Vaccines and Related Biological Products
Advisory Committee meeting
February 28, 2023

Biologics License Application for Respiratory Syncytial Virus Vaccine (ABRYSVO)

Applicant: Pfizer Inc.

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Division of Vaccines and Related Products Applications (DVRPA)
Office of Vaccines Research and Review (OVRR)/CBER/FDA

Outline

- Respiratory Syncytial Virus (RSV) disease in older adults
- Description of ABRYSVO
- Overview of the ABRYSVO Biologics License Application (BLA)

  -Clinical Package
- Overview of Today's Agenda
- Voting Question for the Committee

Respiratory Syncytial Virus Disease in Older Adults

- RSV is one of the leading cause of respiratory infection in older adults. RSV has 2 major subgroups, A and B, which cocirculate. Both can cause severe disease.
- Palivizumab, a monoclonal antibody is approved by FDA for prevention of serious LRTD caused by RSV in children <2 years of age.
- In the US, RSV is responsible for approximately 177,000 hospitalizations and 14,000 deaths annually in adults 65 years of age and older.
- Currently, there is no licensed vaccine to prevent RSV disease in older adults
- Treatment of RSV disease for older adults consists primarily of supportive care
- **RSV disease represents a serious condition with an unmet medical need**

ABRYSVO: Description

- Each 0.5 mL dose of ABRYSVO Vaccine contains 60 mcg each of lyophilized recombinant prefusion F protein from RSV-A and RSV-B subgroups expressed in CHO cells (120 mcg of total protein)

- Dosing regimen: A single dose of 0.5 mL, administered intramuscularly

- **Applicant's Proposed Indication**: Active immunization to prevent acute respiratory disease and lower respiratory tract disease caused by RSV in individuals 60 years of age and older

ABRYSVO BLA Clinical Package

FDA received a BLA for ABRYSVO on September 30, 2022

The clinical package includes:

- Safety, immunogenicity and efficacy data from an ongoing Phase 3 study (C3671013) conducted in the US, Canada, Finland, The Netherlands, South Africa, Argentina and Japan with approximately 34,000 participants
- Additional safety data from approximately 1,200 ABRYSVO recipients across five clinical studies conducted in the US, Australia and UK (C3671001, C3671002, C3671004, C3671014 and WI257521)

Overview of Today's Agenda

- **FDA Introduction**
  Background/Introduction of the Topic (10 Min)
  - Goutam Sen, Ph.D., Review Committee Chair, DVRPA, OVRR, CBER, FDA

- **RSV Virology, Strain Variation, and Surveillance Measures (15 Min)**
  - Natalie Thornburg, Ph.D., Centers for Disease Control and Prevention
- **RSV Epidemiology and Disease Burden in older adults (15 Min)**
  - Fiona Havers, M.D., MHS, FIDSA; Centers for Disease Control and Prevention
- **Durability of Naturally Acquired Immunity and Susceptibility to Repeated RSV Infections (15 Min)**
  - H. Keipp Talbot, M.D., MPH, FIDSA; Associate Professor, Vanderbilt University Medical Center, Nashville, TN

  - **Break**

- **Sponsor Presentation (60 Min including Q&A)**
  - **Safety and Efficacy of Bivalent RSV Prefusion F Vaccine in Adults ≥60 Years of Age (50 min)**

  Alejandra Gurtman, MD, FIDSA, Vice President, Vaccine Clinical Research and Development, Pfizer Inc.

Overview of Today's Agenda (Continued)

- **FDA Presentation (60 Min including Q&A)**
  - **FDA Review of Efficacy and Safety of ABRYSVO (Respiratory Syncytial Virus Vaccine) in Adults 60 Years of Age and Older (60 Min including Q&A)**
    Nadine Peart, M.D., Lead Medical Officer, DVRPA, OVRR, CBER, FDA

- **Lunch (40 Min)**

- **Open Public Hearing (60 min)**
- **Additional Q & A for CDC, Sponsor and other Presenters (60 min)**

- **Break (10 min)**

- **Committee Discussion and voting (110 min)**
- **Meeting adjourned - DFO**

VRBPAC VOTING QUESTION - 1

Are the available data adequate to support the safety of ABRYSVO (RSVPreF) when administered to individuals 60 years of age and older for the prevention of lower respiratory tract disease caused by RSV?

Please vote “Yes” or “No”

VRBPAC VOTING QUESTION - 2

Are the available data adequate to support the effectiveness of ABRYSVO (RSVPreF) for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older ?

Please vote “Yes” or “No”

Thank you!