Food and Drug Administration
Center for Drug Evaluation and Research

Final Summary Minutes of the Antimicrobial Drugs Advisory Committee Meeting
January 24, 2023

Location: Please note that due to the impact of the COVID-19 pandemic, all meeting participants joined this advisory committee meeting via an online teleconference platform.

Topic: The committee discussed new drug application 217417, for rezafungin lyophilized powder for injection, submitted by Cidara Therapeutics, Inc., for treatment of candidemia and invasive candidiasis in adults.

These summary minutes for the January 24, 2023 meeting of the Antimicrobial Drugs Advisory Committee of the Food and Drug Administration were approved on April 6, 2023.

I certify that I attended the January 24, 2023 meeting of the Antimicrobial Drugs Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

/s/	**/s/**
Joyce Frimpong, PharmD	Lindsey R. Baden, MD
Acting Designated Federal Officer, AMDAC	Chairperson, AMDAC

Summary Minutes of the Antimicrobial Drugs Advisory Committee Meeting
January 24, 2023

The Antimicrobial Drugs Advisory Committee (AMDAC) of the Food and Drug Administration, Center for Drug Evaluation and Research met on January 24, 2023. The meeting presentations were heard, viewed, captioned, and recorded through an online teleconferencing platform. Prior to the meeting, the members and temporary voting members were provided the briefing materials from the FDA and Cidara Therapeutics, Inc. The meeting was called to order by Lindsey Baden, MD (Chairperson). The conflict of interest statement was read into the record by Joyce Frimpong (Acting Designated Federal Officer). There were approximately 509 people in attendance. There were six 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 217417, for rezafungin lyophilized powder for injection, submitted by Cidara Therapeutics, Inc., for treatment of candidemia and invasive candidiasis in adults.

Attendance:
Antimicrobial Drugs Advisory Committee Members Present (Voting): Lindsey R. Baden, MD (Chairperson); Michael D. Green, MD, MPH; W. David Hardy, MD; Sally A. Hunsberger, PhD; Richard A. Murphy, MD, MPH; Nimish Patel, PharmD, PhD; Federico Perez, MD, MS; George K. Siberry, MD, MPH; Sankar Swaminathan, MD; Roblena E. Walker, PhD (Consumer Representative)

Antimicrobial Drugs Advisory Committee Members Not Present (Voting): Ighovwerha Ofotokun, MD, MSc

Antimicrobial Drugs Advisory Committee Member Present (Non-Voting): Richa S. Chandra, MD, MBA (Industry Representative)

Temporary Members (Voting): John E. Bennett, MD; Nina Clark, MD; Arthur Flatau (Patient Representative); Joan F. Hilton, ScD, MPH; Stacey R. Rose, MD, FACP, FIDSA

FDA Participants (Non-Voting): John Farley, MD, MPH; Peter Kim, MD, MS; Heidi Smith, MD, PhD; Shrimant Mishra, MD, MPH; Jalal Sheikh, PhD; Owen McMaster, PhD; Xianbin Li, PhD; Timothy Bensman, PharmD, PhD

Acting Designated Federal Officer (Non-Voting): Joyce Frimpong, PharmD

Open Public Hearing Speakers: Richard Tharp; Megan Morales, MD; George R. Thompson, MD, FIDSA, FECMM; Monica Sikka, MD; Sue Paxton; Kate Trigg

The agenda was as follows:

Call to Order	**Lindsey R. Baden, MD** Chairperson, AMDAC
Introduction of Committee and Conflict of Interest Statement	**Joyce Frimpong, PharmD** Acting Designated Federal Officer, AMDAC
FDA Opening Remarks	**Peter Kim, MD, MS** Director Division of Anti-Infectives (DAI) Office of Infectious Disease (OID) Office of New Drugs (OND), CDER, FDA
APPLICANT PRESENTATIONS	**Cidara Therapeutics, Inc.**
Introduction	**Carol Waldo, MLA, RAC** Senior Vice President Regulatory Affairs and Quality Assurance Cidara Therapeutics, Inc.
Unmet Need	**Jose Vazquez, MD, FACP, FIDSA** Chief of Infectious Disease and Professor of Medicine Medical College of Georgia at Augusta University
Pharmacology and Microbiology	**Shawn Flanagan, PhD** Vice President Clinical Pharmacology & Early Development Cidara Therapeutics, Inc.
Clinical Efficacy	**Anita Das, PhD** Consulting Statistician
Clinical Safety	**Taylor Sandison, MD, MPH** Chief Medical Officer Cidara Therapeutics, Inc.
Clinical Perspective	**Cornelius (Neil) J. Clancy, MD** Professor of Medicine Associate Chief of Infectious Diseases University of Pittsburgh
Clarifying Questions	
BREAK	

FDA PRESENTATIONS

Efficacy Assessment	**Xianbin Li, PhD** Statistical Reviewer Division of Biometrics IV Office of Biostatistics Office of Translational Sciences (OTS) CDER, FDA
Rezafungin Tremors	**Owen McMaster, PhD** Pharmacology-Toxicology Reviewer Division of Pharmacology/Toxicology-Infectious Diseases OID, OND, CDER, FDA
Clinical Safety Assessment	**Shrimant Mishra, MD, MPH** Medical Officer DAI, OID, OND, CDER, FDA
Assessment of Rezafungin's Antimicrobial Activity Relative to the FDA-Approved Echinocandins	**Jalal Sheikh, PhD** Clinical Microbiology Reviewer DAI, OID, OND, CDER, FDA
Clinical Pharmacology Assessment	**Timothy Bensman, PharmD, PhD** Clinical Pharmacology Reviewer Division of Infectious Disease Pharmacology Office of Clinical Pharmacology OTS, CDER, FDA
Summary Comments	**Heidi Smith, MD, PhD** Clinical Team Leader DAI, OID, OND, CDER, FDA
Clarifying Questions	

LUNCH

OPEN PUBLIC HEARING

Charge to the Committee	**Peter Kim, MD, MS**
Questions to the Committee/Committee Discussion	

BREAK

Questions to the Committee/Committee Discussion (cont.)

ADJOURNMENT

Questions to the Committee:

1. **VOTE:** Is the overall benefit-risk assessment favorable for the use of rezafungin for treatment of candidemia/invasive candidiasis in adults with limited or no alternative treatment options?

    - If yes, it would help us to understand the context of use for rezafungin, that is, the clinical scenario(s) in which rezafungin fulfills an unmet need.

    - If no, please comment on the additional information that would be needed for the benefit-risk assessment to be favorable for the use of rezafungin in this/these population(s).

    Vote Result: **Yes: 14** **No: 1** **Abstain: 0**

    Committee Discussion: *The majority of the committee members agreed that the overall benefit-risk assessment is favorable for the use of rezafungin for treatment of candidemia/invasive candidiasis in adults with limited or no alternative treatment options. The committee members who voted "Yes", noted that rezafungin is part of a well-known class of drugs, that weekly IV dosing is advantageous in the clinical setting (compared to daily IV dosing of other echinocandins), and that rezafungin has a favorable set of attributes for patients with no or limited alternatives. It was noted that concerns about safety, e.g., tremor and other adverse events of special interest, must be carefully considered when using this product. Given the limited safety dataset additional safety data is important to develop if this agent were to be used clinically. There was also discussion about the need to study this product in other patient populations, e.g., pediatric populations and pregnant women, in order to guide its potential use. Overall, those who voted "Yes" in support of an indication based on limited safety and efficacy data, recommended that Cidara continue to accrue additional data: (1) to further characterize the patient population in the currently proposed limited use indication, as well as, (2) to ultimately support a full indication for rezafungin for treatment of candidemia/invasive candidiasis. The committee member who voted "No" was concerned that the evidence was insufficient given the severity of the outcome, i.e., mortality. Please see the transcript for details of the committee discussion.*

The meeting was adjourned at approximately 3:55 p.m.