

**RESPONSE TO CBER COMMUNICATION REGARDING OVERVIEW
SUMMARIES FOR CLINICAL AND LABORATORY-SAFETY FINDINGS FROM
PHASE 2 CLINICAL TRIALS RECEIVED ON DECEMBER 04, 2020**

The Sponsor acknowledges CBER's communication regarding overview summaries for clinical and laboratory-safety findings from Phase 2 clinical trials.

This document provides the Sponsor's responses to CBER's requests (in **Bold**).

Item 1:

Please submit any overview summaries for clinical findings from safety labs from your Phase 2 clinical trials.

Sponsor Response:

In the mRNA-1273 P201 study safety laboratory testing was performed on participants in the older cohort (≥ 55 years of age) at baseline, Day 29 and Day 57. Safety laboratory tests included complete blood count with differential, alanine aminotransferase, aspartate aminotransferase, total and direct bilirubin, alkaline phosphatase, blood urea nitrogen/creatinine, prothrombin time (PT), and partial thromboplastin time (aPTT).

At the 50 μ g dose level of mRNA-1273, there were no Grade 3 or 4 changes from baseline in eosinophils, leukocytes (increase or decrease), lymphocytes, neutrophils, alanine aminotransferase, aspartate aminotransferase, bilirubin, creatinine, nor urea nitrogen.

There were 5 participants (5%) who experienced Grade 3 decreases in hemoglobin relative to baseline, however, each of these Grade 3 values was within the normal range and not clinically significant. One participant (1%) had a Grade 3 platelet count although a result at baseline was not reported. One participant (1%) experienced a Grade 3 increase in aPTT from Grade 1 at baseline and a different participant had a Grade 4 increase of PT at Day 29 from Grade 0 at baseline which normalized by Day 57. One participant (1%) experienced a Grade 3 increase in alkaline phosphatase at Day 29 from Grade 0 at baseline which was normal on Day 57.

At the 100 μ g dose level of mRNA-1273, there were no Grade 3 or 4 changes from baseline in eosinophils, leukocytes (increase or decrease), lymphocytes, neutrophils, platelets, alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, bilirubin, creatinine, urea nitrogen, PT, nor aPTT.

There were 2 participants (2%) who experienced Grade 3 decreases in hemoglobin from Grade 0 at baseline, however, both Grade 3 values were within the normal range and not clinically significant.