb 2021 (Study Day 149) - 03 Feb 2021 (Study Day 149)	Adverse Event
Ct abdomen and pelvis*	21 Feb 2021 (Study Day 167) - 21 Feb 2021 (Study Day 167)	Adverse Event
Electrocardiogram*	21 Feb 2021 (Study Day 167) - 21 Feb 2021 (Study Day 167)	Adverse Event
Morphine sulfate	21 Feb 2021 (Study Day 167) - 22 Feb 2021 (Study Day 168)	Sac#3 Partial Small Bowel Obstruction
Ondansetron	21 Feb 2021 (Study Day 167) - 21 Feb 2021 (Study Day 167)	Sac#3 Partial Small Bowel Obstruction
Sodium chloride	21 Feb 2021 (Study Day 167) - 21 Feb 2021 (Study Day 167)	Sac#3 Partial Small Bowel Obstruction
Abdominal x-ray*	22 Feb 2021 (Study Day 168) - 22 Feb 2021 (Study Day 168)	Adverse Event
Morphine sulfate	22 Feb 2021 (Study Day 168) - 22 Feb 2021 (Study Day 168)	Sac#3 Partial Small Bowel Obstruction
Ngt placement*	22 Feb 2021 (Study Day 168) - 22 Feb 2021 (Study Day 168)	Adverse Event
Ngt removal*	22 Feb 2021 (Study Day 168) - 22 Feb 2021 (Study Day 168)	Adverse Event
Probiotics nos	24 Feb 2021 (Study Day 170) - 01 Mar 2021 (Study Day 175)	General Health

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US387-2083 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 65 Years
First Dose of Vaccine in Part A: 07 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Vertigo/Vertigo	SAE	Grade 3/severe	Not related	25 Jan 2021 (Study Day 172) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US387-2083, a 71-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 25 Jan 2021. The participant was unblinded on 25 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 25 Jan 2021 (Study Day 172), 171 days after the first dose in Part A and 143 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of vertigo. Action taken with the IP was not applicable. The event of vertigo was considered to be ongoing. The investigator assessed the event of vertigo to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009736	Vertigo

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Aspirin allergy	1968 - Ongoing
Inguinal hernia	Inguinal hernia	1969 - 1969
Arthritis	Arthritis bilateral hands	2011 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	19 Oct 2020 (Study Day 74) - 19 Oct 2020 (Study Day 74)	Flu
Famotidine	25 Jan 2021 (Study Day 172) - 05 Feb 2021 (Study Day 183)	Gastroesophageal Reflux
12 lead ecg*	28 Jan 2021 (Study Day 175) - 28 Jan 2021 (Study Day 175)	Other, Rule Out Cardiac Involvement
Atorvastatin	28 Jan 2021 (Study Day 175) - 18 Feb 2021 (Study Day 196)	Mixed Hyperlipidemia
Ct scan head w/o contrast*	28 Jan 2021 (Study Day 175) - 28 Jan 2021 (Study Day 175)	Adverse Event
Enoxaparin sodium	28 Jan 2021 (Study Day 175) - 30 Jan 2021 (Study Day 177)	Stroke Prevention
Magnesium sulfate	28 Jan 2021 (Study Day 175) - 28 Jan 2021 (Study Day 175)	Prolonged Qt Interval
Tamsulosin	28 Jan 2021 (Study Day 175) - 18 Feb 2021 (Study Day 196)	Bph
Carotid duplex ultrasound*	29 Jan 2021 (Study Day 176) - 29 Jan 2021 (Study Day 176)	Adverse Event
Clopidogrel bisulfate	29 Jan 2021 (Study Day 176) - 18 Feb 2021 (Study Day 196)	Stroke Prevention
Meclozine	29 Jan 2021 (Study Day 176) - 18 Feb 2021 (Study Day 196)	Vertigo
Fluticasone propionate	22 Feb 2021 (Study Day 200) - 01 Mar 2021 (Study Day 207)	Nasal Congestion

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gastroesophageal Reflux Disease	Grade 2/moderate	Not related	25 Jan 2021 (Study Day 172) - 05 Feb 2021 (Study Day 183)
Aspartate Aminotransferase Increased	Grade 1/mild	Not related	28 Jan 2021 (Study Day 175) - Ongoing
Brain Scan Abnormal	Grade 3/severe	Not related	28 Jan 2021 (Study Day 175) - Ongoing
Carotid Arteriosclerosis	Grade 2/moderate	Not related	28 Jan 2021 (Study Day 175) - Ongoing
Electrocardiogram Qt Prolonged	Grade 2/moderate	Not related	28 Jan 2021 (Study Day 175) - Ongoing
Glucose Tolerance Impaired	Grade 1/mild	Not related	28 Jan 2021 (Study Day 175) - Ongoing
Haemoconcentration	Grade 1/mild	Not related	28 Jan 2021 (Study Day 175) - 29 Jan 2021 (Study Day 176)
Hypercalcaemia	Grade 1/mild	Not related	28 Jan 2021 (Study Day 175) - 29 Jan 2021 (Study Day 176)
Ketonuria	Grade 1/mild	Not related	28 Jan 2021 (Study Day 175) - Ongoing
Nitrite Urine Present	Grade 1/mild	Not related	28 Jan 2021 (Study Day 175) - Ongoing
Type V Hyperlipidaemia	Grade 2/moderate	Not related	28 Jan 2021 (Study Day 175) - Ongoing
Cerebral Ischaemia	Grade 2/moderate	Not related	29 Jan 2021 (Study Day 176) - Ongoing
Hyperbilirubinaemia	Grade 1/mild	Not related	29 Jan 2021 (Study Day 176) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US387-2187 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 14 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 18 Sep 2020 (Study Day 36)
First Dose of Vaccine in Part B: 06 Jan 2021 (Study Day 146)
Second Dose of Vaccine in Part B: 03 Feb 2021 (Study Day 174)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis/Appendicitis	SAE	Grade 3/ severe	Not related	07 Mar 2021 (Study Day 206) – Ongoing	Recovering/ resolving
Appendicitis Perforated/ Perforated Appendix	SAE	Grade 3/ severe	Not related	18 Mar 2021 (Study Day 217) – 24 Mar 2021 (Study Day 223)	Recovered/ resolved with sequelae
Appendiceal Abscess/ Peri-Appendiceal Abscess	SAE	Grade 3/ severe	Not related	23 Mar 2021 (Study Day 222) – 24 Mar 2021 (Study Day 223)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US387-2187, a 64-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 06 Jan 2021 (Study Day 146). The second dose was administered in the left arm on 03 Feb 2021 (Study Day 174).

Event Details

On 07 Mar 2021 (Study Day 206), 205 days after the first dose in Part A/60 days after the first dose in Part B and 170 days after the second dose in Part A/32 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of appendicitis. Action taken with the IP was not applicable. The event of appendicitis was considered to be ongoing. The investigator assessed the event of appendicitis to be not related to the IP.

On 18 Mar 2021 (Study Day 217), 216 days after the first dose in Part A/71 days after the first dose in Part B and 181 days after the second dose in Part A/43 days after the second dose in Part B

of the IP, the participant experienced a Grade 3/severe serious adverse event of appendicitis perforated. Action taken with the IP was not applicable. The event of perforated appendix lasted for 7 days, after which it was considered to be recovered/resolved with sequelae on 24 Mar 2021 (Study Day 223). The investigator assessed the event of appendicitis perforated to be not related to the IP.

On 23 Mar 2021 (Study Day 222), 221 days after the first dose in Part A/76 days after the first dose in Part B and 186 days after the second dose in Part A/48 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of appendiceal abscess. Action taken with the IP was not applicable. The event of peri-appendiceal abscess lasted for 2 days, after which it was considered to be recovered/resolved with sequelae on 24 Mar 2021 (Study Day 223). The investigator assessed the event of appendiceal abscess to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-079803	Appendicitis
MOD-2021-079803	Appendicitis perforated
MOD-2021-079803	Appendiceal abscess

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2002 - Ongoing
Osteoporosis	Osteoporosis	2010 - Ongoing
Postmenopause	Postmenopausal	2010 - Ongoing
Thyroid adenoma	Adenoma thyroid benign	2011 - 2011
Thyroidectomy	1/2 thyroid removed	2011 - 2011
Latent tuberculosis	Latent tuberculosis	2012 - Ongoing
Hysterectomy	Complete hysterectomy	Dec 2017 - Dec 2017
Drug hypersensitivity	Allergy penicillin	2019 - Ongoing
Myopia	Nearsightedness	2019 - Ongoing
Silicosis	Silicosis	Feb 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	2000 - Ongoing	Health Maintenance
Calcium	2000 - Ongoing	Health Maintenance
Vitamin d nos	2000 - Ongoing	Health Maintenance
Vitamins nos	2000 - Ongoing	Health Maintenance
Losartan	2002 - Ongoing	Hypertension
Alendronate sodium	2010 - Ongoing	Osteoporosis
Influenza vaccine	05 Oct 2020 (Study Day 53) - 05 Oct 2020 (Study Day 53)	Influenza Prevention
Naproxen sodium	06 Jan 2021 (Study Day 146) - 06 Jan 2021 (Study Day 146)	Injection Site Arm Pain
Ciprofloxacin	17 Jan 2021 (Study Day 157) - 20 Jan 2021 (Study Day 160)	Urinary Tract Infection
Paracetamol	03 Feb 2021 (Study Day 174) - 03 Feb 2021 (Study Day 174)	Pain At Injection Site
Bismuth subsalicylate	07 Mar 2021 (Study Day 206) - 18 Mar 2021 (Study Day 217)	Indigestion
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	07 Mar 2021 (Study Day 206) - 16 Mar 2021 (Study Day 215)	Body Aches
Naproxen sodium	08 Mar 2021 (Study Day 207) - 16 Mar 2021 (Study Day 215)	Body Aches
Paracetamol	08 Mar 2021 (Study Day 207) - 16 Mar 2021 (Study Day 215)	Body Aches
Ciprofloxacin	09 Mar 2021 (Study Day 208) - Ongoing	Urinary Tract Infection
Paracetamol	09 Mar 2021 (Study Day 208) - 16 Mar 2021 (Study Day 215)	Appendicitis
Ct scan (abdomen and pelvis) without contrast*	18 Mar 2021 (Study Day 217) - 18 Mar 2021 (Study Day 217)	Diagnostic
Cefepime	23 Mar 2021 (Study Day 222) - 23 Mar 2021 (Study Day 222)	Perforated Appendicix
Ct scan (abdomen and pelvis) with contrast*	23 Mar 2021 (Study Day 222) - 23 Mar 2021 (Study Day 222)	Diagnostic
Electrocardiogram*	23 Mar 2021 (Study Day 222) - 23 Mar 2021 (Study Day 222)	Diagnostic
Metronidazole	23 Mar 2021 (Study Day 222) - 23 Mar 2021 (Study Day 222)	Perforated Appendix
Levofloxacin	25 Mar 2021 (Study Day 224) - 29 Mar 2021 (Study Day 228)	Perforated Appendicix
Metronidazole	25 Mar 2021 (Study Day 224) - 31 Mar 2021 (Study Day 230)	Perforated Appendix

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	17 Jan 2021 (Study Day 157) – 20 Jan 2021 (Study Day 160)
Chills	Grade 1/mild	Not related	07 Mar 2021 (Study Day 206) - 15 Mar 2021 (Study Day 214)
Dyspepsia	Grade 2/moderate	Not related	07 Mar 2021 (Study Day 206) - 18 Mar 2021 (Study Day 217)
Fatigue	Grade 2/moderate	Not related	07 Mar 2021 (Study Day 206) - 15 Mar 2021 (Study Day 214)
Pain	Grade 2/moderate	Not related	07 Mar 2021 (Study Day 206) - 16 Mar 2021 (Study Day 215)
Pyrexia	Grade 1/mild	Not related	07 Mar 2021 (Study Day 206) - 15 Mar 2021 (Study Day 214)
Headache	Grade 1/mild	Not related	08 Mar 2021 (Study Day 207) - 11 Mar 2021 (Study Day 210)
Urinary Tract Infection	Grade 2/moderate	Not related	09 Mar 2021 (Study Day 208) - 16 Mar 2021 (Study Day 215)
Diarrhoea	Grade 2/moderate	Not related	10 Mar 2021 (Study Day 209) - 11 Mar 2021 (Study Day 210)
Myalgia	Grade 1/mild	Not related	13 Mar 2021 (Study Day 212) - 16 Mar 2021 (Study Day 215)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US389-2032 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 31 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 15 Feb 2021 (Study Day 169)
Second Dose of Vaccine in Part B: 12 Mar 2021 (Study Day 194)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Stress Fracture/Stress Fracture Left Foot	SAE	Grade 3/ severe	Not related	22 Mar 2021 (Study Day 204) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US389-2032, a 64-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 13 Jan 2021. The participant was unblinded on 15 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 15 Feb 2021 (Study Day 169). The second dose was administered in the left arm on 12 Mar 2021 (Study Day 194).

Event Details

On 22 Mar 2021 (Study Day 204), 203 days after the first dose in Part A/35 days after the first dose in Part B and 175 days after the second dose in Part A/10 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of stress fracture. Action taken with the IP was not applicable. The event of stress fracture left foot was considered to be ongoing. The investigator assessed the event of stress fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-089951	Foot deformity

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dysmenorrhoea	Dysmenorrhea	1990 - 2000
Obesity	Obesity	1990 - Ongoing
Oedema peripheral	Peripheral edema (bilateral- lower extremity)	1990 - Ongoing
Artificial menopause	Surgical post-menopausal	2000 - Ongoing
Hysterectomy	Hysterectomy	2000 - 2000
Osteoarthritis	Generalized osteoarthritis	2000 - Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Insomnia	Insomnia	2011 - Ongoing
Restless legs syndrome	Restless leg syndrome	2011 - Ongoing
Anxiety	Anxiety	2013 - Ongoing
Back pain	Lower back pain	2015 - Ongoing
Peripheral sensory neuropathy	Sensory peripheral neuropathy bilateral legs	2015 - Ongoing
Dry eye	Bilateral dry eyes	2018 - Ongoing
Oesophageal stenosis	Esophageal stricture	2018 - Ongoing
Dermal filler injection	Use of radiesse facial filler for cosmetic use	2019 - 2019
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Estradiol	2003 - Ongoing	Post Menopausal (Hormone Replacement)
Pramipexole	2011 - Ongoing	Restless Leg Syndrom
Trazodone	2011 - Ongoing	Insomnia
Diazepam	2013 - Ongoing	Anxiety
Cyclobenzaprine	2015 - Ongoing	Lower Back Pain
Hydrocodone; paracetamol	2015 - Ongoing	Lower Back Pain
Pregabalin	2015 - Ongoing	Sensory Peripheral Neuropathy Bilateral Legs
Ciclosporin	2018 - Ongoing	Bilateral Dry Eyes
Durapatite	2019 - 2019	Elective
Omeprazole	2019 - 12 Nov 2020 (Study Day 74)	Gastroesophageal Reflux Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amoxicillin	24 Sep 2020 (Study Day 25) - 24 Sep 2020 (Study Day 25)	Dental Prophylaxis
Routine dental cleaning*	24 Sep 2020 (Study Day 25) - 24 Sep 2020 (Study Day 25)	Other, Dental Prophylaxis
Diphenhydramine hydrochloride; paracetamol; phenylephrine hydrochloride	29 Sep 2020 (Study Day 30) - 10 Oct 2020 (Study Day 41)	Myalgia And Arthralgia
Diphenhydramine hydrochloride; paracetamol; phenylephrine hydrochloride	29 Sep 2020 (Study Day 30) - 12 Oct 2020 (Study Day 43)	Viral Syndrome And Headache
Ibuprofen	08 Oct 2020 (Study Day 39) - 12 Oct 2020 (Study Day 43)	Viral Syndrome
Barium swallow*	10 Nov 2020 (Study Day 72) - 10 Nov 2020 (Study Day 72)	Diagnostic
Omeprazole	12 Nov 2020 (Study Day 74) - Ongoing	Worsening Of Gerd
Prednisone	13 Nov 2020 (Study Day 75) - 18 Nov 2020 (Study Day 80)	Rash On Mid Back (Urticaria)
Diphenhydramine hydrochloride; paracetamol; phenylephrine hydrochloride	14 Nov 2020 (Study Day 76) - 19 Nov 2020 (Study Day 81)	Upper Respiratory Infection
Prednisone	18 Nov 2020 (Study Day 80) - 28 Nov 2020 (Study Day 90)	Urticaria
Ondansetron	11 Jan 2021 (Study Day 134) - 13 Jan 2021 (Study Day 136)	Nausea
Chest x-ray*	13 Jan 2021 (Study Day 136) - 13 Jan 2021 (Study Day 136)	Adverse Event
Doxycycline	13 Jan 2021 (Study Day 136) - 22 Jan 2021 (Study Day 145)	Acute Sinusitis
Ipratropium bromide	14 Jan 2021 (Study Day 137) - 20 Jan 2021 (Study Day 143)	Acute Bronchitis
Dextromethorphan hydrobromide; guaifenesin	15 Jan 2021 (Study Day 138) - 22 Jan 2021 (Study Day 145)	Acute Sinusitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Meniscus Injury	Grade 2/moderate	Not related	22 Mar 2021 (Study Day 204) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US389-2042 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 01 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Sep 2020 (Study Day 28)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Thoracic Vertebral Fracture/Spinal Fracture On T11 And T12	SAE	Grade 3/ severe	Not related	20 Feb 2021 (Study Day 173) – 23 Feb 2021 (Study Day 176)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US389-2042, a 44-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Dec 2021. The participant was unblinded on 21 Dec 2020 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 20 Feb 2021 (Study Day 173), 172 days after the first dose in Part A and 145 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of thoracic vertebral fracture. Action taken with the IP was not applicable. The event of spinal fracture on t11 and t12 lasted for 4 days, after which it was considered to be recovered/resolved with sequelae on 23 Feb 2021 (Study Day 176). The investigator assessed the event of thoracic vertebral fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-018794	Thoracic vertebral fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headaches	2000 - Ongoing
Seasonal allergy	Seasonal allergies	2012 - Ongoing
Inguinal hernia	Inguinal hernia	2018 - Jun 2020
Botulinum toxin injection	History of botox for cosmetic purposes	Jan 2020 - Jan 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2000 - Ongoing	Headaches
Cetirizine hydrochloride	2012 - Ongoing	Seasonal Allergies
Botulinum toxin type a	Jan 2020 - Jan 2020	Elective Cosmetic Procedure
Paracetamol	29 Sep 2020 (Study Day 29) - 30 Sep 2020 (Study Day 30)	Pain At The Injection Site And Fever
Steroids	15 Oct 2020 (Study Day 45) - Ongoing	Seasonal Allergies
Influenza vaccine	23 Oct 2020 (Study Day 53) - 23 Oct 2020 (Study Day 53)	Prophylaxis For Influenza
Botulinum toxin type a	Jan 2021 - Jan 2021	Elective Cosmetic Procedure
Cervical, thoracic, and lumbar x-ray*	20 Feb 2021 (Study Day 173) - 20 Feb 2021 (Study Day 173)	Diagnostic
Chest x-ray*	20 Feb 2021 (Study Day 173) - 20 Feb 2021 (Study Day 173)	Diagnostic
Diazepam	20 Feb 2021 (Study Day 173) - 20 Feb 2021 (Study Day 173)	Spinal Fracture
Hydromorphone	20 Feb 2021 (Study Day 173) - 20 Feb 2021 (Study Day 173)	Spinal Fracture
Hydromorphone hydrochloride	20 Feb 2021 (Study Day 173) - 20 Feb 2021 (Study Day 173)	Spinal Fracture
Lumbar ct scan (without contrast)*	20 Feb 2021 (Study Day 173) - 20 Feb 2021 (Study Day 173)	Diagnostic
Macrogol	20 Feb 2021 (Study Day 173) - 23 Feb 2021 (Study Day 176)	Bowel Prophylaxis
Midazolam hydrochloride	20 Feb 2021 (Study Day 173) - 20 Feb 2021 (Study Day 173)	Spinal Fracture
Morphine	20 Feb 2021 (Study Day 173) - 20 Feb 2021 (Study Day 173)	Spinal Fracture

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cyclobenzaprine hydrochloride	21 Feb 2021 (Study Day 174) - 18 Mar 2021 (Study Day 199)	Post Surgical Pain
Cyclobenzaprine hydrochloride	21 Feb 2021 (Study Day 174) - 23 Feb 2021 (Study Day 176)	Spinal Fracture
Ketorolac tromethamine	21 Feb 2021 (Study Day 174) - 22 Feb 2021 (Study Day 175)	Spinal Fracture
Oxycodone	21 Feb 2021 (Study Day 174) - 25 Feb 2021 (Study Day 178)	Spinal Fracture
Paracetamol	21 Feb 2021 (Study Day 174) - 18 Mar 2021 (Study Day 199)	Post Surgical Pain
Paracetamol	21 Feb 2021 (Study Day 174) - 23 Feb 2021 (Study Day 176)	Spinal Fracture
Anesthetics, general	22 Feb 2021 (Study Day 175) - 22 Feb 2021 (Study Day 175)	Spinal Fracture
Spinal fusion*	22 Feb 2021 (Study Day 175) - 22 Feb 2021 (Study Day 175)	Adverse Event
Vancomycin	22 Feb 2021 (Study Day 175) - 22 Feb 2021 (Study Day 175)	Spinal Fracture

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Procedural Pain	Grade 3/severe	Not related	22 Feb 2021 (Study Day 175) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US389-2054 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 02 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Depression/Worsening Of Depression	SAE	Grade 2/ moderate	Not related	01 Feb 2021 (Study Day 151) – 25 Mar 2021 (Study Day 203)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US389-2054, a 41-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 14 Jan 2021. The participant was unblinded on 14 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 01 Feb 2021 (Study Day 151), 150 days after the first dose in Part A and 122 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of depression. Action taken with the IP was not applicable. The event of worsening of depression lasted for 53 days, after which it was considered to be recovered/resolved on 25 Mar 2021 (Study Day 203). The investigator assessed the event of depression to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-066975	Depression

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	1995 - Ongoing
Tobacco user	Smoker	1996 - Ongoing
Fungal skin infection	Dermal fungal infection	1997 - Ongoing
Osteoarthritis	Left osteoarthritis hip	1997 - Ongoing
Anxiety	Anxiety	2009 - Ongoing
Intestinal strangulation	Strangulated bowel	Feb 2020 - Feb 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Aripiprazole	Jun 2020 - Ongoing	Depression
Citalopram hydrobromide	Jun 2020 - 10 Feb 2021 (Study Day 160)	Depression
Hydroxyzine	Jun 2020 - 15 Sep 2020 (Study Day 12)	Anxiety
Norethisterone	Jun 2020 - Ongoing	Birth Control
Buspirone	17 Sep 2020 (Study Day 14) - 21 Mar 2021 (Study Day 199)	Worsening Of Anxiety
Citalopram hydrobromide	10 Feb 2021 (Study Day 160) - 21 Mar 2021 (Study Day 199)	Worsening Of Depression
Buspirone	22 Mar 2021 (Study Day 200) - Ongoing	Worsening Of Anxiety
Paroxetine hydrochloride	22 Mar 2021 (Study Day 200) - Ongoing	Worsening Of Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	24 Mar 2021 (Study Day 202) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US390-2051 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 09 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 07 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Respiratory Syncytial Virus Infection/Respiratory Syncytial Virus	SAE	Grade 3/ severe	Not related	19 Mar 2021 (Study Day 192) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US390-2051, a 66-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 07 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Jan 2021. The participant was unblinded on 21 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 19 Mar 2021 (Study Day 192), 191 days after the first dose in Part A and 163 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of respiratory syncytial virus infection. Action taken with the IP was not applicable. The event of respiratory syncytial virus was considered to be ongoing. The investigator assessed the event of respiratory syncytial virus infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-062879	Respiratory syncytial virus infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1995 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2000 - Ongoing
Hypothyroidism	Hypothyroidism	2000 - Ongoing
Asthma	Asthma	2005 - Ongoing
Type 2 diabetes mellitus	Diabetes 2	2010 - Ongoing
Arthralgia	Right knee pain	May 2019 - Ongoing
Pollakiuria	Frequent urination	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	1995 - Ongoing	Hypertension
Acetylsalicylic acid	2000 - Ongoing	Heart Health
Levothyroxine	2000 - Ongoing	Hypothyroidism
Pravastatin	2000 - Ongoing	Hypercholesterolemia
Fluticasone propionate; salmeterol xinafoate	2005 - Ongoing	Asthma
Ipratropium bromide	2005 - Ongoing	Asthma
Ipratropium bromide; salbutamol sulfate	2005 - Ongoing	Asthma
Metformin	2010 - Ongoing	Diabetes Type Ii
Nifedipine	Mar 2019 - Ongoing	Hypertension
Tramadol	May 2019 - Ongoing	Right Knee Pain
Furosemide	Mar 2020 - Ongoing	Hypertension
Nebivolol hydrochloride	Mar 2020 - Ongoing	Hypertension
Influenza vaccine	08 Aug 2020 (Study Day -32) - 08 Aug 2020 (Study Day -32)	Influenza
Tamsulosin hydrochloride	15 Sep 2020 (Study Day 7) - 18 Nov 2020 (Study Day 71)	Worsening Of Frequent Urination

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US390-2060 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Oct 2020 (Study Day 35)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pancreatitis/Pancreatitis	SAE	Grade 3/severe	Not related	02 Mar 2021 (Study Day 174) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US390-2060, a 61-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 14 Oct 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 09 Feb 2021. The participant was unblinded on 09 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 02 Mar 2021 (Study Day 174), 173 days after the first dose in Part A and 139 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of pancreatitis. Action taken with the IP was not applicable. The event of pancreatitis was considered to be ongoing. The investigator assessed the event of pancreatitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-037755	Pancreatitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Diabetes mellitus	Diabetes	2010 - Ongoing
Gastroesophageal reflux disease	Gastric reflux	2012 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2015 - Ongoing
Hypertriglyceridaemia	Hypertriglyceridemia	2015 - Ongoing
Hypersensitivity	Environmental allergies	2016 - Ongoing
Hypertension	Hypertension	Aug 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	2012 - Ongoing	Diabetes
Omeprazole	2012 - Ongoing	Gastric Reflux
Atorvastatin	2015 - Ongoing	Hypercholesterolemia
Fenofibrate	2015 - Ongoing	Hypertriglyceridemia
Loratadine	2016 - Ongoing	Environmental Allergies
Losartan	Aug 2019 - Ongoing	Hypertension
Paracetamol	15 Oct 2020 (Study Day 36) - 15 Oct 2020 (Study Day 36)	Myalgia
Erythromycin	27 Oct 2020 (Study Day 48) - 30 Oct 2020 (Study Day 51)	Right Earache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US391-2046 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 31 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 26 Feb 2021 (Study Day 180)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Brain Stem Infarction/ Acute Pontine Infarct	SAE, AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	22 Mar 2021 (Study Day 204) – 30 Mar 2021 (Study Day 212)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US391-2046, a 59-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 13 Jan 2021. The participant was unblinded on 13 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 26 Feb 2021 (Study Day 180). The second dose was not administered.

Event Details

On 22 Mar 2021 (Study Day 204), 203 days after the first dose in Part A/24 days after the first dose in Part B and 175 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of brain stem infarction. The IP dose was withdrawn due to the acute pontine infarct. The event of acute pontine infarct lasted for 9 days, after which it was considered to be recovered/resolved with sequelae on 30 Mar 2021 (Study Day 212). The investigator assessed the event of brain stem infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-059203	Brain stem infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - Ongoing
Hyperlipidaemia	Hyperlipidemia	1987 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	1997 - Ongoing
Hypertension	Hypertension	2012 - Ongoing
Erectile dysfunction	Erectile dysfunction	2014 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2014 - Ongoing
Autism spectrum disorder	Aspergers syndrome	2015 - Ongoing
Diabetic neuropathy	Diabetic neuropathy - bilateral feet	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loperamide	2015 - 23 Oct 2020 (Study Day 54)	Irritable Bowel Syndrome
Insulin human	2017 - 22 Mar 2021 (Study Day 204)	Type Ii Diabetes
Insulin human injection, isophane	2017 - 22 Mar 2021 (Study Day 204)	Type Ii Diabetes
Verapamil	2019 - Ongoing	Hypertension
Metformin hydrochloride	Feb 2019 - 30 Mar 2021 (Study Day 212)	Type Ii Diabetes
Losartan	Feb 2020 - 30 Mar 2021 (Study Day 212)	Hypertension
Acetylsalicylic acid	18 Aug 2020 (Study Day -13) - 15 Sep 2020 (Study Day 16)	Cardiac Prophylaxis
Atorvastatin	18 Aug 2020 (Study Day -13) - 30 Mar 2021 (Study Day 212)	Hyperlipidemia
Acetylsalicylic acid	16 Sep 2020 (Study Day 17) - 24 Mar 2021 (Study Day 206)	Cardiac Prophylaxis
Hydrochlorothiazide	19 Sep 2020 (Study Day 20) - 25 Mar 2021 (Study Day 207)	Hypertension (Worsening Of) Ae
Butyric acid	23 Oct 2020 (Study Day 54) - Ongoing	Ibs

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	02 Nov 2020 (Study Day 64) - 02 Nov 2020 (Study Day 64)	Flu Prevention
Acetylsalicylic acid	22 Mar 2021 (Study Day 204) - 22 Mar 2021 (Study Day 204)	Acute Pontine Infarct
Echocardiogram*	22 Mar 2021 (Study Day 204) - 22 Mar 2021 (Study Day 204)	Adverse Event
Enoxaparin sodium	22 Mar 2021 (Study Day 204) - 30 Mar 2021 (Study Day 212)	Acute Pontine Infarct
Magnetic resonance imaging*	22 Mar 2021 (Study Day 204) - 22 Mar 2021 (Study Day 204)	Adverse Event
X-ray chest*	22 Mar 2021 (Study Day 204) - 22 Mar 2021 (Study Day 204)	Adverse Event
Fluoroscopic barium swallow*	23 Mar 2021 (Study Day 205) - 23 Mar 2021 (Study Day 205)	Adverse Event
Transthoracic echocardiogram*	23 Mar 2021 (Study Day 205) - 23 Mar 2021 (Study Day 205)	Adverse Event
Acetylsalicylic acid	24 Mar 2021 (Study Day 206) - Ongoing	Acute Pontine Infarct, Post Care
Atorvastatin	24 Mar 2021 (Study Day 206) - Ongoing	Hyperlipidemia
Insulin aspart	24 Mar 2021 (Study Day 206) - 30 Mar 2021 (Study Day 212)	Diabetes Mellitus
Hydrochlorothiazide	25 Mar 2021 (Study Day 207) - 30 Mar 2021 (Study Day 212)	Hypertension
Labetalol	25 Mar 2021 (Study Day 207) - 25 Mar 2021 (Study Day 207)	Hypertension
Losartan	25 Mar 2021 (Study Day 207) - 30 Mar 2021 (Study Day 212)	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cerebral Artery Stenosis	Grade 2/moderate	Not related	22 Mar 2021 (Study Day 204) - Ongoing
Left Ventricular Hypertrophy	Grade 1/mild	Not related	22 Mar 2021 (Study Day 204) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US391-2076 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 02 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 30 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: 13 Jan 2021 (Study Day 134)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Anaphylactic Reaction/ Acute Anaphylaxis	SAE, AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	31 Jan 2021 (Study Day 152) – 31 Jan 2021 (Study Day 152)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US391-2076, a 51-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 13 Jan 2021. The participant was unblinded on 13 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 13 Jan 2021 (Study Day 134). The second dose was not administered.

Event Details

On 31 Jan 2021 (Study Day 152), 151 days after the first dose in Part A/18 days after the first dose in Part B and 123 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of anaphylactic reaction. The IP dose was withdrawn due to the acute anaphylaxis. The event of acute anaphylaxis lasted for 1 day, after which it was considered to be recovered/resolved on 31 Jan 2021 (Study Day 152). The investigator assessed the event of anaphylactic reaction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009915	Anaphylactic reaction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Goitre	Goiter	1987 - 1991
Hypothyroidism	Hypothyroidism	1987 - Ongoing
Thyroidectomy	Thyroidectomy	1991 - 1991
Asthma	Asthma - moderate	2004 - Ongoing
Cardiac failure congestive	Chf	2008 - Ongoing
Hypertension	Hypertension	2008 - Ongoing
Postmenopause	Post menopausal	2009 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine sodium	1991 - Ongoing	Hypothyroidism
Salbutamol sulfate	2004 - Ongoing	Asthma
Acetylsalicylic acid	2015 - Ongoing	Cardiac Prophylaxis
Montelukast sodium	2019 - Ongoing	Asthma
Amlodipine; olmesartan	Aug 2019 - Ongoing	Hypertension
Diltiazem	Aug 2019 - Ongoing	Hypertension
Prednisone	23 Nov 2020 (Study Day 83) - 04 Dec 2020 (Study Day 94)	Worsening Of Asthma
2 stitches to lip*	24 Jan 2021 (Study Day 145) - 24 Jan 2021 (Study Day 145)	Adverse Event
Epinephrine	31 Jan 2021 (Study Day 152) - 31 Jan 2021 (Study Day 152)	Acute Anaphylaxis
Epinephrine hydrochloride	31 Jan 2021 (Study Day 152) - 31 Jan 2021 (Study Day 152)	Acute Anaphylaxis
Famotidine	31 Jan 2021 (Study Day 152) - 31 Jan 2021 (Study Day 152)	Acute Anaphylaxis
Methylprednisolone sodium succinate	31 Jan 2021 (Study Day 152) - 31 Jan 2021 (Study Day 152)	Acute Anaphylaxis
Salbutamol	31 Jan 2021 (Study Day 152) - 31 Jan 2021 (Study Day 152)	Acute Anaphylaxis
Cetirizine hydrochloride	01 Feb 2021 (Study Day 153) - 02 Feb 2021 (Study Day 154)	Post Acute Anaphylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	01 Feb 2021 (Study Day 153) - Ongoing	Acute Anaphylaxis
Famotidine	01 Feb 2021 (Study Day 153) - 04 Feb 2021 (Study Day 156)	Gi Prophylaxis
Prednisone	01 Feb 2021 (Study Day 153) - 04 Feb 2021 (Study Day 156)	Acute Anaphylaxis
Salbutamol sulfate	01 Feb 2021 (Study Day 153) - Ongoing	Acute Anaphylaxis
Insulin aspart	13 Feb 2021 (Study Day 165) - Ongoing	Insulin Dependent Diabetic Mellitus
Insulin degludec	13 Feb 2021 (Study Day 165) - Ongoing	Insulin Dependent Diabetic Mellitus

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Lip Injury	Grade 2/moderate	Not related	24 Jan 2021 (Study Day 145) - 24 Jan 2021 (Study Day 145)
Type 1 Diabetes Mellitus	Grade 2/moderate	Not related	12 Feb 2021 (Study Day 164) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US392-2043 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 27 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 28 Sep 2020 (Study Day 33)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dyspnoea/Shortness Of Breath	SAE	Grade 2/ moderate	Not related	09 Apr 2021 (Study Day 226) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US392-2043, a 60-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 28 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 05 Feb 2021. The participant was unblinded on 05 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 09 Apr 2021 (Study Day 226), 225 days after the first dose in Part A and 193 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of dyspnoea. Action taken with the IP was not applicable. The event of shortness of breath was considered to be ongoing. The investigator assessed the event of dyspnoea to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-086812	Cardiac failure congestive

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post menopausal	1999 - Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Hypertension	Hypertension	2003 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2013 - Ongoing
Pancreatectomy	Partial pancreatectomy	2013 - 2013
Pancreatic mass	Pancreatic mass (benign)	2013 - 2013
Type 2 diabetes mellitus	Diabetes mellitus type II	2013 - Ongoing
Diabetic neuropathy	Neuropathy diabetic bilateral feet (sensory)	2014 - Ongoing
Psoriasis	Psoriasis	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2013 - Ongoing	Hypertension
Atorvastatin	2017 - Ongoing	Hypercholesterolemia
Empagliflozin	2017 - Ongoing	Type2 Diabetes
Gabapentin	2017 - Ongoing	Sensory Neuropathy Diabetic Bilateral Feet
Hydrochlorothiazide; triamterene	2017 - Ongoing	Hypertension
Insulin aspart; insulin aspart protamine	2017 - Ongoing	Type2 Diabetes
Linagliptin	2017 - Ongoing	Type2 Diabetes
Lisinopril	2017 - Ongoing	Hypertension
Metoprolol	2017 - Ongoing	Hypertension
Pioglitazone	2017 - Ongoing	Type2 Diabestes
Influenza vaccine	11 Sep 2020 (Study Day 16) - 11 Sep 2020 (Study Day 16)	Flu Prophylaxis
Clobetasol propionate	25 Nov 2020 (Study Day 91) - Ongoing	Psoriasis
Insulin lispro	15 Dec 2020 (Study Day 111) - Ongoing	Type II - Diabetes Mellitus

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US392-2088 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 13 Oct 2020 (Study Day 36)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Adrenal Mass/ Adrenal Mass	SAE	Grade 2/ moderate	Not related	10 Mar 2021 (Study Day 184) – 24 Mar 2021 (Study Day 198)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US392-2088, a 63-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 13 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 02 Mar 2021. The participant was unblinded on 02 Mar 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 10 Mar 2021 (Study Day 184), 183 days after the first dose in Part A and 148 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of adrenal mass. Action taken with the IP was not applicable. The event of adrenal mass lasted for 15 days, after which it was considered to be recovered/resolved on 24 Mar 2021 (Study Day 198). The investigator assessed the event of adrenal mass to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-043681	Adrenal mass

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vasectomy	Vasectomy	1996 - 1996
Hypercholesterolaemia	Hypercholesterolemia	2015 - Ongoing
Hypothyroidism	Hypothyroidism	2017 - Ongoing
Trigger finger	R hand trigger finger	2017 - Ongoing
Seasonal allergy	Seasonal allergies	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2015 - Ongoing	Cardiac Prophylaxis
Pravastatin	2015 - Ongoing	Hypercholesterolemia
Vitamins nos	2015 - Ongoing	Supplement
Levothyroxine	2017 - Ongoing	Hypothyroidism
Meloxicam	2017 - Ongoing	R Hand Trigger Finger
Influenza vaccine	22 Aug 2020 (Study Day -17) - 22 Aug 2020 (Study Day -17)	Flu Prophylaxis
Fluticasone propionate	06 Oct 2020 (Study Day 29) - Ongoing	Seasonal Allergies

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US394-2064 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 01 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Phaeochromocytoma/ Right Pheochromocytoma	SAE	Grade 3/ severe	Not related	07 Feb 2021 (Study Day 158) – 16 Mar 2021 (Study Day 195)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US394-2064, a 27-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 01 Feb 2021. The participant was unblinded on 01 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 07 Feb 2021 (Study Day 158), 157 days after the first dose in Part A and 129 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of phaeochromocytoma. Action taken with the IP was not applicable. The event of right pheochromocytoma lasted for 38 days, after which it was considered to be recovered/resolved on 16 Mar 2021 (Study Day 195). The investigator assessed the event of phaeochromocytoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-040166	Phaeochromocytoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headaches	2007 - Ongoing
Anxiety	Anxiety	2016 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit hyperactive disorder	2016 - Ongoing
Tremor	Tremors	2016 - Ongoing
Cerebral haemorrhage	Cerebral hemorrhage	2018 - 2018
Hypertension	Hypertension	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2007 - 2007	Headaches
Paracetamol	2007 - Ongoing	Headches
Amlodipine	Jan 2020 - Ongoing	Hypertension
Bupropion	29 Jul 2020 (Study Day -36) - 25 Sep 2020 (Study Day 23)	Anxiety, Attention Deficit Hyperactive Disorder
Influenza vaccine	29 Jul 2020 (Study Day -36) - 29 Jul 2020 (Study Day -36)	Influenza Prophylaxis
Propranolol	29 Jul 2020 (Study Day -36) - 07 Sep 2020 (Study Day 5)	Hypertension, Anxiety, Tremors
Dexamfetamine	26 Aug 2020 (Study Day -8) - Ongoing	Attention Deficit Hyperactive Disorder
Paracetamol	04 Sep 2020 (Study Day 2) - 05 Sep 2020 (Study Day 3)	Fever
Propranolol	08 Sep 2020 (Study Day 6) - Ongoing	Hypertension, Anxiety, Tremors
Fluoxetine hydrochloride	25 Sep 2020 (Study Day 23) - 08 Feb 2021 (Study Day 159)	Anxiety
Amlodipine	02 Oct 2020 (Study Day 30) - Ongoing	Hypertension
Ct abdomen/pelvis with contrast*	08 Feb 2021 (Study Day 159) - 08 Feb 2021 (Study Day 159)	Diagnostic
Iohexol	08 Feb 2021 (Study Day 159) - 08 Feb 2021 (Study Day 159)	Pheochromocytoma (Ct Scan)
Morphine	08 Feb 2021 (Study Day 159) - 18 Feb 2021 (Study Day 169)	Right Lower Quadrant Abdominal Pain
Ondansetron	08 Feb 2021 (Study Day 159) - 08 Feb 2021 (Study Day 159)	Nausea

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Doxazosin	09 Feb 2021 (Study Day 160) - 16 Feb 2021 (Study Day 167)	Hypertension
Enoxaparin sodium	09 Feb 2021 (Study Day 160) - 19 Feb 2021 (Study Day 170)	Blood Clot Prophylaxis
Fluoxetine hydrochloride	09 Feb 2021 (Study Day 160) - 19 Feb 2021 (Study Day 170)	Anxiety
Ketorolac tromethamine	09 Feb 2021 (Study Day 160) - 09 Feb 2021 (Study Day 160)	Right Lower Quadrant Abdominal Pain
Labetalol	09 Feb 2021 (Study Day 160) - 09 Feb 2021 (Study Day 160)	Hypertension
Oxycodone	09 Feb 2021 (Study Day 160) - 19 Feb 2021 (Study Day 170)	Right Lower Quadrant Abdominal Pain
Propranolol	09 Feb 2021 (Study Day 160) - 09 Feb 2021 (Study Day 160)	Hypertension
Sodium chloride	09 Feb 2021 (Study Day 160) - 11 Feb 2021 (Study Day 162)	Pheochromocytoma
Ultrasound abdomen*	09 Feb 2021 (Study Day 160) - 09 Feb 2021 (Study Day 160)	Diagnostic
Magnesium hydroxide	10 Feb 2021 (Study Day 161) - 11 Feb 2021 (Study Day 162)	Constipation
Piperacillin sodium; tazobactam sodium	10 Feb 2021 (Study Day 161) - 19 Feb 2021 (Study Day 170)	Inflamed Gallbladder
Dexamethasone	11 Feb 2021 (Study Day 162) - 11 Feb 2021 (Study Day 162)	Nausea
Macrogol 3350	11 Feb 2021 (Study Day 162) - 19 Feb 2021 (Study Day 170)	Constipation
Paracetamol	11 Feb 2021 (Study Day 162) - 19 Feb 2021 (Study Day 170)	Right Lower Quadrant Abdominal Pain
Ergocalciferol	12 Feb 2021 (Study Day 163) - 18 Feb 2021 (Study Day 169)	Pheochromocytoma
Mri abdomen*	12 Feb 2021 (Study Day 163) - 12 Feb 2021 (Study Day 163)	Diagnostic
Calcium chloride; potassium chloride; sodium lactate	16 Feb 2021 (Study Day 167) - 17 Feb 2021 (Study Day 168)	Hydration
Chest x-ray*	16 Feb 2021 (Study Day 167) - 16 Feb 2021 (Study Day 167)	Diagnostic
Epinephrine	16 Feb 2021 (Study Day 167) - 16 Feb 2021 (Study Day 167)	Hypotension
Hydrocortisone	16 Feb 2021 (Study Day 167) - 17 Feb 2021 (Study Day 168)	Post-Op
Mri brain*	16 Feb 2021 (Study Day 167) - 16 Feb 2021 (Study Day 167)	Medical History
Norepinephrine	16 Feb 2021 (Study Day 167) - 16 Feb 2021 (Study Day 167)	Hypotension
Partial cholecystectomy*	16 Feb 2021 (Study Day 167) - 16 Feb 2021 (Study Day 167)	Adverse Event
Pheochromocytoma removal*	16 Feb 2021 (Study Day 167) - 16 Feb 2021 (Study Day 167)	Adverse Event
Docusate sodium	17 Feb 2021 (Study Day 168) - 19 Feb 2021 (Study Day 170)	Constipation

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glucose	17 Feb 2021 (Study Day 168) - 19 Feb 2021 (Study Day 170)	Hydration
Hydrocortisone	18 Feb 2021 (Study Day 169) - 19 Feb 2021 (Study Day 170)	Post-Op
Amoxicillin; clavulanic acid	19 Feb 2021 (Study Day 170) - 16 Mar 2021 (Study Day 195)	Pheochromocytoma
Ergocalciferol	19 Feb 2021 (Study Day 170) - 26 Feb 2021 (Study Day 177)	Pheochromocytoma
Hydrocortisone	19 Feb 2021 (Study Day 170) - 26 Feb 2021 (Study Day 177)	Inflamed Gallbladder
Methocarbamol	19 Feb 2021 (Study Day 170) - 16 Mar 2021 (Study Day 195)	Inflamed Gallbladder
Methocarbamol	19 Feb 2021 (Study Day 170) - 19 Feb 2021 (Study Day 170)	Pheochromocytoma
Ondansetron	19 Feb 2021 (Study Day 170) - 16 Mar 2021 (Study Day 195)	Inflamed Gallbladder
Oxycodone	19 Feb 2021 (Study Day 170) - 26 Feb 2021 (Study Day 177)	Inflamed Gallbladder

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Abdominal Pain Lower	Grade 1/mild	Not related	08 Feb 2021 (Study Day 159) - 26 Feb 2021 (Study Day 177)
Cholecystitis	Grade 2/moderate	Not related	08 Feb 2021 (Study Day 159) - Ongoing
Nausea	Grade 1/mild	Not related	08 Feb 2021 (Study Day 159) - 16 Mar 2021 (Study Day 195)
Tachycardia	Grade 2/moderate	Not related	08 Feb 2021 (Study Day 159) - 19 Feb 2021 (Study Day 170)
Post Procedural Hypotension	Grade 1/mild	Not related	16 Feb 2021 (Study Day 167) - 16 Feb 2021 (Study Day 167)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US394-2072 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 08 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 06 Jan 2021 (Study Day 119)
Second Dose of Vaccine in Part B: 04 Feb 2021 (Study Day 148)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Coronary Artery Disease/Coronary Artery Disease	SAE	Grade 3/ severe	Not related	23 Mar 2021 (Study Day 195) – 29 Mar 2021 (Study Day 201)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US394-2072, a 72-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 06 Jan 2021 (Study Day 119). The second dose was administered in the left arm on 04 Feb 2021 (Study Day 148).

Event Details

On 23 Mar 2021 (Study Day 195), 194 days after the first dose in Part A/76 days after the first dose in Part B and 166 days after the second dose in Part A/47 days after the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of coronary artery disease. Action taken with the IP was not applicable. The event of coronary artery disease lasted for 7 days, after which it was considered to be recovered/resolved with sequelae on 29 Mar 2021 (Study Day 201). The investigator assessed the event of coronary artery disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-061861	Coronary artery disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Diabetes mellitus	Diabetes mellitus	1987 - Ongoing
Knee arthroplasty	Knee replacement, right	1993 - 1993
Osteoarthritis	Osteoarthritis right knee	1993 - 1993
Cholecystectomy	Cholecystectomy	1995 - 1995
Cholelithiasis	Cholelithiasis	1995 - 1995
Fracture treatment	Broken thumb repair	2004 - 2004
Hand fracture	Broken right thumb	2004 - 2004
Hypertension	Hypertension	2005 - Ongoing
Knee arthroplasty	Knee replacement, right	2005 - 2005
Osteoarthritis	Osteoarthritis right knee	2005 - 2005
Osteoarthritis	Osteoarthritis right rotator cuff	2005 - 2005
Rotator cuff repair	Rotator cuff surgery right	2005 - 2005
Anxiety	Anxiety	2006 - Ongoing
Cerebrovascular accident	Hospitalization for stroke	2006 - 2006
Cerebrovascular accident	Stroke	2006 - 2006
Hyperlipidaemia	Hyperlipidemia	2006 - Ongoing
Knee arthroplasty	Knee replacement left	2007 - 2007
Osteoarthritis	Osteoarthritis left knee	2007 - 2007
Restless legs syndrome	Restless leg syndrome	2015 - Ongoing
Hypoesthesia	Numbness in hands	2016 - Ongoing
Renal impairment	Reduced kidney function	2017 - Ongoing
Back pain	Chronic back pain	2018 - Ongoing
Hypothyroidism	Hypothyroidism	2018 - Ongoing
Osteoarthritis	Osteoarthritis left rotator cuff	2018 - 2018
Rotator cuff repair	Rotator cuff surgery left	2018 - 2018
Iron deficiency	Iron deficiency	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2005 - 25 Mar 2021 (Study Day 197)	Hypertension
Losartan	2005 - 23 Mar 2021 (Study Day 195)	Hypertension
Clopidogrel bisulfate	2006 - Ongoing	Anti Platelet For Strok
Duloxetine	2006 - Ongoing	Anxiety
Metformin	2006 - Ongoing	Diabetes Mellitus
Paroxetine	2006 - Ongoing	Anxiety
Rosuvastatin	2006 - 23 Mar 2021 (Study Day 195)	Hyperlipidemia
Pramipexole	2015 - Ongoing	Restless Leg Syndrome
Gabapentin	2016 - Ongoing	Numbness In Hands
Levothyroxine	2018 - Ongoing	Hypothyroidism
Iron	Jan 2020 - Ongoing	Iron Deficiency
Cardiac stress test*	01 Feb 2021 (Study Day 145) - 01 Feb 2021 (Study Day 145)	Diagnostic
Heart catheterization*	12 Mar 2021 (Study Day 184) - 12 Mar 2021 (Study Day 184)	Adverse Event
Albumin human	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Aminocaproic acid	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Amiodarone hydrochloride	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Amiodarone; glucose	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Calcium chloride	23 Mar 2021 (Study Day 195) - 24 Mar 2021 (Study Day 196)	Coronary Artery Disease
Calcium chloride; potassium chloride; sodium lactate	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Ceftazidime	23 Mar 2021 (Study Day 195) - 25 Mar 2021 (Study Day 197)	Coronary Artery Disease
Enoxaparin sodium	23 Mar 2021 (Study Day 195) - 24 Mar 2021 (Study Day 196)	Coronary Artery Disease
Epinephrine	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Fentanyl	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Gluconate sodium; magnesium chloride; potassium chloride; sodium acetate; sodium chloride	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Glucose	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Glucose; sodium bicarbonate	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Glyceryl trinitrate	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin	23 Mar 2021 (Study Day 195) - 24 Mar 2021 (Study Day 196)	Coronary Artery Disease
Insulin human	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Ipratropium	23 Mar 2021 (Study Day 195) - 29 Mar 2021 (Study Day 201)	Coronary Artery Disease
Labetalol	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Lidocaine	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Magnesium sulfate	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Metoclopramide	23 Mar 2021 (Study Day 195) - 29 Mar 2021 (Study Day 201)	Coronary Artery Disease
Midazolam hydrochloride	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Morphine	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Mupirocin	23 Mar 2021 (Study Day 195) - 29 Mar 2021 (Study Day 201)	Coronary Artery Disease
Ondansetron	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Paracetamol	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Potassium chloride	23 Mar 2021 (Study Day 195) - 24 Mar 2021 (Study Day 196)	Coronary Artery Disease
Propofol	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Protamine	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Rocuronium bromide	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Sodium chloride	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Vancomycin	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Vasopressin	23 Mar 2021 (Study Day 195) - 23 Mar 2021 (Study Day 195)	Coronary Artery Disease
Acetylsalicylic acid	24 Mar 2021 (Study Day 196) - 29 Mar 2021 (Study Day 201)	Coronary Artery Disease
Atorvastatin	24 Mar 2021 (Study Day 196) - 29 Mar 2021 (Study Day 201)	Coronary Artery Disease
Enoxaparin sodium	24 Mar 2021 (Study Day 196) - 29 Mar 2021 (Study Day 201)	Coronary Artery Disease
Furosemide	24 Mar 2021 (Study Day 196) - 29 Mar 2021 (Study Day 201)	Coronary Artery Disease
Glucagon	24 Mar 2021 (Study Day 196) - 24 Mar 2021 (Study Day 196)	Coronary Artery Disease
Glucose	24 Mar 2021 (Study Day 196) - 24 Mar 2021 (Study Day 196)	Coronary Artery Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glyceryl trinitrate	24 Mar 2021 (Study Day 196) - 24 Mar 2021 (Study Day 196)	Coronary Artery Disease
Hydrocodone bitartrate; paracetamol	24 Mar 2021 (Study Day 196) - 29 Mar 2021 (Study Day 201)	Coronary Artery Disease
Levothyroxine sodium	24 Mar 2021 (Study Day 196) - 29 Mar 2021 (Study Day 201)	Coronary Artery Disease
Losartan	24 Mar 2021 (Study Day 196) - 29 Mar 2021 (Study Day 201)	Coronary Artery Disease
Pantoprazole sodium sesquihydrate	24 Mar 2021 (Study Day 196) - 29 Mar 2021 (Study Day 201)	Coronary Artery Disease
Paracetamol	24 Mar 2021 (Study Day 196) - 24 Mar 2021 (Study Day 196)	Coronary Artery Disease
Potassium chloride	24 Mar 2021 (Study Day 196) - 07 Apr 2021 (Study Day 210)	Coronary Artery Disease
Aluminium hydroxide; magnesium	25 Mar 2021 (Study Day 197) - 28 Mar 2021 (Study Day 200)	Coronary Artery Disease
Amlodipine	25 Mar 2021 (Study Day 197) - 29 Mar 2021 (Study Day 201)	Coronary Artery Disease
Bisacodyl	25 Mar 2021 (Study Day 197) - 25 Mar 2021 (Study Day 197)	Coronary Artery Disease
Guaifenesin	25 Mar 2021 (Study Day 197) - 25 Mar 2021 (Study Day 197)	Coronary Artery Disease
Magnesium hydroxide	25 Mar 2021 (Study Day 197) - 25 Mar 2021 (Study Day 197)	Coronary Artery Disease
Trazodone	25 Mar 2021 (Study Day 197) - 28 Mar 2021 (Study Day 200)	Coronary Artery Disease
Duloxetine	26 Mar 2021 (Study Day 198) - 29 Mar 2021 (Study Day 201)	Coronary Artery Disease
Duloxetine hydrochloride	26 Mar 2021 (Study Day 198) - 26 Mar 2021 (Study Day 198)	Coronary Artery Disease
Guaifenesin	26 Mar 2021 (Study Day 198) - 29 Mar 2021 (Study Day 201)	Coronary Artery Disease
Insulin glargine	26 Mar 2021 (Study Day 198) - 29 Mar 2021 (Study Day 201)	Coronary Artery Disease

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US394-2121 (Part B)
Vaccination Group: mRNA-1273 in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 24 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: Not Administered
First Dose of Vaccine in Part B: 19 Jan 2021 (Study Day 118)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Physical Assault/ Physical Assault	SAE	Grade 3/ severe	Not related	07 Mar 2021 (Study Day 165) – 07 Mar 2021 (Study Day 165)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US394-2121, a 29-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 24 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 19 Jan 2021. The participant was unblinded on 19 Jan 2021 and consented to receive the second dose of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 19 Jan 2021 (Study Day 118). The second dose was not administered.

Event Details

On 07 Mar 2021 (Study Day 165), 164 days after the first dose in Part A/47 days after the first dose in Part B of the IP (second dose Part A not applicable/second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of physical assault. Action taken with the IP was not applicable. The event of physical assault lasted for 1 day, after which it was considered to be recovered/resolved on 07 Mar 2021 (Study Day 165). The investigator assessed the event of physical assault to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-055464	Physical assault

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertonic bladder	Overactive bladder	1996 - Ongoing
Seasonal allergy	Seasonal allergies	1999 - Ongoing
Adenoidectomy	Adenoidectomy	2004 - 2004
Adenoiditis	Adenoiditis	2004 - 2004
Tonsillectomy	Tonsilectomy	2004 - 2004
Tonsillitis	Tonsillitis	2004 - 2004
Obesity	Morbid obesity	2006 - Ongoing
Drug hypersensitivity	Flagyl allergy	2010 - Ongoing
Pain	Generalized pain	2015 - Ongoing
Tendon rupture	Torn achilles tendon	Feb 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	1999 - Ongoing	Seasonal Allergies
Ibuprofen	2015 - Ongoing	Generalized Pain
Drospirenone; ethinylestradiol	2018 - Ongoing	Preventative
Oenothera biennis oil	Aug 2020 - Ongoing	Supplement
Gabapentin	10 Oct 2020 (Study Day 17) - Ongoing	Torn Achilles
Cefalexin	26 Oct 2020 (Study Day 33) - 01 Nov 2020 (Study Day 39)	Urinary Tract Infection
Cyclobenzaprine hydrochloride	26 Oct 2020 (Study Day 33) - 17 Nov 2020 (Study Day 55)	Lower Back Pain
Naproxen	26 Oct 2020 (Study Day 33) - 03 Nov 2020 (Study Day 41)	Lower Back Pain; Torn Achilles
Influenza vaccine	10 Nov 2020 (Study Day 48) - 10 Nov 2020 (Study Day 48)	Influenza Prophylaxis
Imipramine	21 Jan 2021 (Study Day 120) - 14 Feb 2021 (Study Day 144)	Depression
Imipramine	15 Feb 2021 (Study Day 145) - Ongoing	Depression
Ct - brain*	07 Mar 2021 (Study Day 165) - 07 Mar 2021 (Study Day 165)	Adverse Event
Ct - cervical spine*	07 Mar 2021 (Study Day 165) - 07 Mar 2021 (Study Day 165)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ct - lumbar spine*	07 Mar 2021 (Study Day 165) - 07 Mar 2021 (Study Day 165)	Adverse Event
Ct - maxillofacial*	07 Mar 2021 (Study Day 165) - 07 Mar 2021 (Study Day 165)	Adverse Event
X ray - chest*	07 Mar 2021 (Study Day 165) - 07 Mar 2021 (Study Day 165)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Non-Cardiac Chest Pain	Grade 1/mild	Not related	20 Jan 2021 (Study Day 119) - 20 Jan 2021 (Study Day 119)
Pain	Grade 1/mild	Not related	16 Feb 2021 (Study Day 146) - 17 Feb 2021 (Study Day 147)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US394-2151 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 12 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: Not Administered
First Dose of Vaccine in Part B: 19 Jan 2021 (Study Day 100)
Second Dose of Vaccine in Part B: 18 Feb 2021 (Study Day 130)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Anaemia Postoperative/ Acute Blood Loss Anemia Post Op	SAE	Grade 2/ moderate	Not related	19 Apr 2021 (Study Day 190) – 19 Apr 2021 (Study Day 190)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US394-2151, a 54-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 12 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 19 Jan 2021. The participant was unblinded on 19 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 19 Jan 2021 (Study Day 100). The second dose was administered in the left arm on 18 Feb 2021 (Study Day 130).

Event Details

On 19 Apr 2021 (Study Day 190), 189 days after the first dose in Part A/90 days after the first dose in Part B and second dose Part A not applicable/60 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of anaemia postoperative. Action taken with the IP was not applicable. The event of acute blood loss anemia post op lasted for 1 day, after which it was considered to be recovered/resolved on 19 Apr 2021 (Study Day 190). The investigator assessed the event of anaemia postoperative to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000548	Anaemia postoperative

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	1975 - Ongoing
Tonsillar hypertrophy	Tonsil enlargement	1979 - 1979
Tonsillectomy	Tonsilectomy	1979 - 1979
Caesarean section	Cesarean section	24 Sep 1985 (Study Day -12802) - 24 Sep 1985 (Study Day -12802)
Facial bones fracture	Multiple facial fractures	1991 - 1991
Facial operation	Facial repair	1991 - 1991
Hip fracture	Rt hip fracture	1992 - 1992
Hip surgery	Rt hip repair	1992 - 1992
Joint arthroplasty	Rt arm, elbow and wrist repair	1992 - 1992
Limb operation	Right leg repair	1992 - 1992
Lower limb fracture	Rt leg fracture	1992 - 1992
Upper limb fracture	Rt arm fracture	1992 - 1992
Upper limb fracture	Rt elbow fracture	1992 - 1992
Wrist fracture	Rt wrist fracture	1992 - 1992
Cholecystectomy	Cholecystectomy	1993 - 1993
Cholelithiasis	Gall stones	1993 - 1993
Ankle fracture	Left ankle fracture	1996 - 1996
Ankle operation	Lft ankle repair	1996 - 1996
Depression	Depression/anxiety	2000 - Ongoing
Neuropathy peripheral	Neuropathy	2000 - Ongoing
Oedema peripheral	Edema in lower limbs	2000 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus ii	2000 - Ongoing
Pain	Chronic pain	2009 - Ongoing
Drug hypersensitivity	Diflucan allergy	2012 - Ongoing
Bipolar disorder	Bipolar disorder	2013 - Ongoing
Drug hypersensitivity	Januvia allergy	2014 - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2014 - Ongoing
Hypokalaemia	Hypokalemia	2014 - Ongoing
Seasonal allergy	Seasonal allergies	2014 - Ongoing
Osteoarthritis	Osteoarthritis of the right knee	2015 - Ongoing
Hypertension	Hypertension	2016 - Ongoing
Osteoarthritis	Degenerative joint disease pelvis	12 Jan 2016 (Study Day -1735) - Ongoing
Rotator cuff syndrome	Impingement syndrome shoulder	12 Jan 2016 (Study Day -1735) - Ongoing
Breast mass	Nodule of breast skin unspecified site	29 Jan 2016 (Study Day -1718) - Ongoing
Breast mass	Breast lump unspecified location	09 Feb 2016 (Study Day -1707) - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Bronchitis	Bronchitis	19 Jun 2016 (Study Day -1576) - Not reported
Upper respiratory tract infection	Upper respiratory infection	19 Jun 2016 (Study Day -1576) - Not reported
Diarrhoea	Diarrhea	23 Jun 2016 (Study Day -1572) - Ongoing
Anaemia	Anemia	2017 - Ongoing
Hyperlipidaemia	Hyperlipidimia	2017 - Ongoing
Osteoarthritis	Osteoarthritis of the left knee	2017 - 24 Feb 2020 (Study Day -231)
Diabetic retinopathy	Mild non-proliferative diabetic retinopathy	28 Aug 2017 (Study Day -1141) - Ongoing
Upper respiratory tract infection	Acute upper respiratory infection	20 Sep 2017 (Study Day -1118) - 30 Sep 2017 (Study Day -1108)
Ear pain	Bilateral earache	31 Oct 2017 (Study Day -1077) - Nov 2017
Hypoglycaemia	Hypoglycemia	2018 - Ongoing
Postmenopause	Post menopausal	Oct 2018 - Ongoing
Postmenopause	Post menopausal	Oct 2018 - Ongoing
Nail dystrophy	Dystrophia unguium	13 Dec 2018 (Study Day -669) - Ongoing
Dental caries	Tooth decay	2019 - 25 Aug 2020 (Study Day -48)
Onycholysis	Onycholysis	19 Jun 2019 (Study Day -481) - Jul 2019
Osteopenia	Osteopenia	23 Jun 2019 (Study Day -477) - Ongoing
Knee arthroplasty	Left knee arthroplasty/ total replacement	24 Feb 2020 (Study Day -231) - 24 Feb 2020 (Study Day -231)
Nasal congestion	Nasal congestion	20 Aug 2020 (Study Day -53) - Ongoing
Oral surgery	Oral surgery for implants	25 Aug 2020 (Study Day -48) - 25 Aug 2020 (Study Day -48)
Knee arthroplasty	Rt knee arthroplasty/ total replacement	05 Oct 2020 (Study Day -7) - 05 Oct 2020 (Study Day -7)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bupropion hydrochloride	2000 - Ongoing	Depression
Furosemide	2000 - Ongoing	Edema, Lower Limbs
Gabapentin	2000 - Ongoing	Neuropathy
Glipizide	2000 - Ongoing	Diabetes Mellitus Ii
Metformin	2000 - Ongoing	Diabetes Mellitus Ii
Citalopram hydrobromide	2009 - Ongoing	Depression/Anxiety
Meloxicam	2009 - Ongoing	Chronic Pain
Topiramate	2013 - Ongoing	Depression/Anxiety
Omeprazole	2014 - 17 Oct 2020 (Study Day 6)	Gastroesophageal Reflux Disease
Potassium	2014 - Ongoing	Hypokalemia
Losartan	2016 - Ongoing	Hypertension
Acetylsalicylic acid	2017 - Ongoing	Cardiac Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Canagliflozin	2017 - Ongoing	Diabetes Mellitus Ii
Iron	2017 - 17 Oct 2020 (Study Day 6)	Anemia
Montelukast sodium	2017 - Ongoing	Seasonal Allergies
Pravastatin	2017 - 17 Oct 2020 (Study Day 6)	Hyperlipidemia
Doxepin	2018 - Ongoing	Depression/Anxiety
Liraglutide	2018 - Ongoing	Diabetes Mellitus Ii
Tramadol	2018 - Ongoing	Chronic Pain
Ibuprofen	05 Oct 2020 (Study Day -7) - Ongoing	Knee Pain, Osteoarthritis
Paracetamol	05 Oct 2020 (Study Day -7) - 17 Oct 2020 (Study Day 6)	Knee Pain, Osteoarthritis
Oxycodone	10 Oct 2020 (Study Day -2) - 01 Nov 2020 (Study Day 21)	Knee Pain, Osteoarthritis; Left Femur Injury
Left femur xray*	17 Oct 2020 (Study Day 6) - 17 Oct 2020 (Study Day 6)	Adverse Event
Left hip xray*	17 Oct 2020 (Study Day 6) - 17 Oct 2020 (Study Day 6)	Adverse Event
Left knee xray*	17 Oct 2020 (Study Day 6) - 17 Oct 2020 (Study Day 6)	Adverse Event
Pelvis xray*	17 Oct 2020 (Study Day 6) - 17 Oct 2020 (Study Day 6)	Adverse Event
Ascorbic acid	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Supplement
Atorvastatin	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Hyperlipidemia
Ct left knee without contrast*	18 Oct 2020 (Study Day 7) - 18 Oct 2020 (Study Day 7)	Adverse Event
Ferrous sulfate	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Supplement
Gabapentin	18 Oct 2020 (Study Day 7) - 19 Oct 2020 (Study Day 8)	Neuropathy
Hydromorphone	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Left Femur Fracture
Insulin	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Diabetes Mellitus Ii
Loperamide hydrochloride	18 Oct 2020 (Study Day 7) - 18 Oct 2020 (Study Day 7)	Diarrhea
Oxycodone	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Left Femur Fracture
Pantoprazole	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Gastroesophageal Reflux Disease
Paracetamol	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Left Femur Fracture
Pramipexole	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Left Femur Injury
Blood transfusion (6 units)*	19 Oct 2020 (Study Day 8) - 19 Oct 2020 (Study Day 8)	Adverse Event
Calcium chloride; potassium chloride; sodium lactate	19 Oct 2020 (Study Day 8) - 20 Oct 2020 (Study Day 9)	Nutritional Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fentanyl	19 Oct 2020 (Study Day 8) - 19 Oct 2020 (Study Day 8)	Left Femur Fracture
Left distal femur replacement*	19 Oct 2020 (Study Day 8) - 19 Oct 2020 (Study Day 8)	Adverse Event
Left femur xray*	19 Oct 2020 (Study Day 8) - 19 Oct 2020 (Study Day 8)	Adverse Event
Gabapentin	20 Oct 2020 (Study Day 9) - 22 Oct 2020 (Study Day 11)	Neuropathy

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US395-2052 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 13 Oct 2020 (Study Day 36)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pulmonary Embolism/ (R) Pulmonary Embolism	SAE	Grade 3/ severe	Not related	06 Mar 2021 (Study Day 180) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US395-2052, a 74-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 13 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 24 Feb 2021. The participant was unblinded on 24 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 06 Mar 2021 (Study Day 180), 179 days after the first dose in Part A and 144 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of pulmonary embolism. Action taken with the IP was not applicable. The event of (r) pulmonary embolism was considered to be ongoing. The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-040015	Pulmonary embolism

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1947 - 1947
Wisdom teeth removal	Wisdom teeth removal	1963 - 1963
Basal cell carcinoma	Basal cell skin cancer	1975 - 2015
Keratotomy	Radial keratotomy	1982 - 1982
Keratotomy	Radial keratotomy	1984 - 1984
Obesity	Obesity	1994 - Ongoing
Hysterectomy	Complete hysterectomy	1998 - 1998
Hyperlipidaemia	Hyperlipidemia	2012 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2012 - Ongoing
Cataract operation	Bilateral cataract surgery	2015 - 2015
Rotator cuff repair	Bilateral rotator cuff repair	2017 - 2017
Retinal tear	Right torn retina	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2005 - Ongoing	Cardiac Prophylaxis
Exenatide	2012 - Ongoing	Type II Diabetes
Metformin	2012 - 19 Jan 2021 (Study Day 134)	Type II Diabetes
Glipizide	2018 - 15 Oct 2020 (Study Day 38)	Type II Diabetes
Pneumococcal vaccine polysacch 23v	03 Feb 2020 (Study Day -218) - 03 Feb 2020 (Study Day -218)	Pneumonia Vaccine
Influenza vaccine	24 Aug 2020 (Study Day -15) - 24 Aug 2020 (Study Day -15)	Influenza Vaccine
Fenofibrate	Dec 2020 - Ongoing	Hyperlipidemia
Metformin	20 Jan 2021 (Study Day 135) - 09 Feb 2021 (Study Day 155)	Type II Diabetes
Metformin	09 Feb 2021 (Study Day 155) - Ongoing	Type II Diabetes
Azithromycin	24 Feb 2021 (Study Day 170) - 26 Feb 2021 (Study Day 172)	Traveler's Diarrhea
Glipizide	24 Feb 2021 (Study Day 170) - Ongoing	Type II Diabetes
Enoxaparin sodium	06 Mar 2021 (Study Day 180) - 13 Mar 2021 (Study Day 187)	Right Pulmonary Embolism
Metronidazole	08 Mar 2021 (Study Day 182) - 12 Mar 2021 (Study Day 186)	Diarrhea From Giardia
Dabigatran etexilate mesilate	14 Mar 2021 (Study Day 188) - Ongoing	Right Pulmonary Embolism

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US395-2173 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 29 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 29 Oct 2020 (Study Day 31)
First Dose of Vaccine in Part B: 09 Mar 2021 (Study Day 162)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Retinal Artery Occlusion/(L) Eye Retinal Artery Occlusion	SAE	Grade 3/ severe	Not related	24 Mar 2021 (Study Day 177) – 31 Mar 2021 (Study Day 184)	Recovered/ resolved
Chondrocalcinosis Pyrophosphate/Oligoarthritis Secondary To Pseudogout Flare	SAE	Grade 3/ severe	Not related	08 Apr 2021 (Study Day 192) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US395-2173, a 64-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 29 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Oct 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 23 Feb 2021. The participant was unblinded on 23 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 09 Mar 2021 (Study Day 162). The second dose was not administered.

Event Details

On 24 Mar 2021 (Study Day 177), 176 days after the first dose in Part A/15 days after the first dose in Part B and 146 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of retinal artery occlusion. Action taken with the IP was not applicable. The event of (l) eye retinal artery occlusion lasted for 8 days, after which it was considered to be recovered/resolved on 31 Mar 2021 (Study Day 184). The investigator assessed the event of retinal artery occlusion to be not related to the IP.

On 08 Apr 2021 (Study Day 192), 191 days after the first dose in Part A/30 days after the first dose in Part B and 161 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 3/severe serious adverse event of chondrocalcinosis pyrophosphate. Action taken with the IP was not applicable. The event of oligoarthritis secondary

to pseudogout flare was considered to be ongoing. The investigator assessed the event of chondrocalcinosis pyrophosphate to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-070215	Retinal artery occlusion
MOD-2021-074334	Chondrocalcinosis pyrophosphate

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hepatitis B	Hepatitis b	1998 - Ongoing
Limb operation	Left leg surgery	Jun 2000 - Sep 2000
Cancer in remission	Prostate cancer [in remission]	2013 - 2013
Hypertension	Hypertension	2013 - Ongoing
Vision blurred	Right eye blurred vision	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine besilate	2015 - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US396-2005 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 19 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 16 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chest Discomfort/Chest Tightness	SAE	Grade 3/severe	Not related	20 Apr 2021 (Study Day 245) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US396-2005, a 62-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Feb 2021. The participant was unblinded on 12 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 20 Apr 2021 (Study Day 245), 244 days after the first dose in Part A and 216 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of chest discomfort. Action taken with the IP was not applicable. The event of chest tightness was considered to be ongoing. The investigator assessed the event of chest discomfort to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-090017	Chest discomfort

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1976 - Ongoing
Blood cholesterol increased	High cholesterol	2010 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2017 - Ongoing
Osteoarthritis	Osteoarthritis right knee	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2010 - Ongoing	High Cholesterol
Cetirizine hydrochloride	2010 - Ongoing	Seasonal Allergies
Tadalafil	2017 - Ongoing	Benign Prostatic Hyperplasia
Chondroitin sulfate sodium; glucosamine hydrochloride	Jul 2019 - Ongoing	Supplement
Naproxen sodium	16 Sep 2020 (Study Day 29) - 17 Sep 2020 (Study Day 30)	General Body Aches And Pain At The Injection Site
Influenza vaccine	28 Oct 2020 (Study Day 71) - 28 Oct 2020 (Study Day 71)	Prevent Flu
Cefalexin	03 Jan 2021 (Study Day 138) - 10 Jan 2021 (Study Day 145)	Left Middle Finger Injury

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US397-2064 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 31 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 30 Sep 2020 (Study Day 31)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dyspnoea/Shortness Of Breath	SAE	Grade 3/severe	Not related	23 Apr 2021 (Study Day 236) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The MedDRA Preferred Term/Verbatim Term of Dyspnoea/Shortness Of Breath was updated to Cardiac Failure Congestive/Shortness of Breath Congestive Heart Failure after the database lock.

Participant US397-2064, a 69-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 30 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 26 Jan 2021. The participant was unblinded on 26 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 23 Apr 2021 (Study Day 236), 235 days after the first dose in Part A and 205 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of dyspnoea. The IP dose was not changed due to the shortness of breath. The event of shortness of breath was considered to be ongoing. The investigator assessed the event of dyspnoea to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-090698	Cardiac failure congestive

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Acute myocardial infarction	Nstemi type ii	Not reported - Ongoing
Aortic valve incompetence	Severe aortic insufficiency	Not reported - Ongoing
Systemic lupus erythematosus	Systemic lupus erythematosus	Not reported - Ongoing
Drug hypersensitivity	Allergy to penicillin	2000 - Ongoing
Transient ischaemic attack	Transient ischemic attack	2000 - 2000
Peripheral arterial occlusive disease	Peripheral arterial disease 1 leg	2010 - 2011
Postmenopause	Post menopausal	2010 - Ongoing
Cardiac failure	Heart failure with preserved ejection fraction	2014 - Ongoing
Fibromyalgia	Fibromylagia	2014 - Ongoing
Blood cholesterol increased	High cholesterol	2017 - Ongoing
Drug hypersensitivity	Allergy to sulfa drug	2017 - Ongoing
Hypertension	Hypertension	2017 - Ongoing
Seasonal allergy	Seasonal allergy	2018 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2018 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease (copd)	2019 - Ongoing
Coronary artery disease	Non obstructive cad	Oct 2019 - Ongoing
Constipation	Constipation	08 Oct 2019 (Study Day -328) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2012 - Ongoing	Prevention Of Heart Failure
Carvedilol	2014 - Ongoing	Heart Failure With Preserved Ejection Fraction
Tramadol	2014 - Ongoing	Fibromyalgia
Rosuvastatin	2017 - Ongoing	Hypercholesterolemia
Ergocalciferol	2018 - Ongoing	Vitamin D Deficiency
Fluticasone propionate	2018 - Ongoing	Seasonal Allergies
Salbutamol	2019 - Ongoing	Copd
Tiotropium bromide	2019 - Ongoing	Copd
Losartan	Oct 2019 - 17 Sep 2020 (Study Day 18)	Hypertension
Macrogol 3350	08 Oct 2019 (Study Day -328) - Ongoing	Constipation
Bumetanide	Jan 2020 - Ongoing	Heart Failure With Preserved Ejection Fraction

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bumetanide	02 Sep 2020 (Study Day 3) - 02 Sep 2020 (Study Day 3)	Congestive Heart Failure
Losartan	18 Sep 2020 (Study Day 19) - 19 Nov 2020 (Study Day 81)	Hypertension
Benign polypectomy*	06 Oct 2020 (Study Day 37) - 06 Oct 2020 (Study Day 37)	Diagnostic
Routine colonoscopy*	06 Oct 2020 (Study Day 37) - 06 Oct 2020 (Study Day 37)	Diagnostic
Amlodipine	19 Nov 2020 (Study Day 81) - Ongoing	Hypertension
Influenza vaccine	19 Nov 2020 (Study Day 81) - 19 Nov 2020 (Study Day 81)	Flu Prevention
Pneumococcal vaccine	19 Nov 2020 (Study Day 81) - 19 Nov 2020 (Study Day 81)	Pneumonia Prevention
Computed tomography (ct scan) of chest*	30 Nov 2020 (Study Day 92) - 30 Nov 2020 (Study Day 92)	Medical History
Clindamycin	31 Dec 2020 (Study Day 123) - 07 Jan 2021 (Study Day 130)	Tooth Infection (Third Top Molar Abscess)
Diphenhydramine hydrochloride	31 Dec 2020 (Study Day 123) - 07 Jan 2021 (Study Day 130)	Suspected Allergic Reaction To Clindamycin. Per M.D At V4 - Not Determined To Be An Allergic Reaction
Annual mammograms*	13 Jan 2021 (Study Day 136) - 13 Jan 2021 (Study Day 136)	Other, Routine

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US397-2129 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 08 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 05 Oct 2020 (Study Day 28)
First Dose of Vaccine in Part B: 04 Mar 2021 (Study Day 178)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID-19	COVID-19	Grade 1/ mild	Not related	15 Jan 2021 (Study Day 130) – 31 Jan 2021 (Study Day 146)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US397-2129, a 48-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 05 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 20 Jan 2021. The participant was unblinded on 17 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 04 Mar 2021 (Study Day 178). The second dose was not administered.

Severe COVID-19 Details

On 15 Jan 2021 (Study Day 130), 129 days after the first dose in Part A/48 days before the first dose in Part B and 102 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 28, 05 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 20 Jan 2021 (Study Day 135), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
15 Jan 2021 (Study Day 130)	Cough	Mild
15 Jan 2021 (Study Day 130)	Muscle Aches (Myalgia)	Moderate
16 Jan 2021 (Study Day 131)	Body Aches	Mild
17 Jan 2021 (Study Day 132)	Body Aches	Mild
17 Jan 2021 (Study Day 132)	Cough	Mild
18 Jan 2021 (Study Day 133)	Body Aches	Mild
18 Jan 2021 (Study Day 133)	Cough	Mild
18 Jan 2021 (Study Day 133)	Muscle Aches (Myalgia)	Mild
18 Jan 2021 (Study Day 133)	New Loss of Smell	Mild
18 Jan 2021 (Study Day 133)	New Loss of Taste	Mild
19 Jan 2021 (Study Day 134)	Cough	Mild
19 Jan 2021 (Study Day 134)	New Loss of Smell	Mild
20 Jan 2021 (Study Day 135)	Muscle Aches (Myalgia)	Moderate
20 Jan 2021 (Study Day 135)	Nasal Congestion	Moderate
20 Jan 2021 (Study Day 135)	New Loss of Smell	Mild
21 Jan 2021 (Study Day 136)	Muscle Aches (Myalgia)	Mild
21 Jan 2021 (Study Day 136)	Nasal Congestion	Mild
21 Jan 2021 (Study Day 136)	New Loss of Smell	Mild
21 Jan 2021 (Study Day 136)	New Loss of Taste	Mild
22 Jan 2021 (Study Day 137)	Fatigue	Mild
22 Jan 2021 (Study Day 137)	Muscle Aches (Myalgia)	Moderate
22 Jan 2021 (Study Day 137)	Nasal Congestion	Mild
22 Jan 2021 (Study Day 137)	New Loss of Smell	Mild
22 Jan 2021 (Study Day 137)	New Loss of Taste	Mild
23 Jan 2021 (Study Day 138)	Body Aches	Moderate
23 Jan 2021 (Study Day 138)	Nasal Congestion	Mild
23 Jan 2021 (Study Day 138)	New Loss of Smell	Mild
23 Jan 2021 (Study Day 138)	New Loss of Taste	Mild
23 Jan 2021 (Study Day 138)	O2 Saturation (%)	93
23 Jan 2021 (Study Day 138)	Temperature (°F)	100.8
24 Jan 2021 (Study Day 139)	Body Aches	Mild
24 Jan 2021 (Study Day 139)	Fatigue	Mild
24 Jan 2021 (Study Day 139)	Nasal Congestion	Mild
24 Jan 2021 (Study Day 139)	Nausea	Mild
24 Jan 2021 (Study Day 139)	New Loss of Smell	Mild
24 Jan 2021 (Study Day 139)	New Loss of Taste	Mild
24 Jan 2021 (Study Day 139)	Vomiting	Mild
25 Jan 2021 (Study Day 140)	Body Aches	Mild
25 Jan 2021 (Study Day 140)	Nasal Congestion	Mild
25 Jan 2021 (Study Day 140)	New Loss of Smell	Mild

Symptom Date	Symptom	Result
25 Jan 2021 (Study Day 140)	New Loss of Taste	Mild
26 Jan 2021 (Study Day 141)	Body Aches	Mild
26 Jan 2021 (Study Day 141)	Nasal Congestion	Mild
26 Jan 2021 (Study Day 141)	Nausea	Mild
26 Jan 2021 (Study Day 141)	New Loss of Smell	Mild
26 Jan 2021 (Study Day 141)	New Loss of Taste	Mild
27 Jan 2021 (Study Day 142)	Fatigue	Mild
27 Jan 2021 (Study Day 142)	Nausea	Mild
27 Jan 2021 (Study Day 142)	New Loss of Smell	Mild
28 Jan 2021 (Study Day 143)	Body Aches	Mild
28 Jan 2021 (Study Day 143)	Fatigue	Mild
30 Jan 2021 (Study Day 145)	Cough	Mild
30 Jan 2021 (Study Day 145)	Fatigue	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
23 Jan 2021 (Study Day 138)	Oxygen Saturation	93%
23 Jan 2021 - 23 Jan 2021 (Study Day 138-138)	Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 17 days, after which it was considered to be recovered/resolved on 31 Jan 2021 (Study Day 146). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005514	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Hypertension	Hypertension	2012 - Ongoing
Tinea versicolour	Tinea versicolor, latent	2012 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Diabetes type ii	2012 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2014 - Ongoing
Hyperhidrosis	Hyper hydrosis - sweaty hands	2015 - Ongoing
Postmenopause	Post-menopausal	Aug 2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2000 - Ongoing	General Health Supplement
Fluticasone	2010 - Ongoing	Seasonal Allergies
Vitamin d nos	2010 - Ongoing	General Health Supplement
Lisinopril	2012 - Ongoing	Hypertension
Metformin	2012 - Ongoing	Diabetes Mellitus Type II
Atorvastatin	2014 - Ongoing	Hypercholesterolemia
Glycopyrronium	2015 - Ongoing	Sweaty Hands
Liraglutide	2017 - Ongoing	Diabetes Mellitus Type II
Fructose; glucose; sodium citrate dihydrate	26 Jan 2021 (Study Day 141) - 27 Jan 2021 (Study Day 142)	Symptomatic COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US397-2186 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 17 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 15 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypotension/Exacerbation Of Hypotension	SAE	Grade 3/severe	Not related	21 Jan 2021 (Study Day 127) – 21 Jan 2021 (Study Day 127)	Recovered/resolved
Lactic Acidosis/Lactic Acidosis	SAE	Grade 3/severe	Not related	21 Jan 2021 (Study Day 127) – 21 Jan 2021 (Study Day 127)	Recovered/resolved
Syncope/Syncope	SAE	Grade 3/severe	Not related	21 Jan 2021 (Study Day 127) – 21 Jan 2021 (Study Day 127)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US397-2186, a 75-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 17 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 15 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 21 Jan 2021. The participant was unblinded on 21 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 21 Jan 2021 (Study Day 127), 126 days after the first dose in Part A and 98 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of hypotension. Action taken with the IP was not applicable. The event of exacerbation of hypotension lasted for 1 day, after which it was considered to be recovered/resolved on 21 Jan 2021 (Study Day 127). The investigator assessed the event of hypotension to be not related to the IP.

On 21 Jan 2021 (Study Day 127), 126 days after the first dose in Part A and 98 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of lactic acidosis. Action taken with the IP was not applicable. The event of lactic acidosis lasted for 1 day, after which it was considered to be recovered/resolved on 21 Jan 2021 (Study Day 127). The investigator assessed the event of lactic acidosis to be not related to the IP.

On 21 Jan 2021 (Study Day 127), 126 days after the first dose in Part A and 98 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of syncope. Action taken with the IP was not applicable. The event of syncope lasted for 1 day, after which it was considered to be recovered/resolved on 21 Jan 2021 (Study Day 127). The investigator assessed the event of syncope to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-008627	Hypotension
MOD-2021-008627	Lactic acidosis
MOD-2021-008627	Syncope

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - 2019
Orthostatic hypotension	Orthostatic hypotension	Not reported - Ongoing
Syncope	History of syncope	Not reported - Ongoing
Haemorrhoids	Hemorrhoids	1964 - 1964
Autoimmune thyroiditis	Hashimoto's disease	2010 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2014 - Ongoing
Aneurysm	1 aneurysm	2015 - 2015
Aortic aneurysm	Aortic aneurysm	2015 - 2015
Cardiac failure congestive	Congestive heart failure at 40%	2015 - Ongoing
Coronary artery disease	Coronary artery disease	2015 - Ongoing
Myocardial infarction	Heart attack resulting in loss of function in third valve.	2015 - 2015
Urinary retention	Urinary retention	2018 - Ongoing
Constipation	Constipation	2019 - Ongoing
Gastroesophageal reflux disease	Acid reflux	2019 - 2019
Prostatomegaly	Enlarged prostate	2019 - Nov 2019
Urinary tract infection	Recurrent urinary tract infection	27 Aug 2020 (Study Day -21) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2009 - Ongoing	General Health Supplement
Atorvastatin	2010 - Ongoing	Hypercholesterolemia
Thyroid	2010 - 02 Oct 2020 (Study Day 16)	Hashimoto's Disease
Vitamin d nos	2014 - Ongoing	Vitamin D Deficiency
Metoprolol	2015 - 22 Jan 2021 (Study Day 128)	Heart Failure
Other ophthalmologicals	2018 - Ongoing	General Health Supplement
Docusate	2019 - Ongoing	Constipation
Vitamin b12 nos	Jul 2020 - Ongoing	General Health Supplement
Cefdinir	27 Aug 2020 (Study Day -21) - 03 Sep 2020 (Study Day -14)	Recurrent Urinary Tract Infection
Losartan	14 Sep 2020 (Study Day -3) - 08 Oct 2020 (Study Day 22)	Heart Failure
Cefdinir	21 Sep 2020 (Study Day 5) - 28 Sep 2020 (Study Day 12)	Recurrent Urinary Tract Infection (Uti)
Ciprofloxacin	02 Oct 2020 (Study Day 16) - 09 Oct 2020 (Study Day 23)	Recurrent Urinary Tract Injections
Thyroid	03 Oct 2020 (Study Day 17) - 30 Dec 2020 (Study Day 105)	Hashimoto's Disease
Losartan	08 Oct 2020 (Study Day 22) - 22 Jan 2021 (Study Day 128)	Heart Failure
Liraglutide	Dec 2020 - Ongoing	Weight Control
Tetanus vaccine	30 Dec 2020 (Study Day 105) - 30 Dec 2020 (Study Day 105)	Tetanus Prevention
Tamsulosin	31 Dec 2020 (Study Day 106) - 22 Jan 2021 (Study Day 128)	Urinary Retention
Thyroid	31 Dec 2020 (Study Day 106) - Ongoing	Hashimotos Disease
Spironolactone	12 Jan 2021 (Study Day 118) - Ongoing	Heart Failure
Midazolam hydrochloride	21 Jan 2021 (Study Day 127) - 21 Jan 2021 (Study Day 127)	Syncope, Sae
Sodium chloride	21 Jan 2021 (Study Day 127) - 23 Jan 2021 (Study Day 129)	Syncope/Lactic Acidosis/Exacerbation Of Hypotension, Sae

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US398-2013 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 26 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 24 Sep 2020 (Study Day 30)
First Dose of Vaccine in Part B: 15 Jan 2021 (Study Day 143)
Second Dose of Vaccine in Part B: 12 Feb 2021 (Study Day 171)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arthralgia/Joint Pain Multiple Sites	SAE	Grade 2/moderate	Not related	11 Apr 2021 (Study Day 229) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2013, a 73-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 13 Jan 2021. The participant was unblinded on 13 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 15 Jan 2021 (Study Day 143). The second dose was administered in the left arm on 12 Feb 2021 (Study Day 171).

Event Details

On 11 Apr 2021 (Study Day 229), 228 days after the first dose in Part A/86 days after the first dose in Part B and 199 days after the second dose in Part A/58 days after the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of arthralgia. Action taken with the IP was not applicable. The event of joint pain multiple sites was considered to be ongoing. The investigator assessed the event of arthralgia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-080995	Arthralgia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Bursitis	Right knee bursitis	1953 - Ongoing
Tonsillectomy	Tonsillectomy	1960 - 1960
Tonsillitis	Tonsillitis	1960 - 1960
Postmenopause	Post menopausal	1997 - Ongoing
Carpal tunnel syndrome	Carpal tunnel hands (bilateral)	2018 - Ongoing
Cataract	Cataract right eye	2018 - 24 Aug 2020 (Study Day -2)
Cataract	Cataracts left eye	2018 - Jul 2020
Osteoarthritis	Osteoarthritis knees (bilateral)	2018 - Ongoing
Hypertension	Hypertension	2019 - Ongoing
Onychomycosis	Toe nail fungus (bilateral)	2019 - Ongoing
Cataract	Cataract nemoral left eye	Jul 2020 - Jul 2020
Cataract	Cataract nemoral right eye	24 Aug 2020 (Study Day -2) - 24 Aug 2020 (Study Day -2)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium	2016 - Ongoing	Supplement
Fish oil	2016 - Ongoing	Supplement
Naproxen	2018 - Ongoing	Bilateral Osteoarthritis Knees
Terbinafine	2019 - Ongoing	Bilateral Toe Nail Fungus
Influenza vaccine	03 Aug 2020 (Study Day -23) - 03 Aug 2020 (Study Day -23)	Preventative
Methocarbamol	09 Oct 2020 (Study Day 45) - 15 Oct 2020 (Study Day 51)	Left Foot Muscle Strain
Amlodipine	14 Jan 2021 (Study Day 142) - Ongoing	Hypertension, Worsening Of
Rosuvastatin	14 Jan 2021 (Study Day 142) - Ongoing	High Cholesterol
Carpal tunnel surgery (right hand)*	22 Jan 2021 (Study Day 150) - 22 Jan 2021 (Study Day 150)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US398-2014 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 26 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 23 Sep 2020 (Study Day 29)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Flutter/ Atrial Flutter	SAE	Grade 3/ severe	Not related	14 Mar 2021 (Study Day 201) – 15 Mar 2021 (Study Day 202)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2014, a 72-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 14 Mar 2021 (Study Day 201), 200 days after the first dose in Part A and 172 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of atrial flutter. Action taken with the IP was not applicable. The event of atrial flutter lasted for 2 days, after which it was considered to be recovered/resolved on 15 Mar 2021 (Study Day 202). The investigator assessed the event of atrial flutter to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-055122	Atrial flutter

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Hyperlipidemia	01 Jan 1970 (Study Day -18500) - Ongoing
Gout	Gout	01 Jan 2000 (Study Day -7543) - Ongoing
Oesophagectomy	Partial esophageal removal	2008 - 2008
Oesophageal carcinoma	Esophageal cancer	01 Jan 2008 (Study Day -4621) - 2008
Deafness	Hearing loss	01 Jan 2010 (Study Day -3890) - Ongoing
Gastroesophageal reflux disease	Gastroesophageal reflux disease	01 Jan 2010 (Study Day -3890) - Ongoing
Cataract	Cataracts bilateral	01 Jan 2013 (Study Day -2794) - 01 Jan 2016 (Study Day -1699)
Vestibular disorder	Vestibulopathy (intermittent)	2015 - Ongoing
Bone operation	Clavical repair	2016 - 2016
Cataract operation	Cataracts repair	2016 - 2016
Clavicle fracture	Clavicle fracture	01 Jan 2016 (Study Day -1699) - 2016
Mitral valve stenosis	Mitral valve stenosis	01 Jan 2018 (Study Day -968) - Jun 2020
Anaemia	Mild anemia	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Indometacin	2000 - Ongoing	Gout
Vitamin d nos	01 Jan 2008 (Study Day -4621) - Ongoing	Cancer Prevention Supplemental
Omeprazole	2010 - Ongoing	Gastroesophageal Reflux Disease
Vitamin b12 nos	01 Jan 2014 (Study Day -2429) - Ongoing	Supplemental
Famotidine	2015 - Ongoing	Gastroesophageal Reflux Disease
Chondroitin; glucosamine	01 Jan 2020 (Study Day -238) - Ongoing	Supplemental
Fish oil	01 Jan 2020 (Study Day -238) - Ongoing	Joint Supplement
Vitamins nos	01 Jan 2020 (Study Day -238) - Ongoing	Supplemental
Atorvastatin	15 Apr 2020 (Study Day -133) - 12 Apr 2021 (Study Day 230)	Hyperlipidemia
Colchicine; probenecid	15 Apr 2020 (Study Day -133) - Ongoing	Gout
Influenza vaccine inact split 4v	15 Oct 2020 (Study Day 51) - 15 Oct 2020 (Study Day 51)	Influenza Prophylaxis
Lisinopril	2021 - Ongoing	Hypertension
Diltiazem	14 Mar 2021 (Study Day 201) - 14 Mar 2021 (Study Day 201)	Atrial Flutter
Enoxaparin	14 Mar 2021 (Study Day 201) - 14 Mar 2021 (Study Day 201)	Atrial Flutter

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Apixaban	15 Mar 2021 (Study Day 202) - Ongoing	Clot Prevention Ae #5
Losartan	15 Mar 2021 (Study Day 202) - Ongoing	Hypertention
Metoprolol	15 Mar 2021 (Study Day 202) - Ongoing	Atrial Flutter

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 2/moderate	Not related	13 Mar 2021 (Study Day 200) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US398-2028 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 03 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 01 Oct 2020 (Study Day 29)
First Dose of Vaccine in Part B: 13 Jan 2021 (Study Day 133)
Second Dose of Vaccine in Part B: 10 Feb 2021 (Study Day 161)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Post Procedural Hypotension/ Orthostatic Hypotension, Post Operative	SAE	Grade 2/ moderate	Not related	21 Jan 2021 (Study Day 141) – 24 Jan 2021 (Study Day 144)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2028, a 69-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 11 Jan 2021. The participant was unblinded on 11 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 13 Jan 2021 (Study Day 133). The second dose was administered in the left arm on 10 Feb 2021 (Study Day 161).

Event Details

On 21 Jan 2021 (Study Day 141), 140 days after the first dose in Part A/8 days after the first dose in Part B and 112 days after the second dose in Part A/20 days before the second dose in Part B of the IP, the participant experienced a Grade 2/moderate serious adverse event of post procedural hypotension. The IP dose was not changed due to the orthostatic hypotension, post operative. The event of orthostatic hypotension, post operative lasted for 4 days, after which it was considered to be recovered/resolved on 24 Jan 2021 (Study Day 144). The investigator assessed the event of post procedural hypotension to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-008100	Post procedural hypotension

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1954 - 1954
Tonsillitis	Tonsillitis	1954 - 1954
Obesity	Obesity	1967 - Ongoing
Vasectomy	Vasectomy	1988 - 1988
Sleep apnoea syndrome	Obstructive sleep apnea	1990 - 2005
Cholecystectomy	Gall bladder removal	13 Feb 1997 (Study Day -8603) - 13 Feb 1997 (Study Day -8603)
Cholecystitis infective	Gall bladder infection	13 Feb 1997 (Study Day -8603) - 13 Feb 1997 (Study Day -8603)
Basal cell carcinoma	Basal cell carcinoma	04 Feb 1998 (Study Day -8247) - 04 Feb 1998 (Study Day -8247)
Basal cell carcinoma	Basal cell carcinoma-nose (skin cancer)	04 Feb 1998 (Study Day -8247) - 04 Feb 1998 (Study Day -8247)
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Osteoarthritis	Osteoarthritis bilateral knee	2000 - Ongoing
Osteoporosis	Osteoporosis	2000 - Ongoing
Rhinitis allergic	Allergic rhinitis	2000 - Ongoing
Sinusitis	Sinusitis	2001 - 06 Nov 2001 (Study Day -6876)
Nasal septal operation	Septoplasty	06 Nov 2001 (Study Day -6876) - 06 Nov 2001 (Study Day -6876)
Carpal tunnel decompression	Carpal tunnel right/left hands surgery	03 Oct 2003 (Study Day -6180) - 03 Oct 2003 (Study Day -6180)
Carpal tunnel syndrome	Carpal tunnel right/left hands	03 Oct 2003 (Study Day -6180) - 03 Oct 2003 (Study Day -6180)
Arthroscopy	Arthroscopic left knee	25 Nov 2003 (Study Day -6127) - 25 Nov 2003 (Study Day -6127)
Meniscus injury	Left knee torn meniscus	25 Nov 2003 (Study Day -6127) - 25 Nov 2003 (Study Day -6127)
Appendicitis	Appendicitis	2004 - 27 Jan 2005 (Study Day -5698)
Hyperparathyroidism	Hyperparathyroidism	2005 - Ongoing
Hypothyroidism	Hypothyroidism	2005 - Ongoing
Appendectomy	Appendectomy	27 Jan 2005 (Study Day -5698) - 27 Jan 2005 (Study Day -5698)
Catheterisation cardiac	Heart cath	28 Feb 2009 (Study Day -4205) - 28 Feb 2009 (Study Day -4205)
Device occlusion	Heart cath blockage	28 Feb 2009 (Study Day -4205) - 28 Feb 2009 (Study Day -4205)
Peyronie's disease	Peyronie's disease	2010 - 2010

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Prostatomegaly	Enlarged prostate	2010 - Ongoing
Rosacea	Rosacea	2015 - 2020
Cataract	Cataracts (bilateral)	2018 - 07 Mar 2018 (Study Day -911)
Anxiety	Anxiety	2019 - Ongoing
Chronic kidney disease	Chronic kidney disease stage 3	2019 - Ongoing
Major depression	Severe major depression	2019 - Ongoing
Salivary gland calculus	Sialolithiasis	Aug 2020 - Ongoing
Arthralgia	Right wrist pain	24 Aug 2020 (Study Day -10) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Denosumab	2000 - Ongoing	Osteoporosis
Famotidine	2000 - Ongoing	Gastroesophageal Reflux Disease
Hydrochlorothiazide	2000 - 20 Jan 2021 (Study Day 140)	Hypertension
Montelukast	2000 - Ongoing	Allergic Rhinitis
Paracetamol	2000 - Ongoing	Osteoarthritis Knee
Telmisartan	2000 - 20 Jan 2021 (Study Day 140)	Hypertension
Calcitriol	2005 - Ongoing	Hyperparathyroidism
Calcium citrate	2005 - Ongoing	Supplement
Fish oil	2005 - Ongoing	Supplement
Levothyroxine sodium	2005 - Ongoing	Hypothyroidism
Melatonin	2005 - Ongoing	Supplement
Potassium citrate	2005 - Ongoing	Supplement
Vitamin b12 nos	2005 - Ongoing	Supplement
Vitamin d nos	2005 - Ongoing	Supplement
Vitamin e nos	2005 - Ongoing	Supplement
Vitamins nos	2005 - Ongoing	Supplement
Finasteride	2010 - Ongoing	Enlarged Prostate
Bupropion	2019 - Ongoing	Anxiety
Paroxetine	2019 - 21 Dec 2020 (Study Day 110)	Severe Major Depression
Tamsulosin	2019 - Ongoing	Enlarged Prostate
Indometacin	31 Aug 2020 (Study Day -3) - 06 Sep 2020 (Study Day 4)	Wrist Pain
Paroxetine	22 Dec 2020 (Study Day 111) - Ongoing	Severe Major Depression
Arthroplasty right knee*	20 Jan 2021 (Study Day 140) - 20 Jan 2021 (Study Day 140)	Medical History
Hydrocodone bitartrate; paracetamol	20 Jan 2021 (Study Day 140) - Ongoing	Arthroplasty Right Knee
Methocarbamol	20 Jan 2021 (Study Day 140) - Ongoing	Arthroplasty Right Knee
Apixaban	24 Jan 2021 (Study Day 144) - 08 Feb 2021 (Study Day 159)	Arthroplasty Right Knee

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	10 Mar 2021 (Study Day 189) - 10 Mar 2021 (Study Day 189)	Headache
Hydrochlorothiazide	25 Mar 2021 (Study Day 204) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 2/moderate	Not related	10 Mar 2021 (Study Day 189) - 10 Mar 2021 (Study Day 189)
Hypertension	Grade 2/moderate	Not related	10 Mar 2021 (Study Day 189) - Ongoing
Prostatic Specific Antigen Increased	Grade 1/mild	Not related	15 Mar 2021 (Study Day 194) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US398-2112 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 65 Years
First Dose of Vaccine in Part A: 04 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Oct 2020 (Study Day 36)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Coronary Artery Disease/Coronary Artery Disease, Worsening	SAE	Grade 3/ severe	Not related	28 Jan 2021 (Study Day 147) – 12 Feb 2021 (Study Day 162)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2112, a 73-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 05 Jan 2021. The participant was unblinded on 05 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 28 Jan 2021 (Study Day 147), 146 days after the first dose in Part A and 111 days after the second dose in Part A of the IP, the participant experienced a Grade 3/severe serious adverse event of coronary artery disease. Action taken with the IP was not applicable. The event of coronary artery disease, worsening lasted for 16 days, after which it was considered to be recovered/resolved on 12 Feb 2021 (Study Day 162). The investigator assessed the event of coronary artery disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010317	Coronary artery disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	2000 - Ongoing
Coronary arterial stent insertion	Cardiac stents	2005 - 2005
Hyperlipidaemia	Hyperlipidemia	2005 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Myocardial infarction	Heart attack	2005 - 2005
Erectile dysfunction	Erectile dysfunction	2008 - Ongoing
Prostate cancer	Prostate cancer	2008 - 2008
Radiotherapy to prostate	Radiation therapy for prostate cancer	2008 - 2008
Urinary retention	Urinary retention	2008 - Ongoing
Intestinal perforation	Perforated bowel	2010 - 2010
Intestinal resection	Bowel resection	2010 - 2010
Seasonal allergy	Seasonal allergies	2017 - Ongoing
Gastroesophageal reflux disease	Acid reflux	2018 - Ongoing
Bradycardia	Bradycardia	15 Apr 2020 (Study Day -142) - Ongoing
Heart rate irregular	Irregular heart beat	15 Aug 2020 (Study Day -20) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bupropion hydrochloride	2000 - Ongoing	Depression
Atorvastatin	2005 - Ongoing	Hyperlipidemia
Clopidogrel bisulfate	2005 - Ongoing	Hyperlipidemia
Sildenafil	2008 - Ongoing	Erectile Dysfunction
Tamsulosin	2008 - Ongoing	Urinary Retention
Fluticasone	2017 - Ongoing	Seasonal Allergies
Citalopram	2018 - Ongoing	Depression
Hydrochlorothiazide	2018 - Ongoing	Hypertension
Omeprazole	2018 - Ongoing	Acid Reflux
Nifedipine	Mar 2020 - Ongoing	Hypertension
Paracetamol	12 Sep 2020 (Study Day 9) - 12 Sep 2020 (Study Day 9)	Fever

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	10 Oct 2020 (Study Day 37) - 11 Oct 2020 (Study Day 38)	Muscle Pain And Headache
Paracetamol	14 Oct 2020 (Study Day 41) - 14 Oct 2020 (Study Day 41)	Muscle Pain And Headache Prevention
Cardiac pacemaker implantation*	17 Dec 2020 (Study Day 105) - 17 Dec 2020 (Study Day 105)	Adverse Event
Cinacalcet hydrochloride	21 Dec 2020 (Study Day 109) - Ongoing	Hyperparathyroidism
Amiodarone	29 Jan 2021 (Study Day 148) - 11 Feb 2021 (Study Day 161)	Post Operative Atrial Fib
Coronary artery bypass grafting x2 with lima to lad and svg to om1*	04 Feb 2021 (Study Day 154) - 04 Feb 2021 (Study Day 154)	Adverse Event
Amiodarone	12 Feb 2021 (Study Day 162) - Ongoing	Post Operative Atrial Fib

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US398-2147 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and at Risk
First Dose of Vaccine in Part A: 10 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 13 Oct 2020 (Study Day 34)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Substance Use Disorder/ Worsening Of Substance Use Disorder	SAE	Grade 2/ moderate	Not related	11 Mar 2021 (Study Day 183) – 18 Mar 2021 (Study Day 190)	Recovered/ resolved with sequelae
Pancreatitis/Pancreatitis	SAE	Grade 1/ mild	Not related	15 Mar 2021 (Study Day 187) – 16 Mar 2021 (Study Day 188)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2147, a 52-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 13 Oct 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 12 Jan 2021. The participant was unblinded on 13 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 11 Mar 2021 (Study Day 183), 182 days after the first dose in Part A and 149 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of substance use disorder. Action taken with the IP was not applicable. The event of worsening of substance use disorder lasted for 8 days, after which it was considered to be recovered/resolved with sequelae on 18 Mar 2021 (Study Day 190). The investigator assessed the event of substance use disorder to be not related to the IP.

On 15 Mar 2021 (Study Day 187), 186 days after the first dose in Part A and 153 days after the second dose in Part A of the IP, the participant experienced a Grade 1/mild serious adverse event of pancreatitis. Action taken with the IP was not applicable. The event of pancreatitis lasted for 2 days, after which it was considered to be recovered/resolved on 16 Mar 2021 (Study Day 188). The investigator assessed the event of pancreatitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-065034	Substance use disorder
MOD-2021-065034	Pancreatitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - Ongoing
Asthma	Asthma	(b) (6) 1967 (Study Day (b) (6) - Ongoing
Seasonal allergy	Seasonal allergies	1972 - Ongoing
Appendectomy	Appendectomy	1985 - 1985
Appendicitis	Appendicitis	1985 - 1985
Bipolar disorder	Bipolar disorder	1995 - Ongoing
Depression	Depression	1995 - Ongoing
Osteonecrosis	Avascular necrosis (bilateral hips)	1995 - Ongoing
Post-traumatic stress disorder	Post traumatic stress disorder	1995 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Erectile dysfunction	Erectile dysfunction	2010 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2010 - Ongoing
Anxiety	Anxiety	2017 - Ongoing
Arthralgia	Bilateral hip apin	2019 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2019 - Ongoing
Pneumonia	Pneumonia	Dec 2019 - Dec 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1990 - Ongoing	Asthma
Amlodipine	2010 - Ongoing	Hypertension
Atorvastatin	2010 - Ongoing	Hypercholesterolemia
Lisinopril	2010 - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Prazosin	2010 - Ongoing	Post Traumatic Stress Disorder
Quetiapine	2010 - Ongoing	Bipolar Disorder
Buspirone	2015 - Ongoing	Anxiety
Fish oil	2015 - Ongoing	Supplement
Montelukast	2015 - Ongoing	Seasonal Allergies
Venlafaxine	2018 - Ongoing	Depression / Bipolar Disorder
Diclofenac	2019 - Ongoing	Avascular Necrosis Bilateral Hips
Hydrocodone; paracetamol	2019 - Ongoing	Avascular Necrosis Bilateral Hips
Insulin glargine	2019 - Ongoing	Diabetes Mellitus Type 2
Lorazepam	2019 - Ongoing	Anxiety
Metformin	2019 - Ongoing	Type II Diabetes
Oxycodone	2019 - Ongoing	Avascular Necrosis Bilateral Hips
Pioglitazone	2019 - Ongoing	Type II Diabetes
Paracetamol	14 Oct 2020 (Study Day 35) - Ongoing	Viral Syndrome Vs Reactogenicity To 2nd Dose Ip.
Naproxen	15 Oct 2020 (Study Day 36) - Ongoing	Viral Syndrome Vs Reactogenicity To 2nd Dose Ip
Dextromethorphan; paracetamol; phenylephrine	16 Oct 2020 (Study Day 37) - Ongoing	Viral Syndrome Vs Reactogenicity To 2nd Dose Ip, Ae #10
Empagliflozin	03 Nov 2020 (Study Day 55) - Ongoing	Type 2 Diabetes
Influenza vaccine	05 Nov 2020 (Study Day 57) - 05 Nov 2020 (Study Day 57)	Flu Prophylaxis
Ciprofloxacin hydrochloride; dexamethasone	09 Nov 2020 (Study Day 61) - 14 Dec 2020 (Study Day 96)	Otitis Externa
Azithromycin	09 Dec 2020 (Study Day 91) - 14 Dec 2020 (Study Day 96)	Bronchopneumonia
Chlorphenamine maleate; dextromethorphan hydrobromide; paracetamol	09 Dec 2020 (Study Day 91) - Ongoing	Bronchopneumonia
Dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	09 Dec 2020 (Study Day 91) - Ongoing	Bronchopneumonia
Dextromethorphan; guaifenesin	09 Dec 2020 (Study Day 91) - Ongoing	Bronchopneumonia
Methylprednisolone	09 Dec 2020 (Study Day 91) - 09 Dec 2020 (Study Day 91)	Bronchopneumonia
Sutures*	17 Jan 2021 (Study Day 130) - 17 Jan 2021 (Study Day 130)	Adverse Event
Doxycycline	24 Jan 2021 (Study Day 137) - 02 Feb 2021 (Study Day 146)	Laceration To Foot
Azithromycin	05 Feb 2021 (Study Day 149) - 08 Feb 2021 (Study Day 152)	Laceration To Foot
Prednisone	16 Feb 2021 (Study Day 160) - 23 Feb 2021 (Study Day 167)	Uri
Buprenorphine hydrochloride; naloxone hydrochloride	18 Mar 2021 (Study Day 190) - Ongoing	Worsening Of Substance Use Disorder.
Prednisone	25 Mar 2021 (Study Day 197) - 29 Mar 2021 (Study Day 201)	Bronchitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Skin Laceration	Grade 2/moderate	Not related	17 Jan 2021 (Study Day 130) - 09 Mar 2021 (Study Day 181)
Bronchitis	Grade 2/moderate	Not related	25 Mar 2021 (Study Day 197) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US398-2169 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥65 Years
First Dose of Vaccine in Part A: 14 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 09 Oct 2020 (Study Day 26)
First Dose of Vaccine in Part B: 06 Jan 2021 (Study Day 115)
Second Dose of Vaccine in Part B: 03 Feb 2021 (Study Day 143)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nephrolithiasis/Worsening Of Renal Stones	SAE	Grade 3/ severe	Not related	03 Feb 2021 (Study Day 143) – 06 Feb 2021 (Study Day 146)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2169, an 81-year-old not Hispanic or Latino male, received the first dose of Placebo in the left arm on 14 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Jan 2021. The participant was unblinded on 04 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 06 Jan 2021 (Study Day 115). The second dose was administered in the left arm on 03 Feb 2021 (Study Day 143).

Event Details

On 03 Feb 2021 (Study Day 143), 142 days after the first dose in Part A/28 days after the first dose in Part B and 117 days after the second dose in Part A/on the day of the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of nephrolithiasis. Action taken with the IP was not applicable. The event of worsening of renal stones lasted for 4 days, after which it was considered to be recovered/resolved on 06 Feb 2021 (Study Day 146). The investigator assessed the event of nephrolithiasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014084	Nephrolithiasis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nephrolithiasis	Renal stone	Not reported - Ongoing
Inguinal hernia	(r) groin hernia	1995 - 1995
Inguinal hernia repair	(r) groin hernia repair	1995 - 1995
Inguinal hernia	(l) groin hernia	2000 - 2000
Inguinal hernia repair	(l) groin hernia repair	2000 - 2000
Hyperlipidaemia	Hyperlipidemia	2005 - Ongoing
Umbilical hernia	Umbilical hernia	2005 - 2005
Umbilical hernia repair	Umbilical hernia repair	2005 - 2005
Cataract	Cataracts (bilateral)	2010 - 2010
Cataract operation	Bilateral cataract surgery	2010 - 2010
Erectile dysfunction	Erectile dysfunction	2010 - Ongoing
Syncope	Syncope	2016 - 2016
Balance disorder	Balance issue	2017 - Ongoing
Osteoarthritis	Arthritis (osteoarthritis)	2017 - Ongoing
Peripheral arterial occlusive disease	Peripheral artery disease (legs)	2018 - Ongoing
Deafness	Hearing loss (mild)	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2005 - Ongoing	Hyperlipidemia
Acetylcysteine; calcium mefolinate; mecobalamin	2015 - Ongoing	To Prevent Memory Loss
Acetylsalicylic acid	2015 - Ongoing	To Prevent Blood Clots
Bisoprolol	2015 - Ongoing	To Prevent Hypertension
Vitamins nos	2015 - Ongoing	Supplement
Vitamin d nos	2017 - Ongoing	Supplement
Vitamins nos	2017 - Ongoing	Supplement
Minocycline	30 Dec 2020 (Study Day 108) - 13 Jan 2021 (Study Day 122)	Left Leg Anterior Infection
Cefdinir	23 Jan 2021 (Study Day 132) - 02 Feb 2021 (Study Day 142)	Left Anterior Leg Infection

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metronidazole	23 Jan 2021 (Study Day 132) - 02 Feb 2021 (Study Day 142)	Left Anterior Leg Infection
Lithotripsy for renal stones*	06 Feb 2021 (Study Day 146) - 06 Feb 2021 (Study Day 146)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US398-2194 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥ 18 and < 65 Years and Not at Risk
First Dose of Vaccine in Part A: 17 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 14 Oct 2020 (Study Day 28)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Bradycardia/Symptomatic Bradycardia	SAE	Grade 2/ moderate	Not related	06 Apr 2021 (Study Day 202) – 08 Apr 2021 (Study Day 204)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2194, a 59-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 17 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 14 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 10 Feb 2021. The participant was unblinded on 23 Feb 2021 and had already received both doses of mRNA-1273 in Part A.

Event Details

On 06 Apr 2021 (Study Day 202), 201 days after the first dose in Part A and 174 days after the second dose in Part A of the IP, the participant experienced a Grade 2/moderate serious adverse event of bradycardia. Action taken with the IP was not applicable. The event of symptomatic bradycardia lasted for 3 days, after which it was considered to be recovered/resolved with sequelae on 08 Apr 2021 (Study Day 204). The investigator assessed the event of bradycardia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-078649	Bradycardia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Hypothyroidism	Hypothyroidism	2019 - Ongoing
Nasal congestion	Nasal congestion	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxymetazoline	Mar 2020 - Mar 2021	Nasal Congestion
Ibuprofen	15 Oct 2020 (Study Day 29) - 15 Oct 2020 (Study Day 29)	Pain At Injection Site
Paracetamol	01 Jan 2021 (Study Day 107) - 02 Jan 2021 (Study Day 108)	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US398-2269 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and at Risk
First Dose of Vaccine in Part A: 09 Oct 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 06 Nov 2020 (Study Day 29)
First Dose of Vaccine in Part B: 17 Feb 2021 (Study Day 132)
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Gait Disturbance/Gait Balance And Motility Dysfunction	SAE	Grade 2/ moderate	Not related	03 Mar 2021 (Study Day 146) – 22 Mar 2021 (Study Day 165)	Recovered/ resolved
Pneumonia/Bilateral Perihilar Pneumonia	SAE	Grade 2/ moderate	Not related	03 Mar 2021 (Study Day 146) – 22 Mar 2021 (Study Day 165)	Recovered/ resolved
Cystitis/Acute Cystitis	SAE	Grade 2/ moderate	Not related	18 Mar 2021 (Study Day 161) – 22 Mar 2021 (Study Day 165)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2269, a 58-year-old not Hispanic or Latino female, received the first dose of Placebo in the left arm on 09 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 06 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 13 Feb 2021. The participant was unblinded on 13 Feb 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 17 Feb 2021 (Study Day 132). The second dose was not administered.

Event Details

On 03 Mar 2021 (Study Day 146), 145 days after the first dose in Part A/14 days after the first dose in Part B and 117 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 2/moderate serious adverse event of gait disturbance. The IP dose was not changed due to the gait balance and motility dysfunction. The event of gait balance and motility dysfunction lasted for 20 days, after which it was considered to be recovered/resolved on 22 Mar 2021 (Study Day 165). The investigator assessed the event of gait disturbance to be not related to the IP.

On 03 Mar 2021 (Study Day 146), 145 days after the first dose in Part A/14 days after the first dose in Part B and 117 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 2/moderate serious adverse event of pneumonia.

The IP dose was not changed due to the bilateral perihilar pneumonia. The event of bilateral perihilar pneumonia lasted for 20 days, after which it was considered to be recovered/resolved on 22 Mar 2021 (Study Day 165). The investigator assessed the event of pneumonia to be not related to the IP.

On 18 Mar 2021 (Study Day 161), 160 days after the first dose in Part A/29 days after the first dose in Part B and 132 days after the second dose in Part A of the IP (second dose Part B not applicable), the participant experienced a Grade 2/moderate serious adverse event of cystitis. The IP dose was not changed due to the acute cystitis. The event of acute cystitis lasted for 5 days, after which it was considered to be recovered/resolved on 22 Mar 2021 (Study Day 165). The investigator assessed the event of cystitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-064928	Gait disturbance
MOD-2021-064928	Pneumonia
MOD-2021-064928	Cystitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	Not reported - Ongoing
Obesity	Obesity	Not reported - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	07 Jul 1990 (Study Day -11052) - Ongoing
Deafness bilateral	Hearing loss bilateral	Jun 2000 - Ongoing
Gastroesophageal reflux disease	Acid reflux	2013 - Ongoing
Intervertebral disc degeneration	Lumbar disk degeneration	2015 - Ongoing
Osteoarthritis	Osteoarthritis right knee	15 Jul 2015 (Study Day -1913) - Ongoing
Blood cholesterol increased	High cholesterol	28 Jun 2016 (Study Day -1564) - Ongoing
Hypertension	Hypertension	28 Jun 2016 (Study Day -1564) - Ongoing
Transient ischaemic attack	Transient ischemic attack	15 Jul 2016 (Study Day -1547) - 15 Jul 2016 (Study Day -1547)
Nausea	Nausea intermittent	2017 - Ongoing
Postmenopause	Post menopausal	2017 - Ongoing
Seasonal allergy	Seasonal allergies	2017 - Ongoing
Neuropathy peripheral	Peripheral neuropathy	2018 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Spinal fusion surgery	Spinal fusion	2018 - 2018
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2019 - Ongoing
Hypertonic bladder	Overactive bladder	09 Oct 2019 (Study Day -366) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cyclobenzaprine	Not reported - Ongoing	Lumbar Disc Degenerations
Insulin human	1990 - Ongoing	Type 2 Diabetes
Insulin lispro	1990 - 03 Dec 2020 (Study Day 56)	Type 2 Diabetes
Glipizide	25 Jul 1990 (Study Day -11034) - 02 Dec 2020 (Study Day 55)	Type 2 Diabetes
Acetylsalicylic acid	2017 - Ongoing	Cardiac Prophylaxis
Atorvastatin	2017 - Ongoing	High Cholesterol
Lisinopril	2017 - Ongoing	Hypertension
Loratadine	2017 - Ongoing	Seasonal Allergies
Ondansetron	2017 - Ongoing	Intermittent Nausea
Pantoprazole	2017 - Ongoing	Acid Reflux
Baclofen	2018 - Ongoing	Neuropathy
Duloxetine	2018 - 17 Dec 2020 (Study Day 70)	Neuropathy
Gabapentin	Jun 2018 - Ongoing	Neuropathy
Salbutamol	2019 - Ongoing	Chronic Obstructive Pulmonary Disease
Oxybutynin	Oct 2019 - Ongoing	Overactive Bladder
Ct brain perfusion scan*	02 Dec 2020 (Study Day 55) - 02 Dec 2020 (Study Day 55)	Adverse Event
Ct brain*	03 Dec 2020 (Study Day 56) - 03 Dec 2020 (Study Day 56)	Adverse Event
Cta brain*	03 Dec 2020 (Study Day 56) - 03 Dec 2020 (Study Day 56)	Adverse Event
Ecg*	03 Dec 2020 (Study Day 56) - 03 Dec 2020 (Study Day 56)	Adverse Event
X-ray chest*	03 Dec 2020 (Study Day 56) - 03 Dec 2020 (Study Day 56)	Adverse Event
X-ray hip*	03 Dec 2020 (Study Day 56) - 03 Dec 2020 (Study Day 56)	Adverse Event
Mri brain*	05 Dec 2020 (Study Day 58) - 05 Dec 2020 (Study Day 58)	Adverse Event
Amlodipine	17 Dec 2020 (Study Day 70) - Ongoing	Hypertension
Carvedilol	17 Dec 2020 (Study Day 70) - Ongoing	Hypertension
Dicycloverine	17 Dec 2020 (Study Day 70) - Ongoing	Irritable Bowel Syndrome
Metformin	Feb 2021 - Ongoing	Diabetes Mellitus 2

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ceftriaxone	05 Feb 2021 (Study Day 120) - 07 Feb 2021 (Study Day 122)	Cystitis Acute
Glucose	05 Feb 2021 (Study Day 120) - 05 Feb 2021 (Study Day 120)	Hypoglycemia
Insulin glargine	05 Feb 2021 (Study Day 120) - 08 Mar 2021 (Study Day 151)	Type Two Diabetes
Insulin lispro	05 Feb 2021 (Study Day 120) - Ongoing	Type Two Diabetes
Sodium chloride	05 Feb 2021 (Study Day 120) - 05 Feb 2021 (Study Day 120)	Hypoglycemia
Cefdinir	08 Feb 2021 (Study Day 123) - 10 Feb 2021 (Study Day 125)	Cystitis Acute
Fluconazole	08 Feb 2021 (Study Day 123) - 08 Feb 2021 (Study Day 123)	Prophylaxis For Cystitis Acute
Occupational therapy*	03 Mar 2021 (Study Day 146) - 03 Mar 2021 (Study Day 146)	Other, Motility Dysfunctional
Physical therapy*	03 Mar 2021 (Study Day 146) - 03 Mar 2021 (Study Day 146)	Other, Motility Dysfunctional
Meropenem	04 Mar 2021 (Study Day 147) - 07 Mar 2021 (Study Day 150)	Urinary Tract Infection
Cefdinir	06 Mar 2021 (Study Day 149) - 16 Mar 2021 (Study Day 159)	Bilateral Pneumonia
Fluconazole	06 Mar 2021 (Study Day 149) - 12 Mar 2021 (Study Day 155)	Vaginal Candidiasis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Vulvovaginal Candidiasis	Grade 2/moderate	Not related	06 Mar 2021 (Study Day 149) - 12 Mar 2021 (Study Day 155)

Preferred terms are coded using MedDRA version 23.0.

Participant Number: US399-2024 (Part B)
Vaccination Group: mRNA-1273 in Part A and no mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 23 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 27 Oct 2020 (Study Day 35)
First Dose of Vaccine in Part B: Not Administered
Second Dose of Vaccine in Part B: Not Administered
Reason for Narrative: Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 2/ moderate	Not related	19 Jan 2021 (Study Day 119) – 04 Feb 2021 (Study Day 135)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US399-2024, a 27-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 23 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 27 Oct 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 04 Jan 2021. The participant was unblinded on 04 Jan 2021 and had already received both doses of mRNA-1273 in Part A.

Severe COVID-19 Details

On 19 Jan 2021 (Study Day 119), 118 days after the first dose in Part A and 84 days after the second dose in Part A of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 35, 27 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 21 Jan 2021 (Study Day 121), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
19 Jan 2021 (Study Day 119)	Chills	Mild
19 Jan 2021 (Study Day 119)	Nasal Congestion	Mild
19 Jan 2021 (Study Day 119)	Runny Nose (Rhinorrhea)	Mild
20 Jan 2021 (Study Day 120)	Body Aches	Mild
20 Jan 2021 (Study Day 120)	Chills	Mild
20 Jan 2021 (Study Day 120)	Fatigue	Moderate
20 Jan 2021 (Study Day 120)	Muscle Aches (Myalgia)	Mild
20 Jan 2021 (Study Day 120)	Nasal Congestion	Mild
20 Jan 2021 (Study Day 120)	Runny Nose (Rhinorrhea)	Mild
21 Jan 2021 (Study Day 121)	Body Aches	Mild
21 Jan 2021 (Study Day 121)	Chills	Mild
21 Jan 2021 (Study Day 121)	Fatigue	Moderate
21 Jan 2021 (Study Day 121)	Headache	Moderate
21 Jan 2021 (Study Day 121)	Muscle Aches (Myalgia)	Mild
21 Jan 2021 (Study Day 121)	Nasal Congestion	Mild
21 Jan 2021 (Study Day 121)	O2 Saturation (%)	87
21 Jan 2021 (Study Day 121)	Runny Nose (Rhinorrhea)	Mild
22 Jan 2021 (Study Day 122)	Body Aches	Moderate
22 Jan 2021 (Study Day 122)	Chills	Mild
22 Jan 2021 (Study Day 122)	Fatigue	Moderate
22 Jan 2021 (Study Day 122)	Headache	Moderate
22 Jan 2021 (Study Day 122)	Muscle Aches (Myalgia)	Moderate
22 Jan 2021 (Study Day 122)	Nasal Congestion	Mild
22 Jan 2021 (Study Day 122)	Runny Nose (Rhinorrhea)	Mild
23 Jan 2021 (Study Day 123)	Body Aches	Moderate
23 Jan 2021 (Study Day 123)	Chills	Mild
23 Jan 2021 (Study Day 123)	Fatigue	Moderate
23 Jan 2021 (Study Day 123)	Headache	Moderate
23 Jan 2021 (Study Day 123)	Muscle Aches (Myalgia)	Moderate
23 Jan 2021 (Study Day 123)	Nasal Congestion	Mild
23 Jan 2021 (Study Day 123)	Runny Nose (Rhinorrhea)	Mild
24 Jan 2021 (Study Day 124)	Body Aches	Moderate
24 Jan 2021 (Study Day 124)	Chills	Mild
24 Jan 2021 (Study Day 124)	Fatigue	Moderate
24 Jan 2021 (Study Day 124)	Headache	Moderate
24 Jan 2021 (Study Day 124)	Muscle Aches (Myalgia)	Moderate
24 Jan 2021 (Study Day 124)	Nasal Congestion	Mild
24 Jan 2021 (Study Day 124)	Runny Nose (Rhinorrhea)	Mild
25 Jan 2021 (Study Day 125)	Body Aches	Moderate
25 Jan 2021 (Study Day 125)	Chills	Mild

Symptom Date	Symptom	Result
25 Jan 2021 (Study Day 125)	Fatigue	Moderate
25 Jan 2021 (Study Day 125)	Headache	Mild
25 Jan 2021 (Study Day 125)	Muscle Aches (Myalgia)	Moderate
25 Jan 2021 (Study Day 125)	Nasal Congestion	Mild
25 Jan 2021 (Study Day 125)	Runny Nose (Rhinorrhea)	Mild
26 Jan 2021 (Study Day 126)	Body Aches	Moderate
26 Jan 2021 (Study Day 126)	Fatigue	Moderate
26 Jan 2021 (Study Day 126)	Headache	Mild
26 Jan 2021 (Study Day 126)	Muscle Aches (Myalgia)	Moderate
26 Jan 2021 (Study Day 126)	Nasal Congestion	Mild
26 Jan 2021 (Study Day 126)	Runny Nose (Rhinorrhea)	Mild
27 Jan 2021 (Study Day 127)	Body Aches	Mild
27 Jan 2021 (Study Day 127)	Fatigue	Moderate
27 Jan 2021 (Study Day 127)	Headache	Mild
27 Jan 2021 (Study Day 127)	Muscle Aches (Myalgia)	Mild
27 Jan 2021 (Study Day 127)	Nasal Congestion	Mild
27 Jan 2021 (Study Day 127)	Runny Nose (Rhinorrhea)	Mild
28 Jan 2021 (Study Day 128)	Body Aches	Mild
28 Jan 2021 (Study Day 128)	Fatigue	Mild
28 Jan 2021 (Study Day 128)	Muscle Aches (Myalgia)	Mild
29 Jan 2021 (Study Day 129)	Body Aches	Mild
29 Jan 2021 (Study Day 129)	Fatigue	Mild
29 Jan 2021 (Study Day 129)	Muscle Aches (Myalgia)	Mild
30 Jan 2021 (Study Day 130)	Body Aches	Mild
30 Jan 2021 (Study Day 130)	Fatigue	Mild
30 Jan 2021 (Study Day 130)	Muscle Aches (Myalgia)	Mild
31 Jan 2021 (Study Day 131)	Fatigue	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
21 Jan 2021 (Study Day 121)	Oxygen Saturation	87%
21 Jan 2021 - 22 Jan 2021 (Study Day 121-122)	Oxygen Saturation of SpO ₂ ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 17 days, after which it was considered to be recovered/resolved on 04 Feb 2021 (Study Day 135). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-007739	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	2004 - 2004
Anxiety	Anxiety	2013 - Ongoing
Depression	Depression	2013 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Duloxetine	Apr 2019 - Oct 2020	Anxiety / Depression
Duloxetine	09 Oct 2020 (Study Day 17) - 30 Nov 2020 (Study Day 69)	Anxiety / Depression
Influenza vaccine	17 Nov 2020 (Study Day 56) - 17 Nov 2020 (Study Day 56)	Influenza Prophylaxis
Escitalopram oxalate	01 Dec 2020 (Study Day 70) - 11 Jan 2021 (Study Day 111)	Anxiety And Depression
Escitalopram oxalate	12 Jan 2021 (Study Day 112) - 23 Feb 2021 (Study Day 154)	Anxiety And Depression
Diphenhydramine hydrochloride; paracetamol	21 Jan 2021 (Study Day 121) - 31 Jan 2021 (Study Day 131)	COVID 19 (Pain From Headache, Muscle Aches, Body Aches)
Apixaban	24 Jan 2021 (Study Day 124) - Ongoing	Dvt Prophylaxis
Escitalopram oxalate	24 Feb 2021 (Study Day 155) - Ongoing	Anxiety/Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number: US399-2037 (Part B)
Vaccination Group: Placebo in Part A and mRNA-1273 in Part B
Randomization Strata: ≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A: 26 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A: 30 Oct 2020 (Study Day 35)
First Dose of Vaccine in Part B: 06 Jan 2021 (Study Day 103)
Second Dose of Vaccine in Part B: 05 Feb 2021 (Study Day 133)
Reason for Narrative: SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis/Acute Appendicitis	SAE	Grade 3/severe	Not related	10 Jan 2021 (Study Day 107) – 13 Jan 2021 (Study Day 110)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US399-2037, a 23-year-old Hispanic or Latino male, received the first dose of Placebo in the left arm on 26 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Oct 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative. The participant proceeded to Part B, the Open-Label Observational Phase, on 06 Jan 2021. The participant was unblinded on 06 Jan 2021 and consented to receive 2 doses of mRNA-1273. The participant received their first dose of mRNA-1273 in the left arm on 06 Jan 2021 (Study Day 103). The second dose was administered in the left arm on 05 Feb 2021 (Study Day 133).

Event Details

On 10 Jan 2021 (Study Day 107), 106 days after the first dose in Part A/4 days after the first dose in Part B and 72 days after the second dose in Part A/26 days before the second dose in Part B of the IP, the participant experienced a Grade 3/severe serious adverse event of appendicitis. Action taken with the IP was not applicable. The event of acute appendicitis lasted for 4 days, after which it was considered to be recovered/resolved on 13 Jan 2021 (Study Day 110). The investigator assessed the event of appendicitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-003790	Appendicitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bupivacaine	13 Jan 2021 (Study Day 110) - 13 Jan 2021 (Study Day 110)	Pre-Operative Anesthesia
Ct scan abdomen/pelvis*	13 Jan 2021 (Study Day 110) - 13 Jan 2021 (Study Day 110)	Diagnostic
Laparoscopic appendectomy*	13 Jan 2021 (Study Day 110) - 13 Jan 2021 (Study Day 110)	Adverse Event
Lidocaine	13 Jan 2021 (Study Day 110) - 13 Jan 2021 (Study Day 110)	Pre-Operative Anesthesia
Oxycodone hydrochloride	14 Jan 2021 (Study Day 111) - Ongoing	Abdominal Pain; Op-Related Pain
Paracetamol	14 Jan 2021 (Study Day 111) - Ongoing	Abdominal Pain, Post Op-Related Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

16 Appendices

16.1 Study Information

- 16.1.1 Protocol and Protocol Amendments
- 16.1.2 Sample Case Report Form (Unique Pages Only)
- 16.1.3 List of IECs and IRBs (Plus the Name of the Committee Chair if Required by the Regulatory Authority) and Representative Written Information for Subject and Sample Consent Forms
- 16.1.4 List and Description of Investigators and Other Important Participants in the Study, Including Brief (One Page) Curricula Vitae or Equivalent Summaries of Training and Experience Relevant to the Performance of the Study
- 16.1.5 Signatures of Principal or Coordinating Investigator(s) and Sponsor's Responsible Medical Officer, Depending on the Regulatory Authority's Requirement, and Signature of Responsible Biostatistician
- 16.1.6 Listing of Participants Receiving Investigational Product/Investigational Product(s) From Specific Batches, Where More Than One Batch Was Used
- 16.1.7 Randomization Scheme and Codes (Subject Identification and Treatment Assigned)
- 16.1.8 Audit Certificates (if available)
- 16.1.9 Documentation of Statistical Methods
- 16.1.10 Documentation of Interlaboratory Standardization Methods and Quality Assurance Procedures if Used
- 16.1.11 Publications Based on the Study
- 16.1.12 Important Publications Referenced in the Report
- 16.1.13 Optional Appendix

16.2 Participant Data Listings

- 16.2.1 Discontinued Subjects
- 16.2.2 Protocol Deviations
- 16.2.3 Subjects Excluded From the Efficacy Analysis
- 16.2.4 Demographic Data
- 16.2.5 Compliance or Drug Concentration Data (or both, if available)
- 16.2.6 Individual Efficacy Response Data
- 16.2.7 Adverse Event Listings (Each Participant)
- 16.2.8 Listing of Individual Laboratory Measurements by Subject, When Required by Regulatory Authorities

16.3 Case Report Forms (CRFs)

16.3.1 CRFs for Deaths, Serious Adverse Events, and Withdrawals for Adverse Events

16.3.2 Other CRFs Submitted

16.4 Individual Participant Data Listings