



Vaccines and Related Biological Products  
Advisory Committee meeting  
June 15, 2022

Moderna COVID-19 Vaccine  
Request for Emergency Use Authorization (EUA)  
Amendment, Use of a 2-Dose Primary Series in Children  
6 months through 5 Years of Age

Applicant: ModernaTX Inc.,  
Sudhakar Agnihothram, B. Pharm., Ph.D.  
Division of Vaccines and Related Products Applications  
Office of Vaccines Research and Review/CBER/FDA

# Background Outline

- Currently available COVID-19 vaccines (licensed and EUA)
- Overview of the EUA request and the clinical package from ModernaTX, Inc.
- Overview of the EUA request and the clinical package from BioNTech Manufacturing GmbH
- Emergency Use Authorization
- Overview of Today's Agenda
- Voting Questions

## Currently Available COVID-19 Vaccines for Primary Vaccination in Pediatric Population

### ➤ **Pfizer-BioNTech COVID-19 Vaccine (available under EUA)**

- ❖ 2-dose primary series (3 weeks apart), individuals 5 years of age and older
- ❖ 3<sup>rd</sup> primary series dose, (at least 28 days after the second dose) in individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise

### ➤ **COMIRNATY**

- ❖ FDA-approved for use as a two dose primary series in individuals 16 years of age and older and can be used interchangeably with Pfizer-BioNTech COVID-19 Vaccine as currently authorized

## EUA Amendment Request for Individuals 6 months through 5 Years of Age

- Submission Date: April 28, 2022
  
- Proposed dose and regimen:  
A primary series of 2 doses (0.25 mL each, 25 mcg of mRNA), 1 month apart, administered intramuscularly in individuals 6 months through 5 years of age
  
- The clinical package includes safety, efficacy and immunogenicity data
  - ❖ ~1,800 vaccine recipients (6-23 months of age)
  - ❖ ~3,000 vaccine recipients (2-5 years of age)



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**Pfizer-BioNTech COVID-19 Vaccine  
Emergency Use Authorization Amendment Request  
for Use in Children 6 months through 4 Years of Age**

Applicant: BioNTech Manufacturing GmbH

Ramachandra Naik, Ph.D.

Division of Vaccines and Related Products Applications  
Office of Vaccines Research and Review/CBER/FDA

## EUA Amendment Request for Children 6 months through 4 Years of Age

- Submission Date: May 27, 2022
- Current proposed dose and regimen:  
A primary series of 3 doses (0.2 mL each, 3 mcg of mRNA), first two doses administered 3 weeks apart followed by a third dose administered at least 8 weeks after the second dose, intramuscularly, in individuals 6 months through 4 years of age
- The clinical package includes safety and effectiveness data from ~3,000 vaccine recipients

# Emergency Use Authorization

- FDA may issue an Emergency Use Authorization (EUA) of an unapproved medical product following an EUA declaration, if the following statutory requirements\* are met:
  - The agent referred to in the EUA declaration can cause a serious or life-threatening disease or condition
  - The medical product may be effective to prevent, diagnose, or treat the serious or life-threatening condition caused by the agent
  - The known and potential benefits of the product outweigh the known and potential risks of the product
  - No adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition

\*Section 564 of the FD&C Act (21 U.S.C. 360bbb-2)

## Overview of Today's Agenda

### ➤ FDA Introduction (20 min)

#### ❖ Welcome

Peter Marks, M.D., Ph.D., Center Director, CBER, FDA

#### ❖ Background for the EUA Amendment Requests

- **Moderna COVID-19 Vaccine: Use of a 2-Dose Primary Series in Infants and Children 6 Months through 5 Years of Age**

Sudhakar Agnihotram, Ph.D., Review Committee Chair, DVRPA, OVRP, CBER, FDA

- **Pfizer-BioNTech COVID-19 Vaccine: Use of a 3-Dose Primary Series in Infants and Children 6 Months through 4 Years of Age**

Ramachandra Naik, Ph.D., Review Committee Chair, DVRPA, OVRP, CBER, FDA

### ➤ Sponsor Presentation (ModernaTX, Inc.) (45 min)

- ❖ Carla Vinals, Ph.D., Vice President, Regulatory Affairs Strategy, Infectious Diseases, ModernaTX, Inc.
- ❖ Evan Anderson, M.D., FAAP, Associate Professor, Pediatrics and Medicine, Emory University School of Medicine
- ❖ Jacqueline Miller, M.D., FAAP, Senior Vice President, Therapeutic Area Head, Infectious Diseases, ModernaTX, Inc.
- ❖ Rituparna Das, M.D., Ph.D., Vice President, Clinical Development, COVID-19 Vaccines, ModernaTX, Inc.

### ➤ FDA Presentation (45 min)

#### **FDA Review of Effectiveness and Safety of Moderna COVID-19 Vaccine in Infants and Children 6 Months through 5 Years of Age**

Robin Wisch, M.D., Medical Officer, Clinical Review Staff, Immediate Office of Director, DVRPA, OVRP, CBER



## Overview of Today's Agenda, continued

- **Break (15 min)**
- **Sponsor Presentation (Pfizer, Inc.) (45 min)**  
William C. Gruber, M.D., FAAP, FIDSA, FPIDS  
Senior Vice President, Vaccine Clinical Research and Development, Pfizer Inc.
- **FDA Presentation (45 min)**  
**FDA Review of Effectiveness and Safety of Pfizer-BioNTech COVID-19 Vaccine in Infants and Children 6 Months through 4 Years of Age**  
Susan Wollersheim, M.D., Medical Officer, Clinical Review Branch 1, DVRPA, OVRP, CBER
- **Lunch (30 min)**
- **Open Public Hearing (60 min)**
- **Additional Q & A for FDA and Sponsor Presenters – Moderna COVID-19 Vaccine (25 Min)**
- **Committee Discussion and Voting – Moderna COVID-19 Vaccine (60 Min)**
- **Break (10 min)**
- **Additional Q & A for FDA and Sponsor Presenters – Pfizer-BioNTech COVID-19 Vaccine (25 Min)**
- **Committee Discussion and Voting – Pfizer-BioNTech COVID-19 Vaccine (60 min)**
- **Meeting adjourned - DFO**

## Question to the Committee - Moderna COVID-19 Vaccine

Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine when administered as a 2-dose series (25 mcg each dose) outweigh its risks for use in children 6 months through 5 years of age?

**Please vote Yes or No.**

## Question to the Committee – BioNTech Manufacturing GmbH

Based on the totality of the scientific evidence available, do the benefits of the Pfizer-BioNTech COVID-19 Vaccine, when administered as a 3-dose series (3 mcg each dose), outweigh its risks for use in infants and children 6 months through 4 years of age?

**Please vote Yes or No.**



**Thank you!**