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

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
October 16, 2019

AGENDA

The committee will discuss new drug application (NDA) 209445, cefiderocol lyophilized powder for intravenous administration, submitted by Shionogi Inc., proposed for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis due to Gram-negative bacteria in patients with limited or no alternative treatment options.

8:00 a.m.	Call to Order and Introduction of Committee	**Lindsey R. Baden, MD** Chairperson, AMDAC
8:10 a.m.	Conflict of Interest Statement	**Lauren Tesh Hotaki, PharmD, BCPS, BCIDP** Designated Federal Officer, AMDAC
8:15 a.m.	FDA Introductory Comments	**Edward Weinstein, MD, PhD** Clinical Team Leader Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:25 a.m.	**APPLICANT PRESENTATIONS**	**Shionogi Inc.**
	Introduction to the Cefiderocol Program	**Tsutae "Den" Nagata, MD, PhD, FFPM** Chief Medical Officer Shionogi & Co., Ltd.
	Medical Need	**George H. Karam, MD, MACP** Paula Garvey Manship Chair of Medicine Louisiana State University School of Medicine
	Microbiology and Clinical Pharmacology of Cefiderocol	**Roger Echols, MD, FIDSA** Principal Member Infectious Disease Drug Development Consulting, LLC Medical Consultant to Shionogi & Co., Ltd.
	cUTI Efficacy and Safety, Other Cefiderocol Studies	**Simon Portsmouth, MD, FRCP** Executive Medical Director Clinical Development Shionogi Inc.

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AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Benefit/Risk of Cefiderocol for cUTI	**David Paterson, MBBS, PhD, FRACP, FRCPA** Infectious Disease Physician Royal Brisbane and Women's Hospital Professor of Medicine University of Queensland, Australia
9:55 a.m.	Clarifying Questions	
10:20 a.m.	**BREAK**	
10:30 a.m.	**FDA PRESENTATIONS**	
	Clinical Microbiology Considerations	**Kalavati Suvarna, PhD** Clinical Microbiology Reviewer DAIP, OAP, OND, CDER, FDA
	Efficacy Assessment of Cefiderocol for the Treatment of cUTI	**Daniel Rubin, PhD** Biometrics Reviewer Division of Biometrics IV, Office of Biostatistics Office of Translational Sciences, CDER, FDA
	Clinical Assessment and Safety of Cefiderocol for the Treatment of cUTI	**Shabnam Naseer, DO, MS** Clinical Reviewer DAIP, OAP, OND, CDER, FDA
	Statistical Assessment of the Study in Carbapenem-Resistant Organisms (CREDIBLE-CR)	**Daniel Rubin, PhD**
	Clinical Assessment of the CREDIBLE-CR Study	**Shabnam Naseer, DO, MS**
	Summary Comments	**Edward Weinstein, MD, PhD**
12:00 p.m.	Clarifying Questions	
12:30 p.m.	**LUNCH**	
1:30 p.m.	**OPEN PUBLIC HEARING**	

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AGENDA (cont.)

2:30 p.m.	Questions to the Committee/Committee Discussion
3:20 p.m.	**BREAK**
3:30 p.m.	Questions to the Committee/Committee Discussion (cont.)
4:30 p.m.	**ADJOURNMENT**