FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
186th Meeting of the Vaccines and Related Biological Products Advisory Committee
September 20, 2024
AGENDA

Topic I: The committee will meet in open session to discuss considerations related to the use of pertussis controlled human infection models [CHIMs] in pivotal studies to demonstrate efficacy of pertussis vaccines for the purpose of licensure.

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 (Total 15 Min including Q&A)** David C. Kaslow, M.D. (10 Min) Director Office of Vaccines Research and Review (OVRR) CBER, FDA Q&A: 5 Min
9:05 a.m.	**CDC Presentations (Total 25 Min including Q&A)** **Pertussis Epidemiology in the Acellular Vaccine Era** Susan Hariri, Ph.D. (20 Min) Deputy Chief for Science Meningitis, Pertussis, and Diphtheria Epidemiology Branch Division of Bacterial Diseases National Center for Immunization and Respiratory Diseases, CDC Q&A: 5 Min

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9:30 a.m.	**CHIM Model (Total 80 Min including Q&A)** **Lessons Learned from the European Bordetella Pertussis Controlled Human Infection Model (Total 40 Min including Q&A)** Robert Read, M.D., FRCP (30 Min) Professor, University Hospital Southampton, United Kingdom Q&A: 10 Min **The First North American Pertussis Controlled Human Infection Model Using the Pertactin-Producing D420 Isolate (Total 40 Min including Q&A)** Scott Halperin, M.D. Director, Canadian Center for Vaccinology, Dalhousie University, Nova Scotia, Canada May ElSherif, M.D., MPH, MSc Adjunct Assistant Professor, Department of Microbiology and Immunology Clinical Scientist and Director of Laboratory Operations, Canadian Center for Vaccinology, Dalhousie University, Nova Scotia, Canada Q&A: 10 Min
10:50 a.m.	**Break (10 Min)**
11:00 a.m.	**FDA CBER's Perspective on Use of CHIMs for Demonstration of Efficacy of New Pertussis Vaccines (Total 40 Min including Q&A)** Tod Merkel, Ph.D. (30 Min) Associate Director for Research Office of Vaccines Research and Review CBER, FDA Q&A: 10 min
11:40 a.m.	**Additional Q&A (20 Min)**

12:00 p.m.	**Lunch (30 min)**
12:30 p.m.	**OPH (45 Min)**
1:15 p.m.	**Committee Discussion of Considerations for Development and Licensure of New Pertussis Vaccines (105 Min)**
3:00 p.m.	**Topic I adjourned** **Break (10 Min)**

Topic II: The committee will meet in open session to hear an overview of the Laboratory of Mucosal Pathogens and Cellular Immunology (LMPCI) research program in the Division of Bacterial, Parasitic, and Allergenic Products (DBPAP), 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.	**Site Visit Process and Overview of Research conducted in CBER, OVRR, and DBPAP (Total 20 Min including Q&A)** Tod Merkel, Ph.D. Associate Director for Research Office of Vaccines Research and Review CBER, FDA Q&A: 5 Min **Overview of Research in the Laboratory of Mucosal Pathogens and Cellular Immunology (LMPCI) (Total 20 Min including Q&A)** Scott Stibitz, Ph.D. Chief and Principal Investigator Laboratory of Mucosal Pathogens and Cellular Immunology (LMPCI) Division of Bacterial, Parasitic, and Allergenic Products Office of Vaccines Research and Review, CBER Q&A: 5 Min
3:55 p.m.	**Open Public Hearing (15 Min)**
4:10 p.m.	**Transition to Closed Session (5 Min)** Verification of members/TVMs to be present and absence of non-voting IR
4:15 p.m.	**Closed Session: Committee Discussion, Recommendation and Voting (45 min)**
5:00 p.m.	**Meeting Adjourned - DFO**