

**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, the Great Room (Rm. 1503)

10903 New Hampshire Avenue, Silver Spring, Maryland

June 6, 2019

**QUESTION**

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1. **VOTE:** Has the Applicant provided substantial evidence of the effectiveness and sufficient evidence of the safety of pretomanid as part of a combination regimen with bedaquiline and linezolid, in adults for the treatment of pulmonary extensively drug resistant (XDR) or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis?
  - a. If yes, please provide any recommendations concerning labeling.
  - b. If no, what additional studies/analyses are needed?