RESPONSE TO BLA IR#1 RECEIVED ON 14 SEPTEMBER 2021

The Sponsor acknowledges FDA comments in **Bold**

Information Request #1

ITEM 1:

Please refer to Section 11, Table 5 of your Agreed Initial Pediatric Development Plan (iPSP). Please provide the estimated dates for protocol submission, study initiation, study completion and final study report submission for the following studies:

A Phase 2/3, randomized, observer-blind, placebo controlled, dose-finding, age de-escalation study to evaluate safety, reactogenicity, and effectiveness of the mRNA-1273 SARS-CoV-2 vaccine administered as two (or three) doses in healthy children 6 months to <12 years of age.

Safety and effectiveness study of mRNA-1273 SARS-CoV-2 vaccine administered in healthy infants birth to <6 months of age.

Sponsor Response:

The milestone dates for P204 (children 6 months to <12 years of age) are included in the table below. A response for the <6 months of age study will be sent separately, ASAP.

Development Phase	
A Phase 2/3, randomized, observer-blind, placebo-controlled, dose-finding, age de-escalation study to evaluate safety, reactogenicity, and effectiveness of the mRNA-1273 SARS-CoV-2 vaccine administered as two (or three) doses in healthy children 6 months to <12 years of age	
Protocol submission date:	FEB 2021
Study initiation date:	MAR 2021
Estimated study completion date:	JUN 2023
Estimated final report submission date:	SEP 2023
Safety and effectiveness study of mRNA-1273 SARS-CoV-2 vaccine administered in healthy infants birth to <6 months of age	
Estimated protocol submission date:	TBD
Estimated study initiation date:	TBD
Estimated study completion date:	TBD

Estimated final report submission date:	TBD

ITEM 2:

Please confirm that there are no changes to the dates listed for the study "A Phase 2/3, randomized, observer-blind, placebo-controlled study to evaluate safety, reactogenicity, and effectiveness of the mRNA-1273 SARS-CoV-2 vaccine administered as two doses in healthy adolescents 12 to <18 years of age."

Sponsor Response:

The updated milestone timelines are presented in the table below. The milestone dates for estimated study completion and final report submission have been updated with respect to the actual study timelines based on completion of enrollment and are based on the current protocol (Amendment 2).

A Phase 2/3, randomized, observer-blind, placebo-controlled study to evaluate safety, reactogenicity, and effectiveness of the mRNA-1273 SARS-CoV-2 vaccine administered as two doses in healthy adolescents 12 to <18 years of age	
Estimated protocol submission date:	NOV 2020
Estimated study initiation date:	DEC 2020
Estimated study completion date:	APR 2022
Estimated final report submission date:	JUL 2022

ITEM 3:

Please also refer to form 3674 (Certificate of Compliance). Please submit a revised form which includes all NCT numbers in section 10 of the form.

Sponsor Response

The revised form is included in the submission.