Lefamulin Demonstrates Favorable Safety and Tolerability in Adults with Community-Acquired Bacterial Pneumonia (CABP) in the Phase 3 Lefamulin Evaluation Against Pneumonia (LEAP 1) Study

Thomas File, Lisa Goldberg, Anita Das, Carolyn Sweeney, Steven P. Gelone, John Sawiski, Elyse Seltzer, George H. Talbot, Leanne B. Gasink

Sunna Health System, Akron, OH, USA; Nabriva Therapeutics US Inc., King of Prussia, PA, USA; Daq Consulting, Guerneville, CA, USA; Vivion Pharma, New York, NY, USA. Talbot Advisers LLC, Anna Maria, FL, USA

ABSTRACT

The novel pleuromutilin antibiotic Lefamulinfingerprints with antibacterial activity against Staphylococcus aureus, Streptococcus pneumoniae and other Gram-positive pathogens. Lefamulin, studied as a novel pleuromutilin antibiotic for IV or oral use in development for treating CABP. Lefamulin inhibit protein synthesis by binding selectively and specifically to the 50S ribosomal subunit, thereby blocking bacterial protein synthesis.

METHODS

Study Design
- A multicenter, double-blind, placebo-controlled, randomized trial.
- Adult patients with CABP (≥18 years of age) were included.
- Patients were randomized to receive lefamulin 150 mg IV every 12 hours (q12h) or moxifloxacin 400 mg IV every 24 hours (q24h) for 7 days of therapy.
- The study was conducted at 36 sites in the United States.

Assessments
- Clinical response (IACR) was assessed at the end of therapy (EOT) and at 14 days post EOT.
- Adverse event (AE) and laboratory data were collected during the study.

RESULTS

Patients
- 551 patients were enrolled in the study, 275 in the lefamulin arm and 276 in the moxifloxacin arm.
- The median age of patients was 67 years, and 54% were male.
- Most patients were Caucasian (74% in the lefamulin arm and 73% in the moxifloxacin arm).

Clinical Response
- The incidence of gastrointestinal system AEs was similar between the groups (9% in the lefamulin arm and 8% in the moxifloxacin arm).
- No patients met the laboratory criteria for Hy's law, an indicator of drug-induced liver injury.

Safety
- TEAE=treatment-emergent adverse event.
- TEAEs leading to study discontinuation occurred in 1.8% (5/273) of patients taking lefamulin.
- Fewer patients taking lefamulin discontinued the study drug or study due to a TEAE, compared with those taking moxifloxacin ± linezolid (0.7% [2/273] vs 7.7% [21/273]; p<0.001).

REFERENCES


CONCLUSIONS

Lefamulin demonstrated high response rates for ECR and IACR in CABP, similar safety and tolerability to those of moxifloxacin ± linezolid, and a favorable tolerability and safety profile compared to moxifloxacin ± linezolid.

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