

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 8, 2018

QUESTIONS

1. **VOTE:** Has the applicant provided substantial evidence of the safety and effectiveness of omadacycline for the treatment of acute bacterial skin and skin structure infections?
 - a. If yes, please provide any recommendations concerning labeling.
 - b. If no, what additional studies/analyses are needed?

2. **VOTE:** Has the applicant provided substantial evidence of the safety and effectiveness of omadacycline for the treatment of community acquired bacterial pneumonia?
 - a. If yes, please provide any recommendations concerning labeling.
 - b. If no, what additional studies/analyses are needed?