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

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 Introductory Comments	**Yuliya Yasinskaya, MD** Medical 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

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AGENDA (cont.)

9:40 a.m.	Clarifying Questions	
10:05 a.m.	**BREAK**	
10:20 a.m.	**FDA PRESENTATIONS**	
	Presentation of Clinical Efficacy	**Daniel Rubin, PhD** Statistical Reviewer Division of Biometrics IV, Office of Biostatistics Office of Translational Sciences, CDER, FDA
	Presentation of 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**	