



Global Product Development

10 August 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
WO71, G112
Silver Spring, MD 20993-0002

THIS DOCUMENT CONTAINS CONFIDENTIAL AND/OR TRADE SECRET INFORMATION THAT IS DISCLOSED ONLY IN CONNECTION WITH THE LICENSING AND/OR REGISTRATION OF PRODUCTS FOR PFIZER INC OR ITS AFFILIATED COMPANIES. THIS DOCUMENT SHOULD NOT BE DISCLOSED OR USED, IN WHOLE OR IN PART, FOR ANY OTHER PURPOSE WITHOUT THE PRIOR WRITTEN CONSENT OF PFIZER INC.

SN 0443

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

IND Amendment –

- **Clinical: Study C4591007 Protocol Amendment**
- **Informed Consent Document 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 which was initially submitted to the IND on 08 February 2021 (SN 0203) and the current C4591007 Clinical Protocol incorporating Amendment 1 submitted to the IND on 09 March 2021 (SN 0236).

The present submission provides C4591007 Protocol Amendment 2 and the study title has been updated as follows, in alignment with Amendment 2 “*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*”, [Clean copy](#) and [Tracked change copy](#).

Protocol Amendment 2 includes the following key changes:

- Made the following updates in response to commitments made to CBER concerning myocarditis and pericarditis:
 - Insertion of additional row in risk assessment table in risk assessment section
 - Addition of myocarditis and pericarditis in Adverse Events of Special Interest section.
 - Addition of a procedure to any visit that occurs sooner than 1 month after any vaccination.
 - Addition of an unplanned visit to capture data pertaining to myocarditis and pericarditis.
- Revised protocol title to reflect the changes in age and dose evaluation.
- Updated to allow an additional 2250 Phase 2/3 selected-dose participants to enlarge the size of the pediatric safety database.
- Added Phase 1/2/3 evaluation of lower dose levels for children and young adults with corresponding objectives.
- Revised the order of Visit 1 activities to clarify when procedures should be conducted in relation to study intervention administration when the visit occurs over 2 consecutive days.
- Added updates and reformatted activities in the Schedule of Activities.
- Removed the requirement to conduct a potential COVID 19 convalescent visit following each potential COVID 19 illness visit. The collection of the blood sample was to support an exploratory endpoint, which will be addressed with external data and thereby reduce burden to participants and caregivers.
- Added a country-specific appendix that allows flexibility to conduct scheduled visits in the participant's home, ie, site-arranged home health visits, as permitted per local guidelines (applicable to Poland only).

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

- C4591007 PA2 Phase 2/3 Children Assent Placebo-Controlled Selected Dose 06 Aug 2021 version 3 - [Clean copy](#) & [track changes copy](#)
- C4591007 PA2 Phase 2/3 Parent ICD Placebo-Controlled Selected Dose 06 Aug 2021 version 5 - [Clean copy](#) & [track changes copy](#)

Finally, the following new Informed Consent Documents are being added to Study C4591007 and are included in Module 5.3.5.1:

- C4591007 PA2 Phase 1 Younger Children Assent Lower Dose Evaluation 09 Aug 2021 version 1 – [Clean copy](#)
- C4591007 PA2 Phase 1 Older Children Assent Lower Dose Evaluation 09 Aug 2021 version 1 – [Clean copy](#)
- C4591007 PA2 Phase 1 Parent ICD Lower Dose Evaluation 09 Aug 2021 version 1 – [Clean copy](#)
- C4591007 PA2 Phase 1 Adult Participant ICD Lower Dose Evaluation 09 Aug 2021 version 1 – [Clean copy](#)
- C4591007 PA2 Phase 2/3 Younger Children Assent Lower Dose Evaluation 09 Aug 2021 version 1 – [Clean copy](#)

- C4591007 PA2 Phase 2/3 Older Children Assent Lower Dose Evaluation 09 Aug 2021 version 1 – [Clean copy](#)
- C4591007 PA2 Phase 2/3 Parent ICD Lower Dose Evaluation 09 Aug 2021 version 1 – [Clean copy](#)
- C4591007 PA2 Phase 2/3 Adult Participant ICD Lower Dose Evaluation 09 Aug 2021 version 1 – [Clean 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 212-733-2613; via facsimile at 845-474-3500; or via e-mail at neda.aghajanimemar@pfizer.com.

Sincerely,

Neda Aghajani Memar, Pharm.D.
Director
Pfizer Global Regulatory Affairs

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