

**FOOD AND DRUG ADMINISTRATION (FDA)**

Center for Drug Evaluation and Research (CDER)

**Antimicrobial Drugs Advisory Committee (AMDAC) Meeting**

January 24, 2023

**AGENDA**

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*The committee will discuss new drug application (NDA) 217417, for rezafungin lyophilized powder for injection, submitted by Cidara Therapeutics, Inc. for treatment of candidemia and invasive candidiasis in adults.*

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9:00 a.m.	Call to Order	<b>Lindsey R. Baden, MD</b> Chairperson, AMDAC
9:10 a.m.	Introduction of Committee and Conflict of Interest Statement	<b>Joyce Frimpong, PharmD</b> Acting Designated Federal Officer, AMDAC
9:15 a.m.	FDA Opening Remarks	<b>Peter Kim, MD, MS</b> Director Division of Anti-Infectives (DAI) Office of Infectious Disease (OID) Office of New Drugs (OND), CDER, FDA
9:25 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>Cidara Therapeutics, Inc.</b>
	Introduction	<b>Carol Waldo, MLA, RAC</b> Senior Vice President Regulatory Affairs and Quality Assurance Cidara Therapeutics, Inc.
	Unmet Need	<b>Jose Vazquez, MD, FACP, FIDSA</b> Chief of Infectious Disease and Professor of Medicine Medical College of Georgia at Augusta University
	Pharmacology and Microbiology	<b>Shawn Flanagan, PhD</b> Vice President Clinical Pharmacology & Early Development Cidara Therapeutics, Inc.
	Clinical Efficacy	<b>Anita Das, PhD</b> Consulting Statistician

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**AGENDA (cont.)**

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**APPLICANT PRESENTATIONS (CONT.)**

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

10:40 a.m. Clarifying Questions

11:00 a.m. **BREAK**

11:10 a.m. **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

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**AGENDA (cont.)**

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**FDA PRESENTATIONS (CONT.)**

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

12:25 p.m. Clarifying Questions

12:45 p.m. **LUNCH**

1:30 p.m. **OPEN PUBLIC HEARING**

2:30 p.m. Charge to the Committee

**Peter Kim, MD, MS**

2:35 p.m. Questions to the Committee/Committee  
Discussion

3:50 p.m. **BREAK**

4:00 p.m. Questions to the Committee/Committee  
Discussion (cont.)

4:30 p.m. **ADJOURNMENT**