

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

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
September 9, 2024

AGENDA

The Committee will discuss new drug application (NDA) 213972, for oral sulopenem etzadroxil/probenecid tablets consisting of 500 milligrams (mg) sulopenem etzadroxil and 500 mg probenecid, submitted by Iterum Therapeutics US Ltd., for the proposed indication of treatment of uncomplicated urinary tract infections (uUTIs) caused by designated susceptible bacteria in adult women 18 years of age and older.

9:00 a.m.	Call to Order and Introduction of Committee	Lindsey R. Baden, MD Acting Chairperson, AMDAC
9:05 a.m.	Conflict of Interest Statement	LaToya Bonner, PharmD Acting Designated Federal Officer, AMDAC
9:10 a.m.	FDA Opening Remarks	Peter Kim, MD, MS Director Division of Anti-Infectives (DAI) Office of Infectious Diseases (OID) Office of New Drugs (OND) CDER, FDA
9:25 a.m.	APPLICANT PRESENTATIONS	Iterum Therapeutics
	Introduction	Michael Dunne, MD, FIDSA Board Member, Consultant Iterum Therapeutics
	Unmet Need	Marjorie Golden, MD, FIDSA Site Chief, Infectious Disease St. Raphael Campus Yale New Haven Hospital
	Efficacy, Microbiology and Pharmacology	Michael Dunne, MD, FIDSA
	Safety	Steven Aronin, MD, FIDSA Senior VP and Head of Clinical Development Iterum Therapeutics
	Benefit-Risk	Michael Dunne, MD, FIDSA
10:25 a.m.	Clarifying Questions	

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AGENDA (cont.)

10:50 a.m.	BREAK	
11:05 a.m.	FDA PRESENTATIONS	
	Efficacy and Safety Assessments	Angela Kopack, MD Clinical Reviewer DAI, OID, OND, CDER, FDA
		Xianbin Li, PhD Statistical Reviewer Division of Biometrics IV Office of Biostatistics Office of Translational Sciences (OTS) CDER, FDA
	Microbiology Assessment	Jalal Sheikh, PhD Clinical Microbiology Reviewer DAI, OID, OND, CDER, FDA
	Clinical Pharmacology Assessment	Henrietta Abodakpi, PharmD, PhD Clinical Pharmacology Reviewer Division of Infectious Disease Pharmacology Office of Clinical Pharmacology OTS, CDER, FDA
12:05 p.m.	Clarifying Questions	
12:35 p.m.	LUNCH	
1:35 p.m.	Clarifying Questions	
1:45 p.m.	OPEN PUBLIC HEARING	
2:45 p.m.	Charge to the Committee	Peter Kim, MD, MS
2:50 p.m.	Questions to the Committee/Committee Discussion	
4:00 p.m.	ADJOURNMENT	