Study Design and Patients

Both patients were randomized, double-blind, double-dummy, phase 3 trials. In each trial, 557 patients were randomized to receive either LEF or MOX for 7 days. Patients were stratified by PORT risk class (class II, III, IV/V) and, in the LEF trial, age ≥65 years. Demographic characteristics and baseline characteristics were well-balanced between treatment arms (Table 1).

RESULTS

Efficacy

• Efficacy was determined by investigator assessment of clinical response (IACR) at day 14 after the start of study treatment. The European Medicines Agency coprimary endpoints were IACR and time to clinical improvement.

• The IACR criteria were met by 90.9% of patients treated with LEF (95% CI: 86.8, 94.2) vs 82.8% of patients treated with MOX (95% CI: 77.6, 87.4). The difference in favor of LEF was statistically significant (p = 0.0065) (Figure 3, Table 3).

• LEF was noninferior to MOX in terms of clinical response at test of cure (CE-TOC). The percentage of patients with clinical response at CE-TOC was 69.8% (95% CI: 59.1, 78.0) with LEF vs 65.3% (95% CI: 53.5, 74.3) with MOX. The difference of 4.5% was not statistically significant (p = 0.395) (Table 3).

Safety

• Adverse events (AEs) were generally similar with LEF and MOX treatment in patients with PORT III and IV/V risk classes (Table 4).

• The most common treatment-emergent adverse events (TEAEs) leading to discontinuation were nausea, vomiting, and headache. The most common TEAEs leading to death were pneumonia and bacteremia.

CONCLUSIONS

• LEF demonstrated high and similar rates of efficacy in both the LEF 1 and LEF 2 phase 3 trials in adult and adolescent patients with community-acquired bacterial pneumonia.

• Similarly, among patients with PORT III and IV/V risk classes, effective ECR and sustained clinical response were seen with LEF.

• LEF and MOX had similar safety profiles overall, with similar AE rates in patients with PORT III and IV/V risk classes.

REFERENCES
