U.S. FOOD & DRUG ADMINISTRATION

Vaccines and Related Biological Products
Advisory Committee Meeting
March 1, 2023

Biologics License Application for Respiratory Syncytial Virus (RSV) Vaccine Recombinant, Adjuvanted (AREXVY)

Applicant: GlaxoSmithKline Biologicals

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Outline

- RSV disease in older adults
- Description of AREXVY
- Overview of clinical trials submitted in support of licensure of AREXVY
- Overview of today's agenda
- Voting Questions for the Committee

RSV Disease in Older Adults

- RSV is a leading cause of lower respiratory tract disease (LRTD) in older adults.
- Older adults, particularly with underlying medical conditions are at risks for severe disease.
- RSV causes a significant number of hospitalizations and deaths annually in the United States, particularly in individuals 65 years of age and older, and **RSV disease represents a serious condition with an unmet medical need**.
- There are **no specific treatment options for RSV disease among adults**.

AREXVY: Description

- The vaccine is a lyophilized recombinant **RSVPreF3** glycoprotein antigen derived from an RSV-A strain, stabilized in the pre-fusion trimeric conformation, reconstituted at the time of use with **$AS01_E$ adjuvant** suspension.

- After reconstitution, each 0.5-mL dose of AREXVY contains:
  - 120 ug of recombinant RSVPreF3 antigen
  - 25 µg of MPL and
  - 25 µg of QS-21

- $AS01_E$ contains half the amount of MPL and QS-21 contained in $AS01_B$ adjuvant used in SHINGRIX.

- AREXVY is administered intramuscularly as a single 0.5 mL dose.

- **Applicant's Proposed Indication**: Active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus RSV-A and RSV-B subtypes in adults 60 years of age and older

AREXVY: BLA Clinical Package

- FDA received a BLA for AREXVY on September 2, 2022
- The clinical package included data from five clinical studies to support the safety and effectiveness of AREXVY.
- Efficacy of AREXVY to prevent RSV-associated LRTD (primary endpoint) in adults ≥60 YOA is evaluated in an ongoing, pivotal phase 3, randomized, placebo controlled, observer-blind, international study RSV OA=ADJ-**006**.
- A total of 24,966 participants (12,467 vaccine and 12,499 saline placebo) were enrolled in the study.

Overview of Today's Agenda

9:00 am: **Opening Remarks: Call to Order and Welcome (5 min)**
Hana El Sahly, M.D. Chair, VRBPAC

Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 Min)
Sussan Paydar, Ph.D. Designated Federal Officer, FDA

9:25 am: **FDA Introduction Welcome (5 Min)**
David C. Kaslow, M.D.
Director, Office of Vaccines and Research and Review
Center for Biologics Evaluation and Research (CBER)

Overview for Biologics License Application for AREXVY (15 Min)
Santosh Nanda, DVM, Ph.D.
Review Committee Chair
Office of Vaccines Research and Review (OVRR), CBER

Today's Agenda (Continued)

9:50 am: **Sponsor GSK Presentation: (60 Min including Q&A)**
RSVPreF3 Vaccine for Respiratory Syncytial Virus (RSV) in Older Adults
Introduction

Bishoy Rizkalla, PhD
Vice President & Global Medical Affairs Lead, GSK

Burden of Respiratory Disease in the Older Adult Population
Ann R. Falsey, MD
Professor of Medicine, University of Rochester, New York

Efficacy & Immunogenicity
Bishoy Rizkalla, PhD
Vice President & Global Medical Affairs Lead, GSK

Safety / Benefit Risk
Peggy Webster, MD, MBA
Vice President & Head of Vaccine Safety, GSK
Q & A: 10 Min

Today's Agenda (Continued)

10:50 am: **FDA presentation (60 Min including Q &A)**
FDA Review of Efficacy and Safety of AREXVY (60 min including Q & A)
Nicholas Geagan, D.O.
Office of Vaccines Research and Review (OVRR), CBER

11:50 am: **Lunch (40 min)**

12:30 pm: **Open Public Hearing (60 Min)**

1:30 pm: **Additional Q & A for FDA and Sponsor Presenters (30 Min)**

2:00 pm: **Committee Discussion and Voting - GSK RSV Vaccine (110 Min)**

3:50 pm: **Meeting Adjourned - DFO**

VRBPAC VOTING QUESTION - 1

- Are the available data adequate to support the safety of AREXVY (RSVPreF3+AS01$_E$) 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 AREXVY (RSVPreF3+AS01$_E$) 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!