Food and Drug Administration
Center for Drug Evaluation and Research

Final Summary Minutes of the Antimicrobial Drugs Advisory Committee Meeting
May 1, 2018

Location: DoubleTree by Hilton Hotel Bethesda – Washington DC, Grand Ballroom 8120 Wisconsin Avenue Bethesda, Maryland

Topic: The committee discussed new drug application (NDA) 208627 for tecovirimat, sponsored by SIGA Technologies Inc., for the proposed indication of the treatment of smallpox disease caused by variola virus in adults and pediatric patients. This product was developed under the Animal Rule (21 CFR part 314, subpart I).

These summary minutes for the May 1, 2018 meeting of the Antimicrobial Drugs Advisory Committee of the Food and Drug Administration were approved on 6/19/18.

I certify that I attended the May 1, 2018 meeting of the Antimicrobial Drugs Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

/s/
Cindy Chee, PharmD
Acting Designated Federal Officer
Antimicrobial Drugs
Advisory Committee (AMDAC)

/s/
Lindsey R. Baden, MD
Acting Chairperson, AMDAC

Summary Minutes of the Antimicrobial Drugs Advisory Committee Meeting
May 1, 2018

The Antimicrobial Drugs Advisory Committee (AMDAC) of the Food and Drug Administration, Center for Drug Evaluation and Research met on May 1, 2018, at the DoubleTree by Hilton Hotel Bethesda – Washington DC, Grand Ballroom 8120 Wisconsin Avenue Bethesda, Maryland. Prior to the meeting, the members and temporary voting members were provided the briefing materials from the FDA and SIGA Technologies, Inc. The meeting was called to order by Lindsey R. Baden, MD (Acting Chairperson). The conflict of interest statement was read into the record by Cindy Chee, PharmD, (Acting Designated Federal Officer). There were approximately 180 people in attendance. There were three Open Public Hearing (OPH) speaker presentations.

A verbatim transcript will be available, in most instances, at approximately ten to twelve weeks following the meeting date.

Agenda: The committee discussed new drug application (NDA) 208627 for tecovirimat, sponsored by SIGA Technologies Inc., for the proposed indication of the treatment of smallpox disease caused by variola virus in adults and pediatric patients. This product was developed under the Animal Rule (21 CFR part 314, subpart I).

Attendance:
AMDAC Members Present (Voting): Nina M. Clark, MD; Demetre C. Daskalakis, MD, MPH; Dean A. Follmann, PhD; Michael D. Green, MD, MPH; Barbara M. Gripshover, MD; Jonathan R. Honegger, MD; Vincent Lo Re, MD, MSCE; Joanna M. Schaenman, MD, PhD; Peter Weina, PhD, MD, FACP, FIDSA

AMDAC Members Not Present (Voting): Amanda H. Corbett, PharmD, BCPS, FCCP; Ighovwerha Ofotokun, MD, MSc

AMDAC Member Present (Non-Voting): Nicholas A. Kartsonis, MD (Industry Representative)

Temporary Members (Voting): Lindsey R. Baden, MD (Acting Chairperson); Joel G. Breman, MD; Richard C. Condit, PhD; Debra Dunn (Patient Representative); Randy W. Hawkins, MD (Acting Consumer Representative); C. Rick Lyons, MD, PhD; Brett W. Petersen, MD, MPH; Jurgen Venitz, MD, PhD

FDA Participants (Non-Voting): Edward Cox, MD, MPH; Debra Birnkrant, MD; Adam Sherwat, MD; Kirk Chan-Tack, MD; Su-Young Choi, PharmD, PhD; Jules O'Rear, PhD; Patrick Harrington, PhD; Laine Peyton Myers, PhD

Acting Designated Federal Officer (Non-Voting): Cindy Chee, PharmD

Open Public Hearing Speakers: Kieren Knapp, DO, FACOFPd (Jacobus Medical Center); William Smith, MD, FACC (New Orleans Center for Clinical Research-Knoxville);

Grant McFadden, PhD (Center for Immunotherapy, Vaccines, and Virotherapy, Biodesign Institute)

The agenda was as follows:

Call to Order and Introduction of Committee	**Lindsey R. Baden, MD** Acting Chairperson, AMDAC
Conflict of Interest Statement	**Cindy Chee, PharmD,** Acting Designated Federal Officer, AMDAC
FDA Opening Remarks	**Debra Birnkrant, MD** Director, Division of Antiviral Products (DAVP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
APPLICANT PRESENTATIONS	**SIGA Technologies, Inc.**
Introduction	**Annie Frimm** Vice President, Regulatory, Clinical and Quality SIGA Technologies, Inc.
Unmet Need Efficacy Safety Benefit/Risk	**Dennis Hruby, PhD** Chief Scientific Officer SIGA Technologies, Inc.
FDA PRESENTATIONS	
Animal Efficacy and Human Safety	**Kirk Chan-Tack, MD** Medical Officer DAVP, OND, CDER, FDA
Selection of an Effective Dose in Humans	**Su Young Choi, PharmD, PhD** Clinical Pharmacology Reviewer Division of Clinical Pharmacology IV (DCP IV) Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS), CDER, FDA
Clarifying Questions	
LUNCH	
OPEN PUBLIC HEARING	
Questions to the Committee/Committee Discussion	
ADJOURNMENT	

Questions to the Committee:

1. **VOTE:** Based on the available data, does the risk-benefit profile of tecovirimat support its use for the treatment of human smallpox?

   Vote Result: Yes: 17 No: 0 Abstain: 0

   Committee Discussion: *The committee unanimously agreed that the risk-benefit profile of tecovirimat supports its use for the treatment of human smallpox. The members commented that the animal efficacy data was clear and the human safety study included diverse populations. The panel applauded the development of the animal rule and the applicant's fulfilment of these criteria. Committee members also noted that tecovirimat fills this unmet need since there is no current approved treatment for smallpox. Members commented on the lack of serious safety signals, but encouraged continued safety studies in more patients and subgroups to augment the currently limited data. Please see the transcript for details of the committee discussion.*

The meeting was adjourned at approximately 2:35 p.m.