

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 4, 2016

QUESTIONS

1. **VOTE:** Has the Applicant provided substantial evidence of the efficacy of solithromycin for the treatment of community acquired bacterial pneumonia (CABP)?
 - a. If yes, please provide recommendations for labeling.
 - b. If no, please discuss additional studies/analyses that are needed.
2. **VOTE:** Has the risk of hepatotoxicity with solithromycin been adequately characterized?
 - a. If yes, please provide any recommendations for labeling.
 - b. If no, please discuss additional studies that are needed to further characterize the risk.
3. **VOTE:** Do the efficacy results of solithromycin for the treatment of CABP, outweigh the risks including hepatotoxicity?
 - a. If yes, please provide any recommendations for labeling.
 - b. If no, please discuss additional studies/analyses that are needed.