

Efficacy and Safety of CEM-102 in a Phase 2, Randomized, Double-Blind Study in Patients with Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

Abstract L1-1762

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Background:

CEM-102, sodium fusidate, is a fusidane antibiotic under development for treatment of gram-positive ABSSSI. Sodium fusidate has been used for many years outside the US to treat infections caused by *Staphylococcus aureus*, including methicillin-resistant *Staphylococcus aureus* (MRSA).

Methods:

This was a Phase 2, randomized, double-blind, multi-center study to evaluate the efficacy and safety of an oral CEM-102 loading dose regimen (CEM-102 LD), 1500 mg BID Day 1 followed by 600 mg BID, compared to oral linezolid (LZ) 600 mg BID, both administered for 10 to 14 days. Patients must not have received prior antibacterial therapy or must have failed other therapy (≥ 48 hours) to be eligible. Primary efficacy endpoints were clinical success in the intent to treat (ITT) and clinically evaluable (CE) populations at the test of cure (TOC) visit.

Results:

155 patients with cellulitis (n=100 [65%]) or wound infections (n=55 [35%]) were randomized to CEM-102 LD (n=78 [24 failed prior therapy]) or LZ (n=77 [22 failed prior therapy]). Clinical success rates at TOC were 85.9% CEM-102 LD and 94.8% LZ in the ITT population and 92.3% CEM-102 LD and 98.5% LZ in the CE population. *S. aureus* was isolated in 72% of patients, of which 70% were MRSA. MRSA eradication in the microbiologically evaluable (ME) population was CEM-102 LD 30/31 and LZ 37/37; methicillin-susceptible *S. aureus* (MSSA) eradication CEM-102 LD 16/17, LZ 10/11. Both drugs were well tolerated and AEs were comparable (62% CEM-102 LD and 64% LZ); gastrointestinal (GI) AEs (40% CEM-102 LD and 42% LZ).

Conclusions:

Clinical success rates for CEM-102 LD and LZ in treatment of ABSSSI were comparable in the ITT and CE populations at TOC; ME eradication rates for MRSA and MSSA were also comparable. Safety analyses demonstrated a favorable safety and tolerability profile for CEM-102 LD.