Objective Measures of Clinical Efficacy in a Phase 2b Exploratory Study of Delafloxacin Compared to Vancomycin and Linezolid in Adults with Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

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Abstract

Objectives: To evaluate the performance of Delafloxacin (DLX), comparator Vancomycin (VAN) and Linezolid (LNZ) in a Phase 2b exploratory study of DLX compared to VAN and LNZ in treating ABSSSI.

Methods: In this randomized, open-label, stratified, multicenter, double-blind study, 256 patients were treated with DLX 300 mg every 12 hours for 5 days, followed by 75 mg every 12 hours for 9 days, or LNZ 600 mg every 12 hours for 5 days, followed by 300 mg every 12 hours for 9 days, or VAN 15 mg/kg/dose over 30 minutes every 12 hours for 5 days, followed by 15 mg/kg/dose over 30 minutes every 24 hours for 9 days. Lead criteria for enrollment included patients aged ≥18 years with ABSSSI due to susceptible or susceptible-to-minor resistance S. aureus or Gram-negative bacteria, with cellulitis/erysipelas, major cutaneous abscess or burn wound infections. The primary end point was clinical success at the end of treatment. The secondary end point was the proportion of patients achieving ≥38°C fever resolution by 48 hours.

Results: At baseline, patient demographics were well-balanced across groups. At both 48 and 72 hours, DLX demonstrated superior clinical response compared with LNZ and VAN. DLX also achieved ≥38°C fever resolution at 72 hours in 80.5% of patients, whereas LNZ and VAN achieved 74.1% and 77.9% resolution, respectively.

Conclusions: DLX was statistically superior to LNZ and VAN with respect to clinical efficacy and fever reduction in ABSSSI patients. DLX was generally well tolerated with no unexpected safety signals observed.

References