

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
181st Meeting of the Vaccines and Related Biological Products
Advisory Committee
May 18, 2023
AGENDA**

Topic: The committee will meet in open session to discuss and make recommendations on the safety and effectiveness of ABRYSV0 (Respiratory Syncytial Virus Vaccine), manufactured by Pfizer Inc., with a requested indication, in Biologics License Application # 125768 (STN 125768/0), for the prevention of lower respiratory tract disease and severe lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age by active immunization of pregnant individuals.

Time EST	Presentation/Presenter
8:30 a.m.	<p><u>Opening Remarks: Call to Order and Welcome (5 Min)</u></p> <p>Hana El Sahly, M.D. Chair, VRBPAC Professor, Department of Molecular Virology and Microbiology Baylor College of Medicine</p> <p><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 Min)</u></p> <p>Prabhakara Atreya, Ph.D., Designated Federal Officer and Director Valerie Vashio, B.Pharm., Designated Federal Officer Division of Scientific Advisors and Consultants (DSAC), CBER, FDA</p>
8:55 a.m.	<p><u>FDA Introduction (25 Min total)</u></p> <p>Welcome (5 Min) and Presentation (15 Min)</p> <ul style="list-style-type: none"> • David C. Kaslow, M.D. Director Office of Vaccines Research and Review (OVR), CBER <p>Biologics License Application for Respiratory Syncytial Virus Vaccine (ABRYSV0) Immunization During Pregnancy to Prevent RSV Lower Respiratory Tract Disease [LRTD] and Severe RSV LRTD in Infants: Applicant: Pfizer Inc.</p> <ul style="list-style-type: none"> • Goutam Sen, Ph.D. Review Committee Chair Division of Vaccines and Related Products Applications (DVRPA) OVR, CBER <p>Q & A: 5 Min</p>

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9:20 a.m.	<p><u>Centers for Disease Control and Prevention (CDC) Presentations: (40 Min including Q & A)</u></p> <p>RSV Virology, Strain Variation, and Surveillance Measures (15 Min)</p> <ul style="list-style-type: none"> • Natalie J. Thornburg, Ph.D. Acting Chief, Laboratory Branch Coronavirus and Other Respiratory Viruses Division National Center for Immunization and Respiratory Diseases, CDC <p>RSV Epidemiology and Disease Burden in Infants from birth through 6 months of age (15 Min)</p> <ul style="list-style-type: none"> • Katherine E. Fleming-Dutra, M.D. Team Lead (acting), Vaccine Effectiveness and Policy Team Surveillance and Prevention Branch Coronavirus and Other Respiratory Viruses Division National Center for Immunization and Respiratory Diseases, CDC <p>Q & A: 10 Min</p>
10:00 a.m.	<p><u>Clinical Considerations of RSV in Infants from birth through 6 months of age (20 Min including Q & A)</u></p> <p>Durability of Naturally Acquired Immunity and Susceptibility to Repeated RSV Infections (15 Min)</p> <ul style="list-style-type: none"> • Helen Chu, M.D., M.P.H. Associate Professor Departments of Medicine, Global Health, and Epidemiology University of Washington <p>Q & A: 5 Min</p>
10:20 a.m.	Break 10 Min
10:30 a.m.	<p><u>Sponsor Presentations: (60 Min including Q & A)</u></p> <p>Bivalent RSV Prefusion F Vaccine for Maternal Immunization to Protect Infants</p>

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	<ul style="list-style-type: none"> • William C. Gruber, M.D., FAAP, FIDSA Senior Vice President Vaccine Clinical Research and Development, Pfizer, Inc. • Eric A. Simoes, M.B.B.S., DCH, M.D. Professor of Pediatrics Children’s Hospital Colorado University of Colorado School of Medicine Professor of Epidemiology Colorado School of Public Health • Iona Munjal, M.D. Senior Director Vaccine Clinical Research and Development, Pfizer, Inc. • Jamie Wilkins, PharmD Senior Director, Head of Risk Management Center of Excellence Worldwide Safety Surveillance and Risk Management, Pfizer, Inc. <p>Q & A: 10 Min</p>
11:30 a.m.	<p><u>FDA Presentation: (60 Min including Q & A)</u></p> <p>Review of Efficacy and Safety of Respiratory Syncytial Virus Vaccine (ABRYSVO) Immunization During the Second or Third Trimester of Pregnancy (24-36 weeks gestational age) to Prevent RSV Lower Respiratory Tract Disease [LRTD] and Severe RSV LRTD in Infants, From Birth Through 6 Months of Age</p> <ul style="list-style-type: none"> • Yugenia Hong-Nguyen, M.D Medical Officer DVRPA, OVRR, CBER <p>Q & A: 10 Min</p>
12:30 p.m.	Lunch (45 Min)
1:15 p.m.	Open Public Hearing (60 Min)
2:15 p.m.	Additional Q & A for CDC, FDA, Sponsor, & other Presenters (60 Min)

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3:15 p.m.	Break (15 Min)
3:30 p.m.	Committee Discussion and Voting – Pfizer RSV Vaccine (120 Min)
5:30 p.m.	Meeting Adjourned – DFO