Oral Lefamulin Demonstrates Favorable Safety and Tolerability in Adults With Community-Acquired Bacterial Pneumonia (CABP) in the Phase 3 Lefamulin Evaluation Against Pneumonia (LEAP 2) Study

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Background

The most frequent TEAEs in 2.2% and 2.4% of patients receiving LEF and MOX, respectively, were diarrhea and nausea. Hypersensitivity reactions, including anaphylaxis, occurred in 0.3% of patients receiving LEF and in 0.8% of patients receiving MOX, respectively. Any postbaseline increase in ALT or AST was reported in 6.6% and 5.9% of patients receiving LEF and MOX, respectively. No patients discontinued because of ALT or AST increase. Any postbaseline increase in ALT >3xULN; or AST >2xULN was reported in 4.2% and 4.7% of patients receiving LEF and MOX, respectively. No patients discontinued because of ALT >3xULN. Thirty patients discontinued because of TEAEs: 27 patients receiving LEF and 3 patients receiving MOX. No patients discontinued because of diarrhea.

Methods

LEF (500 mg q12h) was generally well tolerated with low discontinuation rates due to TEAEs. Most frequent LEF TEAEs were GI, predominantly diarrhea, which were mostly mild and rarely led to discontinuation. This contrasts with LEAP 1 in which diarrhea was more common with MOX. QTC prolongation was shorter with LEF than with MOX with no associated cardiac arrhythmias. These results add to the developing favourable safety/tolerability profile of IV and oral LEF.

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