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

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

**DRAFT AGENDA**

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*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.*

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

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**DRAFT AGENDA (cont.)**

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| 10:50 a.m. | **BREAK** | |
| 11:05 a.m. | **FDA PRESENTATIONS** | |
| | Efficacy and Safety Assessments | **Angela Kopack, MD**<br>Clinical Reviewer<br>DAI, OID, OND, CDER, FDA |
| | | **Xianbin Li, PhD**<br>Statistical Reviewer<br>Division of Biometrics IV<br>Office of Biostatistics<br>Office of Translational Sciences (OTS)<br>CDER, FDA |
| | Microbiology Assessment | **Jalal Sheikh, PhD**<br>Clinical Microbiology Reviewer<br>DAI, OID, OND, CDER, FDA |
| | Clinical Pharmacology Assessment | **Henrietta Abodakpi, PharmD, PhD**<br>Clinical Pharmacology Reviewer<br>Division of Infectious Disease Pharmacology<br>Office of Clinical Pharmacology<br>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** | |