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

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
DoubleTree by Hilton Hotel Bethesda – Washington DC, Grand Ballroom
8120 Wisconsin Avenue Bethesda, Maryland
May 2, 2018

AGENDA

The committee will discuss new drug application (NDA) 210303 for plazomicin, sponsored by Achaogen Inc., for the proposed indications for the treatment of complicated urinary tract infections and blood stream infections in adults.

8:30 a.m.	Call to Order and Introduction of Committee	**Lindsey R. Baden, MD** Acting Chairperson, AMDAC
8:40 a.m.	Conflict of Interest Statement	**Cindy Chee, PharmD** Acting Designated Federal Officer, AMDAC
8:45 a.m.	FDA Opening Remarks	**Sumathi Nambiar, MD, MPH** Director Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:55 a.m.	**APPLICANT PRESENTATIONS**	**Achaogen Inc.**
	Introduction	**Anne Keane, PA-C, JD** Head of Regulatory Affairs and Clinical Quality Assurance Achaogen, Inc.
	Unmet Need	**James McKinnell, MD** Assistant Professor of Medicine, Infectious Disease Specialist David Geffen School of Medicine University of California, Los Angeles
	Microbiology and Clinical Pharmacology	**Kevin Krause** Head of Microbiology Achaogen, Inc.
	Efficacy	**Ian Friedland, MD** Clinical Consultant Friedland Strategic Consulting
	Safety	**Lynn Connolly, MD, PhD** Clinical Consultant Achaogen, Inc.
	Concluding Remarks	**Lynn Connolly, MD, PhD**

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AGENDA (cont.)

10:25 a.m.	Clarifying Questions to the Presenters	
10:40 a.m.	**BREAK**	
10:50 a.m.	**FDA PRESENTATIONS**	
	Presentation of Clinical Efficacy	**Hengrui Sun, DrPH** Statistical Reviewer Division of Biometrics IV (DBIV) Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
		Daniel Rubin, PhD Statistical Reviewer DBIV, OB, OTS, CDER, FDA
		Shrimant Mishra, MD, MPH Medical Officer DAIP, OAP, OND, CDER, FDA
	Presentation of Clinical Safety	**Shrimant Mishra, MD, MPH**
	Clinical Pharmacology	**Luning (Ada) Zhuang, PhD** Pharmacometrics Reviewer Division of Pharmacometrics Office of Clinical Pharmacology (OCP) OTS, CDER, FDA
		Kunyi Wu, PharmD Clinical Pharmacology Reviewer Division of Clinical Pharmacology 4 OCP, OTS, CDER, FDA
12:20 p.m.	Clarifying Questions	
12:35 p.m.	**LUNCH**	
1:30 p.m.	**OPEN PUBLIC HEARING**	
2:30 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	**BREAK**	
3:10 p.m.	Questions to the Committee/Committee Discussion (cont.)	
4:00 p.m.	**ADJOURNMENT**	