Table of Abbreviations		
Category	**Abbreviation**	**Text**
Action - Subject	N	No action
	O	Other
	P	Drug withdrawn (study intervention discontinued)
	TC	Concomitant drug treatment given
	TCN	Concomitant nondrug treatment given
	W	Withdrawn from study
Toxicity Grade	1	Mild
	2	Moderate
	3	Severe
	4	Life-threatening
System Organ Class	BLOOD	Blood and lymphatic system disorders
	CARD	Cardiac disorders
	CONG	Congenital, familial and genetic disorders
	EAR	Ear and labyrinth disorders
	ENDO	Endocrine disorders
	EYE	Eye disorders
	GASTR	Gastrointestinal disorders
	GENRL	General disorders and administration site conditions
	HEPAT	Hepatobiliary disorders
	IMMUN	Immune system disorders
	INFEC	Infections and infestations
	INJ&P	Injury poisoning and procedural complications
	INV	Investigations
	METAB	Metabolism and nutrition disorders
	MUSC	Musculoskeletal and connective tissue disorders
	NEOPL	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
	NERV	Nervous system disorders
	PREG	Pregnancy, puerperium and perinatal conditions
	PSYCH	Psychiatric disorders
	RENAL	Renal and urinary disorders
	REPRO	Reproductive system and breast disorders

Table of Abbreviations		
Category	**Abbreviation**	**Text**
	RESP	Respiratory, thoracic and mediastinal disorders
	SKIN	Skin and subcutaneous tissue disorders
	SOCCI	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2008	12	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.5 cm	40.95 kg	15.9 kg/m2	07JAN2021 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PREMENARCHAL	Premenarche	(b) (6) 2008	Present
REFRACTIVE AMBLYOPIA (RIGHT EYE)	Refractive amblyopia	2014	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	07JAN2021 (1)	17:03
2	Placebo	27JAN2021 (21)	16:03
3	BNT162b	17MAY2021 (131)	17:20
4	BNT162b	07JUN2021 (152)	10:59

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	INFEC	Appendicitis	APPENDICITIS	10JUN2021 (155)		10JUN2021 (155)	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	2	TC	Y	Resolved (10JUN2021)	Study Treatment	4	4	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07JAN2021	
Completed	VACCINATION	25FEB2021	
Completed	REPEAT SCREENING 1	17MAY2021	
Completed	OPEN LABEL TREATMENT	06JUL2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1156 11561357, a 12-year-old White female with no pertinent medical history, received Dose 1 on 07 Jan 2021, Dose 2 on 27 Jan 2021 (Day 21), Dose 3 on 17 May 2021 (Day 131), and Dose 4 on 07 Jun 2021 (Day 152). The subject was diagnosed with appendicitis on 10 Jun 2021, 3 days after receiving Dose 4. On 10 Jun 2021 (Day 155), the subject presented to the hospital with abdominal pain and vomiting. The pain was described as moderate, achy, and crampy, located in the periumbilical and right flank areas, which worsened by movement and was relieved by rest. There were no risk factors reported. The subject's laboratory results were within normal limits. An abdominal ultrasound revealed findings consistent with acute appendicitis. The subject was treated with intravenous (IV) dextrose/normal saline/potassium chloride 85 mL hourly, IV metronidazole 1350 mg once, IV morphine 0.25 mL every 2 hours, IV normal saline bolus 1000 mL once, and IV ceftriaxone sodium 2000 mg once. On the same day (Day 155), the subject underwent an appendectomy as an outpatient procedure. The appendicitis (which was considered medically significant) resolved, and the subject was discharged from the hospital on the same day with advice to take oral acetaminophen 325 mg and ibuprofen 400 mg as needed. Per the subject's mother, the subject only took analgesics for 3 days and she completely recovered. In the opinion of the investigator, there was a reasonable possibility that the appendicitis was related to the study intervention but unrelated to concomitant medications or clinical trial procedures. Pfizer did not concur with the investigator's causality assessment. Per Pfizer, there was no reasonable possibility that the appendicitis was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2006	14	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	76 kg	27 kg/m2	05JAN2021 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b	05JAN2021 (1)	17:10

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Pyrexia	Fever (104.7)	06JAN2021 (2)	19:30	08JAN2021 (4)	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	4	TC/P	N	Resolved (08JAN2021)	Study Treatment	1	2	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
BNT162b2 Dose #1 IM/once	TOZINAMERAN	07MAY2021
BNT162b2 Dose #2 IM/once	TOZINAMERAN	04JUN2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05JAN2021	
Withdrawn	VACCINATION	08JAN2021	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1147 11471327, a 14-year-old White male with no reported medical history, received Dose 1 on 05 Jan 2021. The subject experienced pyrexia (fever 104.7ºF) on 06 Jan 2021, 1 day after receiving Dose 1. The pyrexia resolved on 08 Jan 2021 (Day 4). The subject was discontinued from the study intervention on 08 Jan 2021 because of the pyrexia and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the pyrexia was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2006	14	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	50.9 kg	17.6 kg/m2	03DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Drug allergy Amoxicillin	Drug hypersensitivity	2009	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03DEC2020 (1)	16:21
2	Placebo	22DEC2020 (20)	15:18

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Arthralgia	left wrist pain	01MAY2021 (150)		03MAY2021 (152)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC/TCN	N	Resolved (03MAY2021)	NOT RELATED/OTHER: Trauma	2	131	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
SARS-CoV-2 vaccination Pfizer	TOZINAMERAN	13MAY2021
SARS-CoV-2 mRNA vaccine Pfizer	TOZINAMERAN	04JUN2021

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03DEC2020	
Completed	VACCINATION	20JAN2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1007 10071499, a 14-year-old White male with no pertinent medical history, received Dose 1 on 03 Dec 2020 and Dose 2 on 22 Dec 2020 (Day 20). The subject experienced arthralgia (left wrist pain) on 01 May 2021, 130 days after receiving Dose 2. The arthralgia resolved on 03 May 2021 (Day 152). In the opinion of the investigator, there was no reasonable possibility that the arthralgia was related to the study intervention but it was related to trauma.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2006	14	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	47.73 kg	18 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
premenarchal	Premenarche	(b) (6) 2006	Present
TONSILLITIS	Tonsillitis	10AUG2017	Past
BILATERAL HIP PAIN	Arthralgia	2018	Present
BILATERAL ANKLE PAIN	Arthralgia	2018	Present
BILATERAL KNEE PAIN	Arthralgia	2018	Present
facial acne	Acne	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b	19OCT2020 (1)	13:58
2	BNT162b	07NOV2020 (20)	11:10

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Arthralgia	worsening right ankle pain	19OCT2020 (1)	17:00	19OCT2020 (1)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	N	Resolved (19OCT2020)	NOT RELATED/OTHER: dance injury	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19OCT2020	
Completed	VACCINATION	10DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1009 10091221, a 14-year-old White female with a pertinent medical history of arthralgia (bilateral ankle, hip, and knee pain; since 2018), received Dose 1 on 19 Oct 2020 and Dose 2 on 07 Nov 2020 (Day 20). The subject experienced arthralgia (worsening right ankle pain) on 19 Oct 2020, approximately 3 hours after receiving Dose 1. The arthralgia resolved on the same day (Day 1). In the opinion of the investigator, there was no reasonable possibility that the arthralgia was related to the study intervention but was related to a dance injury.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2005	15	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	51.55 kg	17.8 kg/m2	07DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
acne, generalized	Acne	2017	Present
dermatitis, atopic	Dermatitis atopic	2018	Present
menorrhagia	Heavy menstrual bleeding	2018	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	07DEC2020 (1)	11:38
2	Placebo	28DEC2020 (22)	09:36
3	BNT162b	06APR2021 (121)	09:22
4	BNT162b	28APR2021 (143)	09:35

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	MUSC	Arthralgia	bilateral shoulder pain	22DEC2020 (16)		24DEC2020 (18)		3
2	GENRL	Pain	body aches	06APR2021 (121)	18:00	07APR2021 (122)		2

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (24DEC2020)	NOT RELATED/OTHER: lifting heavy object	1	16	Y
2	1	N	N	Resolved (07APR2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07DEC2020	
Completed	VACCINATION	25JAN2021	
Completed	REPEAT SCREENING 1	06APR2021	
Completed	OPEN LABEL TREATMENT	01JUN2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1009 10091294, a 15-year-old White female with no pertinent medical history, received Dose 1 on 07 Dec 2020, Dose 2 on 28 Dec 2020 (Day 22), Dose 3 on 06 Apr 2021 (Day 121), and Dose 4 on 28 Apr 2021 (Day 143). The subject experienced arthralgia (bilateral shoulder pain) on 22 Dec 2020, 15 days after receiving Dose 1. The arthralgia resolved on 24 Dec 2020 (Day 18). In the opinion of the investigator, there was no reasonable possibility that the arthralgia was related to the study intervention but was due to lifting a heavy object.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2006	14	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.02 cm	71 kg	27.7 kg/m2	04JAN2021 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CELIAC DISEASE	Coeliac disease	2013	Present
ANXIETY	Anxiety	2018	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	04JAN2021 (1)	16:30
2	Placebo	25JAN2021 (22)	16:17
3	BNT162b	14MAY2021 (131)	09:08
4	BNT162b	02JUN2021 (150)	09:54

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	MUSC	Arthralgia	RIGHT KNEE PAIN	10JAN2021 (7)		25JAN2021 (22)		16
2	GENRL	Chills	chills	03JUN2021 (151)		03JUN2021 (151)		1
3	NERV	Dizziness	dizziness	15MAY2021 (132)		16MAY2021 (133)		2
4	MUSC	Myalgia	generalized muscle pain	15MAY2021 (132)		20MAY2021 (137)		6
5	GASTR	Nausea	nausea	15MAY2021 (132)		17MAY2021 (134)		3
6	RESP	Rhinorrhoea	rhinorrhea	15MAY2021 (132)		17MAY2021 (134)		3

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	N	N	Resolved (25JAN2021)	NOT RELATED/OTHER: DANCING OVERUSE	1	7	Y
2	1	N	N	Resolved (03JUN2021)	Study Treatment	4	2	N
3	1	N	N	Resolved (16MAY2021)	Study Treatment	3	2	N
4	1	N	N	Resolved (20MAY2021)	Study Treatment	3	2	N

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	1	N	N	Resolved (17MAY2021)	Study Treatment	3	2	N
6	1	N	N	Resolved (17MAY2021)	Study Treatment	3	2	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04JAN2021	
Completed	VACCINATION	25FEB2021	
Completed	REPEAT SCREENING 1	14MAY2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	02JUL2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1009 10091382, a 14-year-old White female with no pertinent medical history, received Dose 1 on 04 Jan 2021, Dose 2 on 25 Jan 2021 (Day 22), Dose 3 on 14 May 2021 (Day 131), and Dose 4 on 02 Jun 2021 (Day 150). The subject experienced arthralgia (right knee pain) on 10 Jan 2021, 6 days after receiving Dose 1. The arthralgia resolved on 25 Jan 2021 (Day 22). In the opinion of the investigator, there was no reasonable possibility that the arthralgia was related to the study intervention but was due to overuse from dancing.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2008	12	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	52.73 kg	18.2 kg/m2	20OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	24APR2009	Present
seasonal allergies	Seasonal allergy	24APR2009	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	20OCT2020 (1)	09:46
2	Placebo	10NOV2020 (22)	10:47
3	BNT162b	01JUN2021 (225)	15:15
4	BNT162b	22JUN2021 (246)	09:22

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NERV	Epilepsy	epilepsy	29JUN2021 (253)	13:30	ONGOING			2
2	NERV	Syncope	syncope	09APR2021 (172)		09APR2021 (172)		1	2

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Y	Yes	NOT RELATED/OTHER: epilepsy-idiopathic	4	8	Y
2	N	N	Resolved (09APR2021)	NOT RELATED/OTHER: unknown-possible dehydration	2	151	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20OCT2020	
Completed	VACCINATION	08DEC2020	
Completed	REPEAT SCREENING 1	01JUN2021	
Completed	OPEN LABEL TREATMENT	20JUL2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1016 10161327, a 12-year-old White male with no pertinent medical history but with a family history of epilepsy (b) (6)), received Dose 1 on 20 Oct 2020, Dose 2 on 10 Nov 2020 (Day 22), Dose 3 on 01 Jun 2021 (Day 225), and Dose 4 on 22 Jun 2021 (Day 246). The subject was diagnosed with epilepsy on 29 Jun 2021, 7 days after receiving Dose 4. On 09 Apr 2021 (Day 172), the subject experienced syncope, possibly caused by dehydration, which resolved on the same day. The subject had a seizure, which lasted for 30 seconds on 29 Jun 2021 (Day 253), after getting out of a hot tub. Per the subject's mother, the subject started seeing "black in vision" and became dizzy, and later his arms and legs were extended, followed by a few whole-body jerks. The subject had no vomiting, incontinence, or postictal symptoms. It was reported that the subject had no history of febrile seizure. The subject visited his physician's office and upon arrival, he was oriented. The epilepsy was considered as an important medical event. On 13 Jul 2021 (Day 267), an electroencephalogram showed rare, isolated moderate to high amplitude nonrhythmic spike and sharp waves in the frontal region. The discharges repeated at a frequency of 3-4 Hz and lasted up to 0.5 seconds. An isolated generalized spike and wave were also noted during photic stimulation. Photic stimulation was performed, which showed epileptiform discharges or a significant increase in occurrence of epileptiform discharges limited to the period of photic stimulation. The subject was advised to follow-up in a month. The epilepsy was ongoing at the time of the last available report. The subject's mother reported that the subject had no further seizures, was not taking any medications or treatment for epilepsy, and would follow-up with a neurologist in 6 months. In the opinion of the investigator, there was no reasonable possibility that the epilepsy was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the epilepsy was more likely associated with a genetic predisposition considering the family historyof epilepsy disorder.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2007	13	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156.1 cm	40.8 kg	16.7 kg/m2	18DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
premenarche	Premenarche	(b) (6) 2007	Present
amoxicillin allergy	Drug hypersensitivity	2010	Present
vegetarian	Vegetarian	2019	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	18DEC2020 (1)	09:59
2	Placebo	08JAN2021 (22)	08:51
3	BNT162b	14MAY2021 (148)	08:35
4	BNT162b	04JUN2021 (169)	08:16

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	MUSC	Arthralgia	Generalized Arthralgia	04JUN2021 (169)	14:00	05JUN2021 (170)	
2	GENRL	Fatigue	fatigue	14MAY2021 (148)	18:00	15MAY2021 (149)	18:00
3	GENRL	Injection site pain	injection site pain	15MAY2021 (149)	08:00	15MAY2021 (149)	
4	MUSC	Myalgia	muscle aches	04JUN2021 (169)	14:00	05JUN2021 (170)	
5	GASTR	Nausea	nausea	14MAY2021 (148)	18:00	15MAY2021 (149)	18:00
6	GASTR	Nausea	nausea	04JUN2021 (169)	14:00	05JUN2021 (170)	
7	GENRL	Pyrexia	fever	04JUN2021 (169)	14:00	05JUN2021 (170)	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	1	N	N	Resolved (05JUN2021)	Study Treatment	4	1	Y
2	2	1	N	N	Resolved (15MAY2021)	Study Treatment	3	1	N
3	1	1	N	N	Resolved (15MAY2021)	Study Treatment	3	2	N

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	2	1	N	N	Resolved (05JUN2021)	Study Treatment	4	1	N
5	2	1	N	N	Resolved (15MAY2021)	Study Treatment	3	1	N
6	2	1	N	N	Resolved (05JUN2021)	Study Treatment	4	1	N
7	2	1	N	N	Resolved (05JUN2021)	Study Treatment	4	1	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18DEC2020	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	05FEB2021	
Completed	REPEAT SCREENING 1	14MAY2021	
Completed	OPEN LABEL TREATMENT	12JUL2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1039 10391285, a 13-year-old White female with no pertinent medical history, received Dose 1 on 18 Dec 2020, Dose 2 on 08 Jan 2021 (Day 22), Dose 3 on 14 May 2021 (Day 148), and Dose 4 on 04 Jun 2021 (Day 169). The subject experienced arthralgia (generalized arthralgia) on 04 Jun 2021, approximately 6 hours after receiving Dose 4. On the same day (Day 169), the subject also experienced nausea, pyrexia, and myalgia. The arthralgia, nausea, pyrexia, and myalgia resolved on 05 Jun 2021 (Day 170). In the opinion of the investigator, there was a reasonable possibility that the arthralgia was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2007	13	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.2 cm	45.5 kg	17.5 kg/m2	11JAN2021 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis seasonal	Seasonal allergy	2014	Present
adenoids removed	Adenoidectomy	2015	Past
fall off diving board	Fall	2015	Past
stiches insertion back of head	Suture insertion	2015	Past
attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2017	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b	11JAN2021 (1)	14:50
2	BNT162b	05FEB2021 (26)	14:06

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Accident	skiing accident	18FEB2021 (39)	11:00	19FEB2021 (40)		2
2	MUSC	Arthralgia	sacroiliac joint pain	15JAN2021 (5)		08FEB2021 (29)		25
3	INJ&P	Clavicle fracture	right clavicle fracture	19FEB2021 (40)	11:00	23APR2021 (103)		64

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC/TCN	N	Resolved (19FEB2021)	NOT RELATED/OTHER: accident	2	14	N
2	2	N	N	Resolved (08FEB2021)	NOT RELATED/OTHER: excess exercise	1	5	Y
3	2	TC/TCN	N	Resolved (23APR2021)	NOT RELATED/OTHER: skiing accident	2	15	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11JAN2021	
Completed	VACCINATION	12MAR2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1131 11311301, a 13-year-old White male with no pertinent medical history, received Dose 1 on 11 Jan 2021 and Dose 2 on 05 Feb 2021 (Day 26). The subject experienced arthralgia (sacroiliac joint pain) on 15 Jan 2021, 4 days after receiving Dose 1. The arthralgia resolved on 08 Feb 2021 (Day 29). In the opinion of the investigator, there was no reasonable possibility that the arthralgia was related to the study intervention but was due to excessive exercise.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2005	15	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179.07 cm	71.82 kg	22.3 kg/m2	08JAN2021 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
dyslexia	Dyslexia	2005	Present
sleep disturbance	Sleep disorder	30JUN2015	Present
intermittent muscle strain	Muscle strain	30JUN2018	Present
Acne	Acne	30JUN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08JAN2021 (1)	16:52
2	Placebo	29JAN2021 (22)	13:53
3	BNT162b	20MAY2021 (133)	16:48
4	BNT162b	10JUN2021 (154)	11:51

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	MUSC	Arthralgia	Bilateral knee pain	11JAN2021 (4)	12:00	15FEB2021 (39)	12:00	36	2	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (15FEB2021)	NOT RELATED/OTHER: overuse injury from running, patellar tendonitis	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08JAN2021	
Completed	VACCINATION	26FEB2021	
Completed	REPEAT SCREENING 1	20MAY2021	
Completed	OPEN LABEL TREATMENT	16AUG2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1139 11391246, a 15-year-old White male with a pertinent medical history of muscle strain (intermittent, since 30 Jun 2018), received Dose 1 on 08 Jan 2021, Dose 2 on 29 Jan 2021 (Day 22), Dose 3 on 20 May 2021 (Day 133), and Dose 4 on 10 Jun 2021 (Day 154). The subject experienced arthralgia (bilateral knee pain) on 11 Jan 2021, 3 days after receiving Dose 1. The arthralgia resolved on 15 Feb 2021 (Day 39). In the opinion of the investigator, there was no reasonable possibility that the arthralgia was related to the study intervention but was due to patellar tendonitis, an overuse injury from running.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2008	12	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
149.86 cm	39.14 kg	17.4 kg/m2	15DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	2018	Present
Premenarchal	Premenarche	NOV2020	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	15DEC2020 (1)	15:10
2	Placebo	07JAN2021 (24)	11:38
3	BNT162b	24MAY2021 (161)	15:13
4	BNT162b	14JUN2021 (182)	15:33

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	MUSC	Arthralgia	Generalized joint Pain	14JUN2021 (182)	18:00	16JUN2021 (184)	
2	GENRL	Fatigue	Fatigue	14JUN2021 (182)	18:00	16JUN2021 (184)	
3	GENRL	Injection site pain	Pain at injection site	24MAY2021 (161)	18:00	26MAY2021 (163)	
4	GENRL	Injection site pain	Pain at injection site	14JUN2021 (182)	18:00	16JUN2021 (184)	
5	MUSC	Myalgia	Muscle Pain	14JUN2021 (182)	18:00	16JUN2021 (184)	
6	GENRL	Pyrexia	Fever	15JUN2021 (183)		15JUN2021 (183)	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	1	N	N	Resolved (16JUN2021)	Study Treatment	4	1	Y
2	3	2	N	N	Resolved (16JUN2021)	Study Treatment	4	1	N
3	3	2	N	N	Resolved (26MAY2021)	Study Treatment	3	1	N
4	3	2	N	N	Resolved (16JUN2021)	Study Treatment	4	1	N

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	3	1	N	N	Resolved (16JUN2021)	Study Treatment	4	1	N
6	1	1	N	N	Resolved (15JUN2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15DEC2020	
Completed	VACCINATION	04FEB2021	
Completed	REPEAT SCREENING 1	24MAY2021	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	13JUL2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1150 11501210, a 12-year-old White female with no pertinent medical history, received Dose 1 on 15 Dec 2020, Dose 2 on 07 Jan 2021 (Day 24), Dose 3 on 24 May 2021 (Day 161), and Dose 4 on 14 Jun 2021 (Day 182). The subject experienced arthralgia (generalized joint pain) on 14 Jun 2021, approximately 2 hours and 30 minutes after receiving Dose 4. The subject also experienced injection site pain, fatigue, and myalgia on 14 Jun 2021 (Day 182), and pyrexia on 15 Jun 2021 (Day 183). The pyrexia resolved on 15 Jun 2021 (Day 183), and the arthralgia, fatigue, injection site pain, and myalgia resolved on 16 Jun 2021 (Day 184). In the opinion of the investigator, there was a reasonable possibility that the arthralgia was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2008	12	Black or African American	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.93 cm	58.91 kg	22.4 kg/m2	11JAN2021 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Oral Allergy Syndrome	Oral allergy syndrome	2010	Present
Asthma	Asthma	2015	Present
Atopic Dermatitis	Dermatitis atopic	2015	Present
Major Depressive Disorder	Major depression	2020	Past
Vitamin D deficiency	Vitamin D deficiency	2020	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	11JAN2021 (1)	14:04
2	Placebo	01FEB2021 (22)	17:17
3	BNT162b	27MAY2021 (137)	14:00
4	BNT162b	16JUN2021 (157)	16:11

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	EAR	Conductive deafness	Left sided mild conductive hearing loss	14JAN2021 (4)		MAY2021 ()	
2	GENRL	Injection site pain	Pain at injection site	27MAY2021 (137)	18:00	29MAY2021 (139)	
3	GENRL	Injection site pain	Pain at injection site	16JUN2021 (157)	18:00	17JUN2021 (158)	
4	GENRL	Injection site swelling	Swollen at injection site	27MAY2021 (137)	18:00	29MAY2021 (139)	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		2	N	N	Resolved (MAY2021)	Study Treatment	1	4	Y
2	3	1	N	N	Resolved (29MAY2021)	Study Treatment	3	1	N
3	2	1	N	N	Resolved (17JUN2021)	Study Treatment	4	1	N
4	3	1	N	N	Resolved (29MAY2021)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11JAN2021	
Completed	VACCINATION	03MAR2021	
Completed	REPEAT SCREENING 1	27MAY2021	
Completed	OPEN LABEL TREATMENT	15JUL2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1150 11501294, a 12-year-old Black/African American female with a pertinent medical history of atopic dermatitis (since 2015) and vitamin D deficiency (since 2020), received Dose 1 on 11 Jan 2021, Dose 2 on 01 Feb 2021 (Day 22), Dose 3 on 27 May 2021 (Day 137), and Dose 4 on 16 Jun 2021 (Day 157). The subject was diagnosed with conductive deafness (left-sided mild conductive hearing loss) on 14 Jan 2021, 3 days after receiving Dose 1. The conductive deafness resolved on an unspecified date in May 2021. In the opinion of the investigator, there was a reasonable possibility that the conductive deafness was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2005	15	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	66.4 kg	23.2 kg/m2	09JAN2021 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09JAN2021 (1)	10:25

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
2	Placebo	29JAN2021 (21)	15:36
3	BNT162b	21MAY2021 (133)	13:12
4	BNT162b	10JUN2021 (153)	09:58

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	CARD	Myocarditis	Myopericarditis	12JUN2021 (155)	19:00	13JUN2021 (156)		2

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (13JUN2021)	NOT RELATED/OTHER: Rhinovirus infection	4	3	Y

Prohibited Concomitant Medications

Investigator Text	WHO Drug Preferred Term	Start Date	End Date	Route
prednisone	PREDNISONE	13JUN2021	ONGOING	ORAL

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09JAN2021	
Completed	VACCINATION	03MAR2021	
Completed	REPEAT SCREENING 1	21MAY2021	
Completed	OPEN LABEL TREATMENT	09JUL2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1223 12231273, a 15-year-old White male with a pertinent medical history of seasonal allergy (since 2005), received Dose 1 on 09 Jan 2021, Dose 2 on 29 Jan 2021 (Day 21), Dose 3 on 21 May 2021 (Day 133), and Dose 4 on 10 Jun 2021 (Day 153). The subject was diagnosed with myocarditis on 12 Jun 2021, 2 days after receiving Dose 4. The subject experienced chest tightness with pain at 7 PM on 12 Jun 2021 (Day 155) after a dance rehearsal, and the subject's mother used a salbutamol nebulizer once at home, without any improvement. Later, he was taken to the emergency department because of the chest pain. Upon arrival at the emergency department, his body temperature was 100.1°F. It was reported that the subject initially had chest tightness, followed by chest pain. On the same day (Day 155), an electrocardiogram (ECG) showed diffuse ST elevations, and his troponin level was 0.27 (units and normal range [NR] not available). The subject received ketorolac 30 mg with almost immediate relief of chest pain. It was reported that the subject had a body temperature of 100.5ºF associated with a cough and rhinorrhea approximately one week prior to the chest pain. On 13 Jun 2021 (Day 156), the chest pain resolved. The subject was then transferred to a children's hospital for further evaluation. On the same day (Day 156), his troponin T levels were 0.18 ng/mL and 0.71 ng/mL (NR: 0 to <0.01 ng/mL) at 05:51 hours and 11:57 hours, respectively. A rhinovirus polymerase chain reaction test was positive on a respiratory virus panel, and enterovirus, parvovirus B 19, and SARS-CoV-2 RNA test results were negative. The subject received a single dose of paracetamol 650 mg orally (PO) and diphenhydramine 25 mg PO on 13 Jun 2021 (Day 156). Additionally, he also received prednisone 30 mg PO twice a day (BID), ibuprofen 600 mg PO every 6 hours, intravenous immunoglobulins infusions, and famotidine 20 mg PO BID (all from 13 Jun 2021). The myocarditis resolved on 13 Jun 2021 (Day 156). The subject was doing well without chest pain, denied fever, chills, and shortness of breath, and was discharged from the hospital on 14 Jun 2021 (Day 157). The subject was advised to follow-up with a pediatric cardiologist. His discharge medications included ibuprofen 600 mg PO as needed (PRN) (until 23 Jun 2021), famotidine 20 mg PO (BID from 14 Jun 2021 to 26 Jun 2021 and once daily from 27 Jun 2021 to 28 Jun 2021), and tapering doses of prednisone PO (to 2.5 mg daily until 17 Jul 2021). There was no recurrence of cough or rhinorrhea. On 24 Jun 2021 (Day 167), the subject had a follow-up with a cardiologist and an ECG was performed, which showed sinus rhythm and ST elevation (probably normal early repolarization pattern), which had significantly improved since the ECG performed on 13 Jun 2021. An echocardiogram showed normal biventricular function, left ventricular global longitudinal strain of 19% (the strain was lower in the basal anterior, anteroseptal, inferoseptal, and inferior segments). The coronaries were normal with no dilation. His troponin T level was <0.01 ng/mL. The cardiologist recommended that the subject limit his activity to not induce tachycardia on exertion and to continue follow-up with cardiology. In the opinion of the investigator, there was no reasonable possibility that the myocarditis was related to the study intervention or clinical trial procedures, but it was related to a rhinovirus infection. Pfizer did not concur with the investigator's causality assessment. Per Pfizer, there was a reasonable possibility that the myocarditis was related to the study intervention, based on the plausible temporal relationship and prior reports of myocarditis and pericarditis in recipients of mRNA vaccines in younger individuals, but without confirmed causal association. However, this subject experienced chest tightness and pain after a dance rehearsal and was then treated with a salbutamol nebulizer by his mother. It was not clear if the subject had a relevant medical history for which the nebulizer was available at home. The reported symptoms and test results could also be due to the rhinovirus infection.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2006	14	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178.31 cm	82.82 kg	26 kg/m2	11JAN2021 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ENVIRONMENTAL ALLERGIES	Hypersensitivity	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b	11JAN2021 (1)	12:48
2	BNT162b	01FEB2021 (22)	11:21

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	Appendicitis	28JUN2021 (169)		29JUN2021 (170)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TCN	Y	Resolved (29JUN2021)	NOT RELATED/OTHER: unknown	2	148	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11JAN2021	
Completed	VACCINATION	01MAR2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1005 10051449, a 14-year-old White male with no pertinent medical history, received Dose 1 on 11 Jan 2021 and Dose 2 on 01 Feb 2021 (Day 22). The subject was diagnosed with appendicitis on 28 Jun 2021, 147 days after receiving Dose 2. On 28 Jun 2021 (Day 169), the subject presented to the emergency department with abdominal pain, mild fever, nausea, and vomiting (once). On the next day (Day 170), the laboratory investigation showed an elevated white blood cell count of 15.8 × 109/L, absolute neutrophils of 13.2 × 109/L, absolute immature granulocyte of 0.1 × 109/L, immature granulocyte of 0.6%, bilirubin of 2.1 mg/dL, direct bilirubin of 0.7 mg/dL; and low lymphocytes of 5.5% (normal ranges were not reported). A rapid SARS-CoV-2 test was negative, and an abdominal ultrasound showed appendicitis. On the same day (Day 170), the subject underwent an appendectomy and the appendicitis (which was considered as an important medical event) resolved, and the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2005	15	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	64.8 kg	21.2 kg/m2	17DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ADHD	Attention deficit hyperactivity disorder	2012	Present
Migraine	Migraine	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17DEC2020 (1)	15:49
2	Placebo	07JAN2021 (22)	15:49
3	BNT162b	24MAY2021 (159)	12:07
4	BNT162b	14JUN2021 (180)	11:23

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	Appendicitis	10MAR2021 (84)		29MAR2021 (103)		20
2	GENRL	Fatigue	fatigue	15JUN2021 (181)		16JUN2021 (182)		2
3	GENRL	Injection site pain	injection site pain	15JUN2021 (181)		16JUN2021 (182)		2
4	MUSC	Myalgia	generalized muscle aches	15JUN2021 (181)		16JUN2021 (182)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (29MAR2021)	NOT RELATED/OTHER: Infection	2	63	Y
2	2	N	N	Resolved (16JUN2021)	Study Treatment	4	2	N
3	1	N	N	Resolved (16JUN2021)	Study Treatment	4	2	N
4	2	TC	N	Resolved (16JUN2021)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17DEC2020	
Completed	VACCINATION	04FEB2021	
Completed	REPEAT SCREENING 1	24MAY2021	
Completed	OPEN LABEL TREATMENT	13JUL2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1007 10071581, a 15-year-old White male with no pertinent medical history, received Dose 1 on 17 Dec 2020, Dose 2 on 07 Jan 2021 (Day 22), Dose 3 on 24 May 2021 (Day 159), and Dose 4 on 14 Jun 2021 (Day 180). Concomitant medications included dexmethylphenidate hydrochloride (since 2019) for attention deficit hyperactivity disorder and naproxen (since 16 Feb 2021) for migraine. The subject was diagnosed with appendicitis on 10 Mar 2021, 62 days after receiving Dose 2. On 11 Mar 2021 (Day 85), the subject presented to the emergency room with a 1-day history of worsening abdominal pain that localized to the right lower quadrant. The subject was subsequently hospitalized for nonoperative pain management. An abdominal ultrasound scan was consistent with acute appendicitis, and the appendix was visualized. The subject remained afebrile while hospitalized. Relevant laboratory tests performed on the same day (Day 85), showed an elevated red blood cell count of 5.43 mcL (normal range [NR]: 4.5-5.3 mcL) and lymphocytes of 47.8% (NR: 34.0%-42.0%); decreased segmented neutrophils of 39.9% (NR: 40.0%-62.0%); and normal white blood cell count of 6.94 mcL (NR: 4.5-13.5 mcL), hemoglobin of 15.3 g/dL (NR: 13.0-16.0 g/dL), hematocrit of 44.9% (NR: 37.0%-49.0%), and platelet count of 357 mcL (NR: 135-466 mcL). A SARS-CoV-2 test performed on 11 Mar 2021 (Day 85) was negative. During hospitalization, the subject received a single dose of intravenous (IV) metronidazole 1000 mg and IV ceftriaxone 2000 mg, both on 11 Mar 2021 (Day 85). On 12 Mar 2021 (Day 86), the subject was discharged from the hospital on oral (PO) amoxicillin/clavulanate 875/125 mg tablet twice a day for 14 days, PO ibuprofen 600 mg every 6 hours as needed (PRN) for moderate pain, and PO acetaminophen 325 mg every 4-6 hours PRN for pain. The appendicitis resolved on 29 Mar 2021 (Day 103) with oral antibiotic treatment and no surgical intervention was required. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2005	15	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.8 cm	48.1 kg	19.1 kg/m2	22DEC2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b	22DEC2020 (1)	10:41
2	BNT162b	14JAN2021 (24)	11:25

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	Appendicitis	09JUL2021 (200)	03:00	10JUL2021 (201)	08:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TCN	Y	Resolved (10JUL2021)	NOT RELATED/OTHER: Appendicitis	2	177	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22DEC2020	
Completed	VACCINATION	15FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1091 10911447, a 15-year-old White male with no reported medical history, received Dose 1 on 22 Dec 2020 and Dose 2 on 14 Jan 2021 (Day 24). The subject was diagnosed with appendicitis on 09 Jul 2021, 176 days after receiving Dose 2. On 12 Jul 2021 (Day 203), the subject contacted the site and reported that he was hospitalized on 10 Jul 2021 (Day 201) because of appendicitis. It was reported that the subject had right lower quadrant pain, fever, and vomiting, and underwent an abdominal ultrasound on 09 Jul 2021 (Day 200), which showed a 10.2 mm appendix with possible perforation and fluid/debris in the pericecal region. On 10 Jul 2021 (Day 201), he had an elevated white blood cell count of 21.8 × 103/mm3 (normal range: 4.5-13.0 × 103/mm3) and a rapid SARS-CoV-2 test (molecular point of care test) result was negative. On the same day (Day 201), the subject underwent a laparoscopic appendectomy without any complications. Gangrene and localized peritonitis were noted during the procedure. The appendicitis resolved on 10 Jul 2021 (Day 201), and the subject was discharged from the hospital on 12 Jul 2021 (Day 203) with instructions to take paracetamol 325 mg and ibuprofen 200 mg alternately. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2007	13	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.5 cm	67.65 kg	22.7 kg/m2	12DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Constipation	Constipation	02JUL2014	Present
Perforation of right tympanic membrane	Tympanic membrane perforation	02JUL2014	Present
Psoriasis	Psoriasis	2016	Present
Other iron deficiency anemia	Iron deficiency anaemia	27MAY2020	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	12DEC2020 (1)	10:44
2	Placebo	04JAN2021 (24)	16:37
3	BNT162b	14MAY2021 (154)	14:36
4	BNT162b	03JUN2021 (174)	10:32

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INFEC	Appendicitis	Acute appendicitis	22JAN2021 (42)	16:00	23JAN2021 (43)	00:01	2
2	INFEC	Focal peritonitis	localized peritonitis, without perforation or gangrene	22JAN2021 (42)	16:00	23JAN2021 (43)	00:01	2

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	TC/TCN	Y	Resolved (23JAN2021)	NOT RELATED/OTHER: Acute appendicitis	2	19	Y
2	4	TC/TCN	Y	Resolved (23JAN2021)	NOT RELATED/OTHER: Acute appendicitis	2	19	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12DEC2020	
Completed	VACCINATION	06FEB2021	
Completed	REPEAT SCREENING 1	14MAY2021	
Completed	OPEN LABEL TREATMENT	07JUL2021	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1147 11471281, a 13-year-old White male with a pertinent medical history of constipation (since 02 Jul 2014), psoriasis (since 2016), and iron deficiency anemia (since 27 May 2020), received Dose 1 on 12 Dec 2020, Dose 2 on 04 Jan 2021 (Day 24), Dose 3 on 14 May 2021 (Day 154), and Dose 4 on 03 Jun 2021 (Day 174). Concomitant medications included polyethylene glycol (since 2013) for constipation, ferrous sulfate (since 27 May 2020) for iron deficiency anemia, and mupirocin (since 22 Dec 2020) for psoriasis. The subject was diagnosed with appendicitis on 22 Jan 2021, 18 days after receiving Dose 2. On 22 Jan 2021 (Day 42), the subject presented to the emergency room (ER) after experiencing localized acute abdominal pain in the right lower quadrant for less than 5 hours. It was reported that the abdominal pain was associated with anorexia. The subject was tachycardic on arrival to the ER, and the right lower quadrant was focally tender. Laboratory tests showed an elevated white blood cell count of 18.63× 103/mm3 (normal range [NR]: 3.90-12.70 × 103/mm3) and an ultrasound scan of the abdomen was consistent with acute appendicitis with lower right quadrant pain with no findings suggestive of appendiceal perforation. A serious adverse event of focal peritonitis (localized peritonitis without perforation or gangrene) was also reported with an onset date of 22 Jan 2021 (Day 42). Other relevant tests included an elevated absolute neutrophil count of 16 × 103/mm3 (NR: 1.8-7.7× 103/mm3) and granulocytes of 85.8% (NR: 38%-73%); decreased lymphocytes of 7.4% (NR: 18%-48%); and an immature granulocyte count of 0.07× 103/mm3 (NR: 0.0-0.5× 103/mm3) and monocyte count of 0.9 × 103/mm3 (NR: 0.3-1.0 × 103/mm3). The subject received unspecified intravenous fluids and immediately had a laparoscopic appendectomy procedure, which was reported to be well tolerated. On 23 Jan 2021 (Day 43), the appendicitis and focal peritonitis resolved, and the subject was discharged from the hospital. The appendicitis and focal peritonitis were considered life-threatening and medically significant events by the investigator. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2007	13	American Indian or Alaska Native	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	69.7 kg	27.2 kg/m2	07JAN2021 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	02DEC2014	Present
Asthma	Asthma	01FEB2016	Present
Anxiety	Anxiety	23AUG2019	Present
Vitamin D Deficiency	Vitamin D deficiency	22JUN2020	Present
Bilateral temporomandibular joint pain	Temporomandibular joint syndrome	16NOV2020	Present
Right foot pain	Pain in extremity	18DEC2020	Present
Allergy to Vancomycins	Drug hypersensitivity	30DEC2020	Present
Pectus Carinatum	Pectus carinatum	30DEC2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07JAN2021 (1)	09:43
3	BNT162b	19MAY2021 (133)	09:55

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Abdominal pain upper	INTERMITTENT STOMACH PAIN	25MAY2021 (139)		13JUL2021 (188)		50
2	GENRL	Chills	CHILLS	19MAY2021 (133)		21MAY2021 (135)		3
3	METAB	Decreased appetite	LOSS OF APPETITE	25MAY2021 (139)		13JUL2021 (188)		50
4	GENRL	Fatigue	FATIGUE	25MAY2021 (139)		13JUL2021 (188)		50
5	NERV	Headache	INTERMITTENT HEADACHES	19MAY2021 (133)		13JUL2021 (188)		56
6	MUSC	Musculoskeletal chest pain	Rib pain on right side	10FEB2021 (35)		10MAR2021 (63)		29
7	GASTR	Nausea	INTERMITTENT NAUSEA	19MAY2021 (133)		13JUL2021 (188)		56
8	GENRL	Non-cardiac chest pain	INTERMITTENT NON-CARDIAC CHEST DISCOMFORT	19MAY2021 (133)		13JUL2021 (188)		56
9	INFEC	Otitis media	LEFT OTITIS MEDIA	29JUN2021 (174)		06JUL2021 (181)		8
10	GENRL	Pyrexia	Fever	20MAY2021 (134)		21MAY2021 (135)		2
11	SKIN	Rash	Rash on Right Foot	05APR2021 (89)		08APR2021 (92)		4
12	GENRL	Thirst	INCREASED THIRST	25MAY2021 (139)		12JUN2021 (157)		19

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	N	N	Resolved (13JUL2021)	Study Treatment	3	7	N
2	1	TC	N	Resolved (21MAY2021)	Study Treatment	3	1	N
3	2	N	N	Resolved (13JUL2021)	Study Treatment	3	7	N
4	3	N	N	Resolved (13JUL2021)	Study Treatment	3	7	N
5	2	TC	N	Resolved (13JUL2021)	Study Treatment	3	1	N
6	1	N	N	Resolved (10MAR2021)	NOT RELATED/OTHER: Unknown	1	35	N
7	2	N	N	Resolved (13JUL2021)	Study Treatment	3	1	N
8	2	TC	N	Resolved (13JUL2021)	Study Treatment	3	1	N
9	1	TC	N	Resolved (06JUL2021)	NOT RELATED/OTHER: UNKNOWN	3	42	N
10	1	TC	N	Resolved (21MAY2021)	Study Treatment	3	2	N
11	1	TC	N	Resolved (08APR2021)	NOT RELATED/OTHER: UNKNOWN	1	89	N
12	1	N	N	Resolved (12JUN2021)	Study Treatment	3	7	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
Fluarix Quadrivalent (Influenza Vaccine)	INFLUENZA VACCINE INACT SPLIT 4V	21DEC2020

SARS-COV-2 Baseline Tests - Central Laboratory

Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	07JAN2021 (1)	07JAN2021 (1)	NASAL_SWAB	POSITIVE
Visit 1	07JAN2021 (1)	07JAN2021 (1)	SERUM	NEGATIVE
Visit 2	17FEB2021 (42)	17FEB2021 (42)	NASAL_SWAB	POSITIVE

Case Details

Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	No
COVID Illness Visit 2	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 20JAN2021 (14)/ 19JAN2021 (13)/ 20JAN2021 (14)	YES	NEW OR INCREASED SHORTNESS OF BREATH	
COVID Illness Visit 2 / 29JAN2021 (23)/ 26JAN2021 (20)/ 26JAN2021 (20)	YES	DIARRHEA	
COVID Illness Visit 3 / 01JUL2021 (176)/ 24JUN2021 (169)/ 06JUL2021 (181)	NO		Ear pain
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Nasal congestion

Diagnosis of Potential COVID-19 Illness

Visit	Visit Date (Study Day)	Respiratory Illness Diagnosis	Date of Diagnosis (Study Day)	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	20JAN2021 (14)	COVID 19	24JAN2021 (18)	1	COVID-19
COVID Illness Visit 3	01JUL2021 (176)	Sinus Infection	30JUN2021 (175)	1	Sinusitis

SARS-COV-2 Test - Central Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	20JAN2021 (14)	21JAN2021 (15)	NASAL_SWAB_SELF	POSITIVE
2	COVID Illness Visit 2	29JAN2021 (23)	29JAN2021 (23)	NASAL_SWAB_SELF	POSITIVE
3	COVID Illness Visit 3	01JUL2021 (176)	01JUL2021 (176)	NASAL_SWAB_SELF	NEGATIVE

SARS-COV-2 Test - Local Laboratory

Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	20JAN2021 (14)	24JAN2021 (18)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 3	01JUL2021 (176)	30JUN2021 (175)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	SARS COV2 TEST CLIA CERT LAB
2	NEGATIVE		OTHER	SARS-COV-2 TEST CLIA CERIFIED LAB

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	20JAN2021 (14)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	29JAN2021 (23)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 3	01JUL2021 (176)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07JAN2021	
Withdrawn	VACCINATION	26JAN2021	NO LONGER MEETS ELIGIBILITY CRITERIA
Completed	REPEAT SCREENING 1	19MAY2021	
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	13JUL2021	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject C4591001 1270 12701237, a 13-year-old American Indian or Alaska native female with a BMI of 27.2 kg/m2, received Dose 1 on 07 Jan 2021.
The subject had a pertinent medical history of depression (since 02 Dec 2014), asthma (since 01 Feb 2016), anxiety (since 23 Aug 2019), vitamin D deficiency (since 22 Jun 2020), and drug hypersensitivity (allergy to vancomycin) and pectus carinatum (both since 30 Dec 2020).
The central laboratory SARS-CoV-2 NAAT results were positive at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1.
On 24 Jan 2021 (Day 18), the subject was diagnosed with COVID-19 and reported new or increased shortness of breath, with the symptom starting on 19 Jan 2021, 12 days after receiving Dose 1, and the symptom resolved on 20 Jan 2021 (Day 14).
The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 21 Jan 2021 (Day 15) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 24 Jan 2021 (Day 18) was positive. The subject did not have any contact with nonstudy healthcare personnel (at COVID illness Visit 1).
On 26 Jan 2021 (Day 20), the subject reported diarrhea, which resolved that same day.
The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Jan 2021 (Day 23) was positive. The subject had a telephone consultation (once, at COVID illness Visit 2).
The subject was discontinued from the study intervention on 26 Jan 2021 since she no longer met the eligibility criteria and remained in the study to be evaluated for safety, immunogenicity, and efficacy.
The subject was rescreened and received an additional dose of study intervention on 19 May 2021 (Day 133).
On 30 Jun 2021 (Day 175), the subject was diagnosed with sinusitis and reported ear pain, new loss of taste or smell, new or increased sore throat, and nasal congestion, with the first symptom starting on 24 Jun 2021, 36 days after receiving the additional dose of study intervention, and the last symptom resolved on 06 Jul 2021 (Day 181).
The local laboratory SARS-CoV-2 NAAT result at the time of the potential COVID-19 illness visit on 30 Jun 2021 (Day 175) was negative. The central laboratory SARS-CoV-2 NAAT result at the time of the potential COVID-19 illness visit on 01 Jul 2021 (Day 176) was negative.
The subject had a telephone consultation (once) and went to her primary care physician (once, at COVID illness Visit 3).
The subject was withdrawn from the study on 13 Jul 2021 because she requested study withdrawal.