FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
179th Meeting of the Vaccines and Related Biological Products Advisory Committee
February 28 – March 1, 2023
AGENDA

Day 1- February 28, 2023

Topic 1: The committee will meet in open session to discuss and make recommendations on the safety and effectiveness of ABRYSVO (Respiratory Syncytial Virus Vaccine), manufactured by Pfizer Inc., with a requested indication, in Biologics License Application # 125769 (STN 125769/0), for active immunization for the prevention of acute respiratory disease and lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 60 years of age and older.

Time EST	Presentation/Presenter
8:30 a.m.	**Opening Remarks: Call to Order and Welcome (5 Min)** Hana El Sahly, M.D. Chair, VRBPAC Professor, Department of Molecular Virology and Microbiology Baylor College of Medicine **Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 Min)** Sussan Paydar, Ph.D. Designated Federal Officer, VRBPAC Division Of Scientific Advisors and Consultants, CBER, FDA
8:55 a.m.	**FDA Introduction (25 Min total)** **Welcome (5 Min)** • David C. Kaslow, M.D. Director, Office of Vaccines and Research and Review Center for Biologics Evaluation and Research (CBER) **Biologics License Application for ABRYSVO (Respiratory Syncytial Virus Vaccine) in Adults 60 Years of Age and Older (15 Min)** • Goutam Sen, Ph.D. Review Committee Chair Division of Vaccines and Related Products Applications (DVRPA) Office of Vaccines Research and Review (OVRR), CBER **Q & A: 5 Min**

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9:20 a.m.	**<u>Centers for Disease Control and Prevention (CDC) Presentations (40 Min including Q&A)</u>** **RSV Virology, Strain Variation, and Surveillance Measures (15 Min)** • Natalie Thornburg, PhD. Acting Chief Laboratory Branch Coronaviruses and Other Respiratory Viruses Division National Center for Immunizations and Respiratory Diseases Centers for Disease Control and Prevention **RSV Epidemiology and Disease Burden in Older Adults (15 Min)** Fiona Havers, M.D., MHS, FIDSA Team Lead RESP-NET Hospitalization Surveillance Team Coronaviruses and Other Respiratory Viruses Division National Center for Immunizations and Respiratory Diseases Centers for Disease Control and Prevention **Q & A: 10 Min**
10:00 a.m.	**<u>Clinical Considerations of RSV in older adults (20 Min including Q&A)</u>** **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 **Q & A: 5 Min**
10:20 a.m.	**Break 10 Min**
10:30 a.m.	**<u>Sponsor Presentation: (60 Min including Q&A)</u>** **Safety and Efficacy of Bivalent RSV Prefusion F Vaccine in Adults ≥60 Years of Age** Alejandra Gurtman, M.D., FIDSA Vice President, Vaccine Clinical Research and Development, Pfizer Inc.

	Q & A: 10 Min
11:30 a.m.	**<u>FDA presentations (60 Min including Q&A)</u>** **FDA Review of Efficacy and Safety of ABRYSVO (Respiratory Syncytial Virus Vaccine) in Adults 60 Years of Age and Older (50 Min)** • Nadine Peart Akindele, M.D. Medical Officer Division of Vaccines and Related Products Applications (DVRPA) Office of Vaccines Research and Review (OVRR), CBER **Q & A: 10 Min**
12:30 p.m.	**Lunch (40 Min)**
1:10 p.m.	**Open Public Hearing (60 Min)**
2:10 p.m.	**Additional Q & A for CDC, FDA, Sponsor and other Presenters – (60 Min)**
3:10 p.m.	**Break (10 Min)**
3:20 p.m.	**Committee Discussion and Voting – Pfizer RSV Vaccine (110 Min)**
5:10 p.m.	**Meeting Adjourned – DFO**

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Day 2- March 1, 2023

Topic 2: The Committee will meet in open session to discuss and make recommendations on the safety and effectiveness of AREXVY (Respiratory Syncytial Virus Vaccine, Recombinant, Adjuvanted), manufactured by GSK, with a requested indication, in Biologics License Application # 125775 (STN 125775/0), for 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.

Time EST	Presentation/Presenter
9:00 a.m.	**Opening Remarks: Call to Order and Welcome (5 Min)** Hana El Sahly, M.D. Chair, VRBPAC Professor, Department of Molecular Virology and Microbiology Baylor College of Medicine **Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 Min)** Sussan Paydar, Ph.D. Designated Federal Officer, VRBPAC Division Of Scientific Advisors and Consultants, CBER, FDA
9:25 a.m.	**FDA Introduction (25 Min Total)** **Welcome (5 Min)** • David C. Kaslow, M.D. Director, Office of Vaccines and Research and Review Center for Biologics Evaluation and Research (CBER) **Biologics License Application for AREXVY (Respiratory Syncytial Virus Vaccine, Recombinant, Adjuvanted) in Adults 60 Years of Age and Older (15 Min)** • Santosh Nanda, DVM, Ph.D. Review Committee Chair Division of Vaccines and Related Products Applications (DVRPA) Office of Vaccines Research and Review (OVRR), CBER **Q & A: 5 Min**

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9:50 a.m.	**<u>Sponsor GSK Presentation: (60 Min including Q&A)</u>** **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**
10:50 a.m.	**<u>FDA presentation (60 Min including Q &A)</u>** **FDA Review of Efficacy and Safety of AREXVY (Respiratory Syncytial Virus Vaccine, Recombinant, Adjuvanted) in Adults 60 Years of Age and Older (50 Min)** • Nicholas Geagan, D.O. Staff Fellow Division of Vaccines and Related Products Applications (DVRPA) Office of Vaccines Research and Review (OVRR), CBER **Q & A- 10 Min**
11:50 a.m.	**Lunch (40 Min)**

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12:30 p.m.	**Open Public Hearing (60 Min)**
1:30 p.m.	**Additional Q & A for FDA and Sponsor Presenters (30 Min)**
2:00 p.m.	**Committee Discussion and Voting - GSK RSV Vaccine (110 Min)**
3:50 p.m.	**Meeting Adjourned - DFO**