Pfizer Global Regulatory Affairs
Pfizer Inc.
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Global Product Development

06 May 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

Re: BLA 125742

COVID-19 mRNA Vaccine (BNT162/PF-07302048)

Part 1 of the Original Submission – Rolling Biologics License Application (BLA)

Request for Priority Review Designation

Dear Dr. Gruber,

Please find enclosed Part 1 of the Original Submission of the rolling Biologics License Application (BLA) for the BNT162b2 vaccine candidate developed by BioNTech and Pfizer under BB-IND 19736 for the prevention of COVID-19 caused by SARS-CoV-2 in individuals ≥16 years of age. This vaccine was granted Fast Track Designation for individuals ≥18 years of age on 07 July 2020. The Grant Fast Track Designation Letter is provided in Module 1.7.4. Submission of this BLA as a rolling application was agreed during the teleconference of 16 April 2021.

BioNTech and Pfizer are requesting Priority Review Designation for this BLA. It meets the criteria for Priority Review Designation, as outlined in the 2014 *Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics* because BNT162b2 prevents a serious and life-threatening condition (COVID-19) and, if approved, would provide a significant improvement in safety and effectiveness because there are currently no vaccines licensed for the prevention of COVID-19 in the US. The Priority Review Designation Request is provided in Module 1.2.

A wire transfer for $2,875,842.00 was made to the U.S. Department of Treasury (TREAS

NYC 33 Liberty Street, New York, NY 10045) on 05 May 2021 (User Fee ID# PD3017966) for the user fee for this application. A copy of the user fee cover sheet (Form 3397) is provided in Module 1.1.

The purpose of this submission is to provide the complete non-clinical and clinical contents of the application. This submission is provided in electronic Common Technical Document (eCTD) format. The Table of Contents is attached. Part 2 of the Original Submission of the BLA containing the rest of the BLA contents will be submitted on 21 May 2021. Additionally, as agreed during the teleconference of 16 April 2016, sequencing data requested by the Agency on 09 March 2021 will be provided by 07 June 2021.

Any reference not included with this submission is available upon request.

In addition, via email on 10 August 2020, it was agreed that BioNTech could be provided their US License Number upon submission of the BLA (as opposed to at approval). We kindly request the US License Number for BioNTech at this time with agreement that they will not use it until after the BLA is approved.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 215-280-5503; via facsimile at 845-474-3500; or via e-mail at elisa.harkinstull@pfizer.com.

Sincerely,

Elisa Harkins
Global Regulatory Lead
Global Regulatory Affairs – Vaccines

CC: Ramachandra S. Naik, Ph.D.

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	R-20-0211 - In vitro Expression of BNT162b2 Drug Substance and Drug Product
	VR-VTR-10671 - BNT162b2 (V9) Immunogenicity and Evaluation of Protection against SARS-CoV-2 Challenge in Rhesus Macaques
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	PF-07302048_06Jul20_072424 - A Single Dose Rat Pharmacokinetic Study of ALC-0315 and ALC-0159 Following Intravenous Bolus Injection of PF-07302048 Nanoparticle Formulation in Wistar Han Rats
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	R-20-0072 - Expression of Luciferase-Encoding ModRNA After I.M. Application of GMP-Ready Acuitas LNP Formulation
	185350 - A Tissue Distribution Study of a [3H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats
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	PF-07302048_05Aug20_043725 - Investigation of the Biotransformation of ALC-0159 and ALC-0315 In Vitro and In Vivo in Rats
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	VR-MVR-10081 - Method Validation Report for the Elecsys Anti-SARS-CoV-2 Assay
	VR-MVR-10083 - Validation Report for the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay
	VR-MQR-10211 - Qualification Report for a Single-plex Direct Luminex Assay (dLIA) for Quantitation of IgG Antibodies to SARS-CoV-2 S1 Protein in Human Sera
	VR-MQR-10212 - Qualification Report for a Single-plex Direct Luminex Assay (dLIA) for Quantitation of IgG Antibodies to SARS-CoV-2 RBD Protein in Human Sera
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	VR-TM-10294 - Single-plex Luminex Assay for Quantitation of IgG Antibodies to SARS-CoV-2 RBD Protein in Human Serum
	VR-TM-10298 - Manual 96-well Neutralization Assay for the Detection of Functional Antibodies to SARS-CoV-2 in Test Serum
	VR-TM-10304 - Test Method for the SARS CoV-2 Nucleocapsid (N) Antigen Detection Assay
	VR-SOP-LC-11120 - Data Review Procedures for Direct Luminex Immunoassays in LIMS v6
	SHI-SOP-10011 - Manual 96-well Neutralization Assay for the Detection of Functional Antibodies to SARS-CoV-2 in Test Serum using Cytation 7 Image Reader
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	C4591001 - A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-CoV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals
	C4591001 - Final Analysis Interim CSR
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	BNT162-01 - A Multi-Site, Phase I/II, 2-Part, Dose-Escalation Trial Investigating the Safety and Immunogenicity of Four Prophylactic SARS-CoV-2 RNA Vaccines Against COVID-19 Using Different Dosing Regimens in Healthy Adults
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