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
November 16, 2017

QUESTIONS

1. **VOTE:** Has the applicant provided substantial evidence of the safety and efficacy for the ciprofloxacin dry powder inhaler (DPI) 14-day regimen in delaying the time to first exacerbation after starting treatment?

    a. If yes, please provide any recommendations concerning labeling.

    b. If no, what additional studies/analyses are needed? Please discuss appropriate endpoints, drug regimens and trial duration.

2. **VOTE:** Has the applicant provided substantial evidence of the safety and efficacy for the ciprofloxacin DPI 28-day regimen in delaying the time to first exacerbation after starting treatment?

    a. If yes, please provide any recommendations concerning labeling.

    b. If no, what additional studies/analyses are needed? Please discuss appropriate endpoints, drug regimens and trial duration.