Vaccines and Related Biological Products
Advisory Committee meeting
September 17, 2021

Comirnaty (COVID-19 Vaccine, mRNA)
Supplemental Biologics License Application
for a booster dose in individuals 16 years of age and older

Applicant: BioNTech Manufacturing GmbH

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Background Outline

- Description of Comirnaty
- Overview of the Comirnaty sBLA and the Clinical Package
- Overview of Today’s Agenda
- Voting and Discussion Questions to the Committee
Comirnaty (COVID-19 Vaccine, mRNA)

- Licensure: August 23, 2021
- Indication and Usage: To prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older
- Dosing Regimen: Two doses administered three weeks apart
- Each 0.3 mL dose contains 30 micrograms of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike glycoprotein of SARS-CoV-2
Comirnaty supplemental BLA

- Submission Date: August 25, 2021

- Proposed booster dose and regimen:
  A single 0.3 mL dose (30 micrograms mRNA) approximately 6 months after dose 2 in individuals 16 years of age and older.

- The clinical package includes safety and immunogenicity data from approximately 330 participants who were reenrolled to receive a booster dose of COMIRNATY approximately 6 months after completing the primary series.
Overview of Today’s Agenda

FDA Introduction
- Welcome
  Peter Marks, M.D., Ph.D., Center Director, CBER, FDA
- Introduction of the Topic
  Marion Gruber, Ph.D., Director, OVRR, CBER, FDA
- Background
  Ramachandra Naik, Ph.D., Review Committee Chair, OVRR, CBER, FDA

Epidemiology of pandemic CDC delta variant/breakthrough infections
Sara Oliver, M.D., M.S.P.H., Centers for Disease Control and Prevention, Division of Viral Disease, National Center for Immunization and Respiratory Diseases

Real-world effectiveness of COVID-19 vaccines
Jonathan Sterne, B.A., M.Sc., Ph.D., Professor of Medical Statistics and Epidemiology, Bristol Medical School, University of Bristol, UK

Booster protection against confirmed infections and severe disease – data from Israel
Sharon Elroy-Preiss, M.D., M.P.H., M.B.A, Director of Public Health Services, Ministry of Health, Israel
Ron Milo, Ph.D., Professor, Weizmann Institute, Israel

Break (5 min)
Overview of Today’s Agenda, cont.

- **Applicant Presentation**
  BNT162b2 [COMIRNATY (COVID-19 Vaccine, mRNA)] Booster (Third) Dose
    - Donna Boyce, MS, Senior Vice President, Global Regulatory Affairs, Pfizer Inc.
    - William C. Gruber, M.D., Pfizer, Senior Vice President, Vaccine Clinical Research and Development

- **FDA Presentation**
  Joohee Lee, M.D., Medical Officer, OVRR, CBER, FDA

- Lunch (25 min)
- Open Public Hearing (60 min)
- Break (10 min)
- Q & A Session regarding the Applicant and FDA presentations
- Committee Discussion and Voting
- Meeting adjourned
Question to the Committee

1. Do the safety and effectiveness data from clinical trial C4591001 support approval of a COMIRNATY booster dose administered at least 6 months after completion of the primary series for use in individuals 16 years of age and older?

Please vote Yes or No.
Thank you!