FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
188th Meeting of the Vaccines and Related Biological Products Advisory Committee
December 12, 2024
AGENDA

Topic I: The committee will meet in open session to discuss considerations for Respiratory Syncytial Virus [RSV] vaccine safety in pediatric populations.

EST Time	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 (15 Min)** Sussan Paydar, Ph.D. Designated Federal Officer, VRBPAC Division of Scientific Advisors and Consultants Center for Biologics Evaluation and Research (CBER), FDA
8:50 a.m.	**Introduction (10 Min)** **Overview of Topic I** David C. Kaslow M.D. Director, Office of Vaccines Research and Review (OVRR) CBER, FDA
9:00 a.m.	**RSV Epidemiology (20 Min Total including Q&A)** **Epidemiology of Respiratory Syncytial Virus in U.S. Children (15 Min)** Fatimah S. Dawood, M.D. Team Lead, Epidemiology and Vaccine Assessment Team Coronavirus and Other Respiratory Viruses Division National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention Q&A: 5 Min

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9:20 a.m.	**Vaccine-Associated Enhanced Respiratory Syncytial Virus Disease (40 Min Total including Q&A)** **Clinical and Nonclinical Aspects of RSV Vaccine Safety in Young Children (30 Min)** Pedro A. Piedra, M.D. Professor, Department of Molecular Virology and Microbiology, and Pediatrics Director, Pandemic Threat Technology Center Director, Respiratory Virus Diagnostic Laboratory Baylor College of Medicine Q&A: 10 Min
10:00 a.m.	**Moderna Presentation (40 Min Total including Q&A)** **Review of Investigational RSV (mRNA-1345) and RSV/hMPV (mRNA-1365) Vaccines in Infants and Children < 2 Years (30 Min)** Christine Shaw, Ph.D. Vice President, Portfolio Head, Infectious Disease Vaccines ModernaTX, Inc. Matthew Snape, M.B.B.S., M.D. Vice President, Clinical Development Infectious Diseases, Paediatric and Maternal Vaccines Moderna Biotech Distributor UK Limited Q&A: 10 Min
10:40 a.m.	**Break (5 Min)**
10:45 a.m.	**FDA Presentations (40 Min Total including Q&A)** **Imbalance in Severe Respiratory Syncytial Virus (RSV) Cases in a Clinical Trial of an RSV vaccine in Infants and Young Children (30 Min)** Mark Connelly, M.D. Team Leader, Clinical Review Branch 3 Division of Clinical and Toxicology Review (DCTR)

	OVRR, CBER, FDA Q&A: 10 Min
11:25 a.m.	**Additional Q&A (20 Min)**
11:45 p.m.	**Lunch (30 Min)**
12:15 p.m.	**OPH (45 Min)**
1:00 p.m.	**Committee Discussion of Considerations for Respiratory Syncytial Virus [RSV] Vaccine Safety in Pediatric Populations (120 Min)**
3:00 p.m.	**Topic I Adjourned** **Break (10 Min)**

Topic II: The committee will meet in open session to hear overviews of the Laboratory of Immunoregulation (LI) and Laboratory of Retroviruses (LR) research programs in the Division of Viral Products, Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER).

Time	Presentation/Presenter
3:10 p.m.	**Opening Remarks: Call to Order and Welcome** Hana El Sahly, M.D. Chair, VRBPAC Professor, Department of Molecular Virology and Microbiology Baylor College of Medicine **Roll Call, Conflict of Interest Statement (5 Min)** Sussan Paydar, Ph.D. Designated Federal Officer, VRBPAC Division of Scientific Advisors and Consultants Center for Biologics Evaluation and Research (CBER), FDA

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3:15 p.m.	**Overview of Research/Site Visit Process, CBER (Total 15 Min including Q&A)** Karen Elkins, Ph.D. (10 Min) Associate Director for Science Office of the Director CBER, FDA Q&A: 5 Min **Overview of Research Conducted in Office of Vaccine Research and Review, CBER and Division of Viral Products (Total 15 Min including Q&A)** Tod Merkel, Ph.D. (10 Min) Associate Director for Research Office of Vaccines Research and Review CBER, FDA Q&A: 5 Min **Overview of Laboratory of Immunoregulation (Total 20 Min including Q&A)** Carol Weiss, M.D., Ph.D. (15 Min) Chief and Principal Investigator Laboratory of Immunoregulation (LI) Division of Viral Products Office of Vaccines Research and Review, CBER Q&A: 5 Min **Overview of Laboratory of Retroviruses (Total 20 Min including Q&A)** Hana Golding, Ph.D. (15 Min) Chief and Principal Investigator Laboratory of Retroviruses (LR) Division of Viral Products Office of Vaccines Research and Review, CBER Q&A: 5 Min

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4:25 p.m.	**Open Public Hearing (15 Min)**
4:40 p.m.	**Transition to Closed Session (5 Min)** Verification of members/TVMs to be present and absence of non-voting IR
4:45 p.m.	**Committee Discussion, Recommendation, and Vote (45 Min)**
5:30 p.m.	**Meeting Adjourned - DFO**