

**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, Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
June 6, 2019

DRAFT AGENDA

The committee will discuss new drug application (NDA) 212862, pretomanid tablets for oral administration, submitted by The Global Alliance for TB Drug Development, Inc., proposed as part of a combination regimen with bedaquiline and linezolid in adults for the treatment of pulmonary extensively drug resistant and treatment-intolerant or non-responsive multidrug-resistant tuberculosis (TB).

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	LaToya Bonner, PharmD Acting Designated Federal Officer, AMDAC
8:15 a.m.	FDA Opening Remarks	Yuliya Yasinskaya, MD 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	The Global Alliance for TB Drug Development, Inc.
	Introduction and Overview of Pretomanid New Drug Application	Mel Spigelman, MD President and Chief Executive Officer TB Alliance
	Unmet Need for Treatment of Highly-Resistant Tuberculosis	Neil Schluger, MD Chief of the Division of Pulmonary, Allergy and Critical Care Medicine Columbia University Department of Medicine
	Nix-TB Results - Efficacy and Safety	Daniel Everitt, MD Vice President and Senior Medical Officer TB Alliance
	Clinical Perspective on Treatment for Highly-Resistant Tuberculosis	Francesca Conradie, MD Deputy Director, Clinical HIV Research Unit University of the Witwatersrand Department of Medicine
9:40 a.m.	Clarifying Questions	

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DRAFT AGENDA (cont.)

10:05 a.m. **BREAK**

10:20 a.m. **FDA PRESENTATIONS**

Presentation Clinical Efficacy

Daniel Rubin, PhD

Statistical Reviewer

Division of Biometrics IV, Office of Biostatistics
Office of Translational Sciences, CDER, FDA

Presentation Clinical Safety

Elizabeth O'Shaughnessy, MD

Clinical Reviewer

DAIP, OAP, OND, CDER, FDA

11:35 a.m. Clarifying Questions

12:00 p.m. **LUNCH**

1:00 p.m. **OPEN PUBLIC HEARING**

2:00 p.m. Questions to the
Committee/Committee Discussion

3:00 p.m. **BREAK**

3:10 p.m. Questions to the Committee/Committee
Discussion

4:00 p.m. **ADJOURNMENT**