Safety Profile of Sulbactam-Durlobactam (SUL-DUR) versus Colistin Therapy in Patients with Acinetobacter baumannii-calcoaceticus Complex (ABC) Infections from The Phase III, Global, Randomized, Active-Controlled Trial (ATTACK)  
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Background: SUL-DUR is a beta-lactam-beta-lactamase inhibitor combination in development for the treatment of ABC, a cause of severe infections associated with substantial mortality. ATTACK was conducted to evaluate the efficacy and safety of SUL-DUR versus colistin, both in combination with imipenem/cilastatin, for patients with serious ABC infections, including multidrug-resistant strains.

Methods: The ATTACK trial was a 2-part trial. Part A was a randomized, open-label, non-inferiority study in ABC hospital-acquired pneumonia, ventilator-associated bacterial pneumonia, ventilated pneumonia and bacteremia in the global, phase 3 ATTACK study. Part B enrolled patients with serious ABC infections, including multidrug-resistant strains.

Overview of AEs

Any adverse event (AE): 80 (87.9) 81 (94.2) 25 (89.3)

Nephrotoxicity (RIFLE classification): Moderate 4 (4.4) 8 (9.3) 1 (3.6)

Primary safety objective achieved: the primary safety objective of reduced incidence of nephrotoxicity was achieved, and was generally well-tolerated. No new safety signals were identified.

Safety Profile

All patients were full-time employees of Entasis Therapeutics or were employees of Entasis at the time of this study.

References


The Favorable Safety Profile of SUL-DUR

Category, n (%) System organ class

Primary Safety Objective Achieved Lower Nephrotoxicity than Colistin

SUL-DUR vs colistin, safety population, as assessed with the RIFLE classification

Primary objective achieved: The primary safety objective of significantly reduced incidence of nephrotoxicity compared with colistin, achieved the primary safety objective of significantly reduced incidence of nephrotoxicity compared with colistin, was generally well tolerated and no new safety signals were identified.

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