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Global Product Development

14 September 2021

Marion Gruber, Ph.D.
Director
Office of Vaccines Research and Review
Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

SN 0487

Re: COVID-19 Vaccine (BNT162/PF-07302048) BB-IND 19736

IND Amendment –

- **Clinical: Study C4591007 Protocol Amendment**
- **Informed Consent Documents for Study C4591007**

Dear Dr. Gruber,

Reference is made to BB-IND 19736 for the COVID-19 Vaccine (BNT162; PF-07302048), which Pfizer and BioNTech are developing for the indication of active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The IND was effective on 29 April 2020.

Reference is also made to Study C4591007 protocol entitled, "*A Phase 1, Open-Label Dose-Finding Study to Evaluate Safety, Tolerability, and Immunogenicity and Phase 2/3 Placebo-Controlled, Observer-Blinded Safety, Tolerability, and Immunogenicity Study of a SARSCOV-2 RNA Vaccine Candidate Against COVID-19 in Healthy Children and Young Adults,"* initially submitted to the IND on 08 February 2021 (SN 0203) and the current C4591007 Clinical Protocol incorporating Amendment 2 submitted to the IND on 10 August 2021 (SN 0443).

The present submission provides C4591007 Clinical Protocol Amendment 3, Clean copy and Tracked change copy.

Protocol Amendment 3 includes the following key changes:

- Updated to allow an additional 2250 Phase 2/3 selected-dose participants <5 years of age, to enlarge the size of the pediatric safety database. This has resulted in the total number of participants in this portion of the study increasing to approximately 9000 participants
- Included blood draws, procedures, and objectives for potential troponin I testing in participants 5 to <12 and 12 to <16 years
- Added the rationale for collecting serum samples for potential troponin I testing.
- Revised the objective and corresponding endpoints to describe severe COVID-19 cases in participants in selected-dose portion of the study
- Clarified the process for participants who become eligible for receipt of BNT162b2 or another COVID-19 vaccine prior Visit 5 (6-month follow-up visit)
- Added a second definition of symptoms of severe COVID-19 disease per CDC definition
- Clarified instructions on how to unblind participants at the 6-month follow-up visit.
- Updated information on the recording of non-study vaccination and concomitant medications

Additionally, the Informed Consent Documents have been revised and are included in Module 5.3.5.1:

- C4591007 PA3 Phase 2/3 Older Children Assent Obtaining Serum Samples for Potential Troponin I Testing V1 13 Sep 2021, version 1 (original) - Clean copy
- C4591007 PA3 Phase 2/3 Younger Children Assent Obtaining Serum Samples for Potential Troponin I Testing V1 13 Sep 2021, version 1 (original) - Clean copy
- C4591007 PA3 Phase 2/3 Parent ICD Obtaining Serum Samples for Potential Troponin I Testing V1 13 Sep 2021, version 1 (original) – Clean copy
- C4591007 PA3 Phase 2/3 Parent ICD Addendum Placebo-Controlled Selected Dose V1 13 Sep 2021, version 1 (original) – Clean copy
- C4591007 PA3 Phase 2/3 Parent ICD Placebo-Controlled Selected Dose V6 13 Sep 2021, version 6 – Clean copy & track changes copy

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free. The submission is being sent via the Gateway.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 214-918-5262 or via e-mail at Amitkumar.Patel@pfizer.com.

Sincerely,

Amit Patel
Director
Global Regulatory Affairs

CC: Ramachandra S. Naik, Ph.D.
CC: Laura Gottschalk, Ph.D.
CC: Captain Michael Smith, Ph.D.