

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
January 24, 2023

AGENDA

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.

9:00 a.m.	Call to Order	Lindsey R. Baden, MD Chairperson, AMDAC
9:10 a.m.	Introduction of Committee and Conflict of Interest Statement	Joyce Frimpong, PharmD Acting Designated Federal Officer, AMDAC
9:15 a.m.	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
9:25 a.m.	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

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AGENDA (cont.)

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.)

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**