

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
April 17, 2023

QUESTIONS

1. **VOTE:** Is the overall benefit-risk assessment favorable for the use of sulbactam-durlobactam for the treatment of patients with hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) caused by susceptible strains of *Acinetobacter baumannii-calcoaceticus* complex (ABC) organisms?
 - a. If yes, please provide your rationale.
 - b. If no, please provide your rationale and describe what additional studies/trials are needed.