**Methods**

- **Study Design**
  - In LEAP 1, patients were randomized to receive LEF 700 mg every 12 hours (Q12h) or LEF 1000 mg every 24 hours (Q24h) for 7 days (Figure 1).
  - This investigation assessed the efficacy and tolerability of LEF vs moxifloxacin (MOX) in adults with community-acquired bacterial pneumonia (CABP) or acute bacterial exacerbation of chronic obstructive pulmonary disease (AECOPD). The safety population included patients with CABP or AECOPD who received at least one dose of treatment. The microbiological intent-to-treat (microITT) population included patients with CABP or AECOPD randomized to receive 7 days* of LEF (Q12h) or LEF (Q24h) who received at least one dose of treatment and had a baseline (BL) pathogen identified.

- **Patients and Assessments**
  - Among patients with atypical pathogens at baseline, TEAE system organ classes that occurred in >1 atypical pathogen (n=345) at ≥15% of patients included gastrointestinal disorders and infections and infestations (18.2%), respiratory system disorders (12.6%), and psychiatric disorders (2.6%).
  - In the microbiological intent-to-treat (microITT) population, the majority of patients had CABP with a lower lobe infiltrate (77.5%).
  - A patient could have had >1 pathogen identified. Multiple isolates of the same species from the same patient were counted separately.

- **RESULTS**
  - Among patients with atypical pathogens at baseline, TEAE system organ classes that occurred in >1 atypical pathogen (n=345) at ≥15% of patients included gastrointestinal disorders and infections and infestations (18.2%), respiratory system disorders (12.6%), and psychiatric disorders (2.6%).
  - In the microbiological intent-to-treat (microITT) population, the majority of patients had CABP with a lower lobe infiltrate (77.5%).
  - A patient could have had >1 pathogen identified. Multiple isolates of the same species from the same patient were counted separately.

**CONCLUSIONS AND CLINICAL IMPLICATIONS**

- Baseline clinical characteristics of patients with atypical pathogens were similar to those of the general patient population with CABP. As with the general patient population, the majority of patients had CABP with a PORT risk class of III, for which outpatient therapy may be appropriate.

- Therapy with LEF led to high efficacy rates (ECR, IACR, and microbiological) in patients with CABP due to atypical pathogens, including when given as short-course (5-day) oral therapy.

- The safety profile of LEF in patients with atypical pathogens was similar to that of LEF in patients with CABP, with a similar low profile of LEF.

- LEF may provide a new empiric IV and oral monotherapy alternative to fluoroquinolones and macrolides in patients with CABP caused by atypical pathogens.

**REFERENCES**

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