RESULTS

POSTER # 1856

PURPOSE: To evaluate the comparative treatment outcomes of a single oral antibiotic, Delafloxacin (DLX), compared to intravenous vancomycin/aztreonam (VAN/AZ) in treatment of patients with acute bacterial skin and skin structure infections (ABSSSI) in Gram-positive and Gram-negative pathogens.

METHODS:

Two multicenter, double-blind, double-dummy trials of ABSSSI, with a number of unique properties that may make it useful in clinical practice.

- **Study Sites:** North America: 116 (58.9%), Europe: 601 (71.1%)
- **Inclusion Criteria:** Patients had wounds, burns, major abscesses, or cellulitis of ≥75 cm² and no prior treatment. Patients with any serious adverse event leading to premature study drug discontinuation, or who died during the treatment period, were included in the safety analysis.

**Endpoints and Analyses:**

- **Primary endpoint:** Objective response at 48-72h (ME) and investigator-assessed response at Follow-up (FU) and Late Follow-up (LFU) visits.

**Baseline Characteristics:**

- **Age, years:** Mean (SD) 50 (15.4) 49 (17.3)
- **Sex, % (n):** Male 103 (51.4) 106 (20.2)
- **Race, % (n):** Black or African American 5 (2.5) 52 (6.2)

**Distribution of Baseline Infections:**

- **Objective response at 48-72h (ME):** 77/90 (85.6) 83/94 (88.3)
- **Investigator-assessed response at FU and LFU visits:** 124/124 (100%) 126/126 (100%)
- **Any serious adverse event:** 14/26 0.12/2 0.03 - >8

**Conclusions:** DLX patients had comparable per-pathogen microbiological response and clinical outcomes compared to VAN/AZ. DLX monotherapy was effective in clinical and microbiological response in ABSSSI patients with Gram-positive or Gram-negative pathogens. DLX is an oral, broad-spectrum fluoroquinolone antibiotic that may be useful in the treatment of ABSSSI patients with Gram-negative infections due to its pharmacology, pharmacokinetics, pharmacodynamics, and clinical efficacy.

**Acknowledgments:** Supported by Melinta Therapeutics, Lincolnshire, IL, USA.

**References:**


2. Department of Health and Human Services (DHHS), Food and Drug Administration, Center for Drug Evaluation and Research. 2013. Delafloxacin (DLX), a novel fluoroquinolone antibiotic in development for treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults with a number of unique properties that may make it useful in clinical practice. Future Microbiol. 8:1145-1154.


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