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

Antimicrobial Drugs Advisory Committee *(AMDAC) Meeting*
April 17, 2023

DRAFT AGENDA

The committee will discuss new drug application (NDA) 216974, for sulbactam-durlobactam for injection, submitted by Entasis Therapeutics, Inc. The Applicant's proposed indication is treatment of hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) caused by susceptible strains of Acinetobacter baumannii-calcoaceticus complex (ABC) 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	**Takyiah Stevenson, PharmD** Acting Designated Federal Officer, AMDAC
9:15 a.m.	FDA Opening Remarks	**Adam Sherwat, MD** Deputy Director Office of Infectious Diseases (OID) Office of New Drugs (OND), CDER, FDA
9:25 a.m.	**APPLICANT PRESENTATIONS**	**Entasis Therapeutics, Inc.**
	Introduction	**Shruta Rege, PhD** Senior Vice President, Head of Regulatory Affairs and Development Operations Entasis Therapeutics
	Unmet Need	**David Paterson, MBBS, PhD, FRACP** Professor Saw Swee Hock School of Public Health National University of Singapore
	Microbiology and Pharmacology	**Alita Miller, PhD** Senior Vice President, Head of Research Entasis Therapeutics
	Efficacy	**David Altarac, MD, MPA** Chief Medical Officer Entasis Therapeutics

---

APPLICANT PRESENTATIONS (CONT.)

Safety	**Drew Lewis, MD, MTM&H, FACP** Vice President, Clinical Development Entasis Therapeutics
Clinical Perspective	**J. Patrik Hornak, MD** Assistant Professor of Medicine Division of Infectious Diseases Assistant Clinical Director, AIDS Education & Training Center University of Texas Medical Branch at Galveston
Concluding Remarks	**Shruta Rege, PhD** Senior Vice President, Head of Regulatory Affairs and Development Operations Entasis Therapeutics

10:25 a.m. Clarifying Questions

10:45 a.m. **BREAK**

10:55 a.m. **FDA PRESENTATIONS**

Efficacy Assessment	**Karen Qi, PhD** Statistical Reviewer Division of Biometrics IV Office of Biostatistics, CDER, FDA
Clinical Safety Assessment	**Mayurika Ghosh, MD** Clinical Reviewer Division of Anti-Infectives (DAI) OID, OND, CDER, FDA
Clinical Microbiology Assessment	**Simone Shurland, PhD** Clinical Microbiology Reviewer DAI, OID, OND, CDER, FDA

	Clinical Pharmacology Assessment	**Xiaohui (Tracey) Wei, PhD** Clinical Pharmacology Reviewer Division of Infectious Disease Pharmacology Office of Clinical Pharmacology, CDER, FDA
11:55 a.m.	Clarifying Questions	
12:15 p.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Charge to the Committee	**Peter Kim, MD, MS** Director DAI, OID, OND, CDER, FDA
2:05 p.m.	Questions to the Committee/Committee Discussion	
3:15 p.m.	**BREAK**	
3:25 p.m.	Questions to the Committee/Committee Discussion (cont.)	
4:30 p.m.	**ADJOURNMENT**	