

## Chest Infections

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TOPIC: Chest Infections

### OUTCOMES IN TREATMENT OF EUROPEAN (EU) PATIENTS WITH COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP) COMPARING DELAFLOXACIN (DLX) AND MOXIFLOXACIN (MOX)

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**PURPOSE:** Report the outcomes in European CABP patients treated with DLX, an IV/oral anionic fluoroquinolone with no QT restrictions, vs MOX in a phase 3 study.

**METHODS:** International, multicenter, randomized, double-blind trial of 859 adults with CABP in PORT Risk Class II-V with  $\geq 2$  clinical symptoms: cough, sputum, dyspnea, and chest pain; physical signs; and radiographic evidence of pneumonia. Patients were randomized 1:1 to IV/oral DLX or MOX for 5-10 days. Primary clinical endpoint: investigator assessment of Clinical Success as complete/near resolution of signs and symptoms and no further antibiotics needed, at Test of Cure (TOC) 5-10 days after last dose.

**RESULTS:** 736 European patients were randomized: 58.2% male; mean age 60.3 (22.3%  $\geq$  age 75); 26.5% PORT IV-V; 28.4% multi-lobar pneumonia. Bacterial pathogens were identified in 62.6% at baseline. DLX was non-inferior to MOX with Clinical Success at TOC in the Intent-To-Treat population, 90.8% (337/371) DLX vs 89.6% (327/365) MOX [ $\Delta$  1.2 (95% CI: -3.1, 5.6)]. All-Cause Mortality at Day 28 was reported in n=3 DLX and n=3 MOX patients. 30.0% DLX and 25.5% MOX patients had  $\geq 1$  treatment-emergent adverse events (AEs). The most common DLX AEs were mild to moderate diarrhea and transaminase elevations which did not leading to treatment discontinuation. Serious AEs were reported in 18 DLX and 15 MOX patients.

**CONCLUSIONS:** Efficacy and safety of DLX were comparable to MOX for treatment of European patients with moderate to severe CABP.

**CLINICAL IMPLICATIONS:** IV/oral DLX appears effective and well tolerated in European CABP patients, making DLX a promising treatment option.

**DISCLOSURE:** Employee of Melinta Therapeutics, Inc.

**KEYWORDS:** delafloxacin, Community-acquired bacterial pneumonia, fluoroquinolone

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