AGENDA

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.

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
AGENDA (cont.)

FDA PRESENTATION

9:10 a.m. The Animal Rule Rosemary Roberts, M.D.
Director
Office of Counterterrorism & Emergency Coordination, CDER, FDA, HHS

GUEST SPEAKER PRESENTATION

9:20 a.m. Orthopoxviruses: Properties, Phylogeny and Spread Professor Geoffrey L. Smith, FRS
Chairman
World Health Organization (WHO) Advisory Committee for Variola Virus Research
Wellcome Trust Principal Research Fellow
Head, Department of Pathology
University of Cambridge, United Kingdom

9:40 a.m. Clarifying Questions for Drs. Styrt, Khan, Kovacs, Roberts, and Smith

9:55 a.m. BREAK

GUEST SPEAKER PRESENTATIONS

10:10 a.m. Mousepox (Ectromelia Virus) Challenge Model R. Mark Buller, Ph.D.
Professor
Department of Molecular Microbiology and Immunology
Saint Louis University School of Medicine

10:35 a.m. The Rabbitpox Virus/Rabbit Model of Poxvirus Infection Elucidates Novel Aspects of Host-Virus Interaction Richard W. Moyer, Ph.D.
Professor
Department of Molecular Genetics and Microbiology
University of Florida College of Medicine

SPEAKER PRESENTATIONS

11:00 a.m. Susceptibility of Marmosets (Callithrix jacchus) to Monkeypox Virus Eric M. Mucker, M.S. (Ph.D. Candidate)
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
Virology Division, Viral Therapeutics Branch
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
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**