

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
158th Meeting of the Vaccines and Related Biological Products
Advisory Committee
FDA White Oak Campus, Building 31, Great Room
Salon B & C
Silver Spring, MD
November 8, 2019

AGENDA
Meeting Link:

<https://collaboration.fda.gov/vrbpac110819/>

Topic: The committee will meet in open session to discuss and make recommendations on the development of chikungunya vaccines.

Note: Committee members are participating in person.

Time	Presentation/Presenter
8:30 AM	<p><u>Opening Remarks: Call to Order, Introduction of Committee</u> (5 minutes) Hana El Sahly, M.D. Chair, VRBPAC</p> <p><u>Administrative Announcements, Conflict of Interest Statement</u> (10 minutes) Prabhakara Atreya, Ph.D. Director, DSAC and Acting Designated Federal Officer, VRBPAC CBER, FDA</p>
8:45 AM	<p>FDA Introduction (10 minutes) Bharat Khurana, DVM, Ph.D., M.B.A. <i>Microbiologist (Regulatory)</i> Office of Vaccines and Related Research (OVRR) Center for Biologics Evaluation and Research (CBER) Division of Vaccines and Related Product Applications (DVRPA) Food and Drug Administration (FDA) Q & A (5 minutes)</p>
9:00 AM	<p>Epidemiology of Chikungunya (25 minutes) Ann Powers, Ph.D. Research Microbiologist and Chief Alphavirus Laboratory Division of Vector-Borne Diseases (DVBD) Centers for Disease Control and Prevention (CDC) Q & A (5 minutes)</p>
9:30 AM	<p>Animal Models of Chikungunya: A Key to Vaccine Validation (25 minutes) Pierre Roques, Ph.D., H.D.R. Senior CEA Expert (Commissariat à l'énergie atomique et aux énergies alternatives) François Jacob Institute of Biology Fontenay-aux-Roses, France Q & A (5 minutes)</p>

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10:00 AM	Break (15 minutes)
10:15 AM	Evidence of Ongoing CHIK Transmission in Southern Thailand (25 minutes) MAJ Damon W. Ellison, Ph.D. Associate Director, Viral Diseases Branch Walter Reed Army Institute of Research Q & A (5 minutes)
10:45 AM	Comments from Manufacturers (15-20 minutes each) Chikungunya Virus-Like Particle Vaccine Development Kelly Warfield, Ph.D. Vice President, Vaccine and Anti-Infectives Research and Development Emergent BioSolutions VRBPAC Presentation on mRNA-based Chikungunya Virus Vaccine Allison August, M.D. Senior Director, Clinical Development ModernaTX Proposed path to licensure for the measles vectored chikungunya vaccine MV-CHIK Christian Mandl, M.D., Ph.D. Chair of the Scientific Advisory Board Themis Live-attenuated Chikungunya Virus Vaccine Candidate (VLA1553) Wolfgang Bender, M.D., Ph.D., M.P.H., M.H.A., D.T.M.P. Chief Medical Officer Valneva Q & A (10 minutes)
12:15 PM	Lunch (60 minutes)
1:15 PM	Open Public Hearing (OPH) (60 minutes) * * No Speakers Registered for OPH
2:15 PM	Passive Transfer Studies to Determine Correlates of Protective Immunity Against Chikungunya Fever (25 minutes) Scott Weaver, Ph.D. John Sealy Distinguished University Chair in Human Infections and Immunity Professor and Chair, Department of Microbiology and Immunology Director, Institute for Human Infections and Immunity Scientific Director, Galveston National Laboratory Director, Western Gulf Center of Excellence for Vector-Borne Diseases University of Texas Medical Branch

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	Q & A (5 minutes)
2:45 PM	FDA Presentation (25 minutes) Sudhakar Agnihothram, B.Pharm., Ph.D. <i>Biologist (Primary Reviewer)</i> Office of Vaccines and Related Research (OVRR) Center for Biologics Evaluation and Research (CBER) Division of Vaccines and Related Product Applications (DVRPA) Food and Drug Administration (FDA) Q & A (5 minutes)
3:15 PM	Break (10 minutes)
3:25 PM	Committee Discussion (65 minutes)
4:30 PM	Adjourn