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

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Abstract

Lefamulin, a novel pleuromutilin antibiotic, was studied in the LEAP 1 study to evaluate its safety and tolerability compared with moxifloxacin ± linezolid in adult patients with community-acquired pneumonia (CABP). Lefamulin showed favorable comparisons in terms of safety and tolerability with standard-of-care comparators.

Introduction

CABP is a common bacterial infection, with community-acquired pneumonia (CAP) being the most prominent form. Lefamulin is a novel pleuromutilin antibiotic that has demonstrated efficacy in the treatment of CABP. This study aimed to evaluate the safety and tolerability of lefamulin in comparison with moxifloxacin ± linezolid.

Methods

Study Design

Patients were randomly assigned to receive lefamulin 150 mg IV every 12 hours or moxifloxacin ± linezolid. The study was a double-blind, randomized, placebo-controlled trial.

Enrollment

Of the 551 patients enrolled, 276 were randomly assigned to receive lefamulin and 275 to receive moxifloxacin ± linezolid. 273 patients in each group received at least one dose of the study drug.

Results

Results of the study showed that safety and tolerability were favorable for lefamulin, with fewer TEAEs and discontinuations compared to moxifloxacin ± linezolid. The most common TEAEs reported were gastrointestinal disorders, with nausea being the most frequent.

Conclusions

Lefamulin shows promise as a safe and well-tolerated targeted antibiotic option for the treatment of CABP. Further studies are needed to confirm these findings.

Acknowledgments & Disclosures

All authors contributed to the study design, data interpretation, and manuscript preparation. The authors report no conflicts of interest.

References


The full abstract can be found in the provided reference.