

**FOOD AND DRUG ADMINISTRATION**

Center for Drug Evaluation and Research

***Antiviral Drugs Advisory Committee (AVDAC) Meeting***

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)

White Oak Conference Center, Silver Spring, Maryland

December 14 - 15, 2011

**AGENDA**

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*The committee will discuss pathways for the development of drugs intended to treat variola virus infection (smallpox) in the event of an outbreak, including the use of animal models of other orthopoxviruses (the group of viruses that includes smallpox) as potential evidence of efficacy.*

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**Day 1: Wednesday, December 14, 2011**

8:00 a.m. Call to Order and Introduction of Committee **Victoria A. Cargill, M.D., M.S.C.E.**  
Acting Chair, AVDAC

8:05 a.m. Conflict of Interest Statement **Paul T. Tran, R.Ph**  
Designated Federal Officer, AVDAC

**FDA PRESENTATION**

8:10 a.m. Welcome and Introduction:  
Approaches to Antiviral Drug  
Development for Treatment of Human  
Smallpox **Debra Birnkrant, M.D.**  
Director, Division of Antiviral Products (DAVP)  
Office of Antimicrobial Products (OAP)  
Office of New Drugs (OND), CDER, FDA  
Health and Human Services (HHS)

8:20 a.m. Historical Perspective on Smallpox **Barbara Styrt, M.D., M.P.H.**  
DAVP, OAP, OND, CDER, FDA, HHS

**SPEAKER PRESENTATION**

8:40 a.m. Smallpox Antivirals for Treatment:  
Public Health Perspective and  
Considerations **Ali S. Khan M.D., M.P.H.**  
Assistant Surgeon General (retired), USPHS  
Director, Office of Public Health Preparedness and  
Response (OPHPR), CDC, HHS

8:55 a.m. HHS Smallpox Antivirals Program **Gerald R. Kovacs, Ph.D.**  
Director  
Division of Chemical, Biological, Nuclear and  
Radiological (CBRN) Countermeasures  
Biomedical Advanced Research and Development  
Authority (BARDA)  
Assistant Secretary for Preparedness and Response  
(ASPR), HHS



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**AGENDA (cont.)**

**SPEAKER PRESENTATIONS (cont.)**

- 11:20 a.m. Non-Human Primate (NHP) Monkeypox Model Development **Mark D. Challberg, Ph.D.**  
Program Officer; Virology Branch  
Division of Microbiology and Infectious Diseases  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health (NIH), HHS
- 11:45 a.m. Animal Models of Smallpox NHP Challenge/Variola Virus **Inger K. Damon, M.D., Ph.D., FIDSA**  
CAPT, USPHS  
Branch Chief, Poxvirus and Rabies  
Division of High Consequence Pathogens and Pathology (DHCPP)  
National Center for Emerging and Zoonotic Infectious Diseases, CDC, HHS
- 12:10 p.m. Clarifying Questions from Committee for Drs. Buller, Moyer, Challberg, Damon, and Mr. Mucker
- 12:30 p.m. **LUNCH**
- 1:30 p.m. **INDUSTRY PRESENTATIONS** **Chimerix, Inc.**
- Developing CMX001 for the Treatment of Smallpox Under the "Animal Rule" **Randall Lanier, Ph.D.**  
Senior Director, Virology  
Chimerix, Inc.
- 2:00 p.m. Clarifying Questions from Committee to Chimerix, Inc.
- 2:15 p.m. **INDUSTRY PRESENTATIONS** **SIGA Technologies, Inc.**
- Towards Approval of a Smallpox Antiviral Drug: Challenges and Progress **Dennis Hruby, Ph.D.**  
Chief Scientific Officer  
SIGA Technologies, Inc.
- 2:45 p.m. Clarifying Questions from the Committee to SIGA Technologies, Inc.
- 3:00 p.m. **BREAK**

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**AGENDA (cont.)**

3:15 p.m. **FDA PRESENTATION**

Challenges and Study Design Issues in Smallpox Drug Development **Kirk Chan-Tack, M.D.**  
Medical Officer  
DAVP, OAP, OND, CDER, FDA, HHS

3:35 p.m. Clarifying Questions from the Committee to FDA

4:00 p.m. Open Public Hearing

5:00 p.m. **ADJOURNMENT**

**Day 2: Thursday, December 15, 2011**

8:00 a.m. Call to Order and Introduction of Committee **Victoria A. Cargill, M.D., M.S.C.E.**  
Acting Chair, AVDAC

8:05 a.m. Conflict of Interest Statement **Paul T. Tran, R.Ph.**  
Designated Federal Officer, AVDAC

8:15 a.m. Charge to the Committee **Debra Birnkrant, M.D.**  
Director  
DAVP, OAP, OND, CDER, FDA, HHS

8:45 a.m. Questions to the Committee/Committee Discussion

10:15 a.m. **BREAK**

10:30 a.m. Questions to the Committee/Committee Discussion

12:00 p.m. **ADJOURNMENT**