Phase 3, Randomized, Double-blind Noninferiority Study of Ceftazidime-Avibactam vs Meropenem in the Treatment of Patients With Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Analyses of the REPROVE Study per FDA Endpoints

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INTRODUCTION

Ceftazidime-avibactam (CAZ-AVI) is a β-lactamase inhibitor/β-lactam antibiotic combination consisting of ceftazidime, an extended-spectrum cephalosporin, and avibactam, a β-lactamase inhibitor structurally distinct from other β-lactamase inhibitors. CAZ-AVI was well-tolerated across diverse patient populations with varied baseline characteristics in a Phase 3, randomized, double-blind, double-dummy, parallel-group study (REPROVE; NCT02736199) of patients with resistant bacteria:HABP/VABP or Pseudomonas aeruginosa (P. aeruginosa) VAP,† treated with CAZ-AVI. CAZ-AVI was noninferior to meropenem with respect to clinical cure at the test-of-cure (TOC) visit (21–25 days from randomization), all-cause mortality at 28 days (ITT population), and safety/ tolerability.