RESPONSE TO FDA ON INFORMATION REQUEST#47 RECEIVED ON JANUARY 24, 2022

The Sponsor acknowledges comments on INFORMATION REQUEST#47 DATED 24 JANUARY 2022 in (**BOLD**)

ITEM 1:
Our review of your August 24, 2021 submission (STN 125752/1) is ongoing. We have the following request for additional information regarding the lot release protocol template:

We note that participant # mRNA-1273-P301-US335-2594 was a 31-year-old Hispanic female with negative baseline serostatus who reported Grade 4 fatigue and arthralgia after Dose 1 and withdrew from study vaccination (did not receive Dose 2), but continued to be followed in the study until Part B.

Please provide a case narrative for this participant that provides all available information about these events, including whether this participant required a visit to the Emergency Room or require hospitalization (Why were these adverse reactions considered Grade 4?).

Sponsor Response:

This report is for a 31-year-old Hispanic or Latino female (Subject US3352594), with no significant medical history, who was randomly assigned to 100 µg mRNA-1273 in Part 1 of the study. The participant received the first dose of 100 µg mRNA-1273 in the right arm on 22 Oct 2020 (Study Day 1). One the same day of the 1st vaccination, on 22 Oct 2020, the participant experienced nonserious, medically attended events of situational anxiety (Grade 2) assessed as not related to study drug, muscle aches all over body (Grade 3) assessed as not related to study drug but related to study procedure and chills (Grade 3) and fatigue (Grade 4) both assessed as related to study drug. On 23 Oct 2020, one day post 1st vaccination, the participant experienced non-serious event of join aches (Grade 4) assessed as related to study drug. The eDiary data states that the participant had a temperature of 100.1 on 23 Oct 2020 and 102.2 24 Oct 2020 which resolved by the next day. Per the eDiary, the participant noted that the fatigue, muscle aches and joint aches resulted in some interference with activity, and no interference was noted on any other days. All events resolved within 1-6 days of onset and did not meet the requirements of a Serious Adverse Event. During safety phone calls conducted on Day 8, 15, 22, 36, 43, 50, 85, no other adverse events were noted. Concomitant medications included Tylenol twice daily for the event of body aches from 23 Oct 2020 to 25 Oct 2020. The participant was discontinued from further vaccination on 18 Nov 2020 and withdrew from the study on 12 Feb 2021 “due to work”.