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
August 7, 2018

DRAFT QUESTIONS

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1. **VOTE:** Is the surrogate endpoint of sputum culture conversion based on three consecutive negative sputum cultures reasonably likely to predict clinical benefit?

2. **VOTE:** Has the applicant provided substantial evidence of the effectiveness and sufficient evidence of the safety of amikacin liposomal inhalation solution (ALIS) for the treatment of nontuberculous mycobacterial lung disease caused by *Mycobacterium avium* complex as part of a combination antibacterial drug regimen for adult patients?

    a. If yes, please provide any recommendations regarding labeling and please comment on the design of the trial that will need to be conducted to confirm clinical benefit.

    b. If no, please provide recommendations regarding additional studies/analyses that are needed.

3. **VOTE:** Has the applicant provided substantial evidence of the effectiveness and sufficient evidence of the safety of ALIS for the treatment of nontuberculous mycobacterial lung disease caused by *Mycobacterium avium* complex as part of a combination antibacterial drug regimen for adult patients with limited or no treatment options?

    a. If yes, please provide any recommendations regarding labeling and please comment on the design of the trial that will need to be conducted to confirm clinical benefit.

    b. If no, please provide recommendations regarding additional studies/analyses that are needed.