TREATMENT OF COMMUNITY ACQUIRED BACTERIAL PNEUMONIA (CABP) IN PATIENTS WITH RENAL IMPAIRMENT: OUTCOMES FROM A GLOBAL PHASE 3 STUDY OF DELAFLOXACIN (DLX)

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BACKGROUND AND PURPOSE

Delafloxacin (DLX) is a novel FQ approved for IV/oral treatment of serious skin infections, active against many gram-positive FQ- or macrolide-resistant strains, including MRSA. DLX has FQ class warnings but no QT restrictions, no phototoxicity, no food restrictions and no major DDIs.

We report the outcomes in a Phase 3 global, randomized 1:1, double-blind, active-controlled study where DLX was evaluated in comparison to moxifloxacin (MOX) in the treatment of CABP. This analysis focuses on patients with renal impairment (CrCl <90 mL/min based on Cockcroft Gault (CG) equation). The study design is based on FDA guidance.

STUDY POPULATION (Planned N=860)

- Clinical and radiographic evidence of CABP: at least 2 symptoms of CABP: sputum, chest pain, dyspnea, or cough
- 18+ years age, male and female
- Normal function or mild or moderate renal impairment: CrCl 30-<60 mL/min
- ESRD: excluded from this study
- Presence pleural effusion
- Multi-lobar pneumonia
- Bacteremia
- Other

MATERIALS AND METHODS

- EOT at 96 h (±24) after first dose of ITT population (NI margin: 12.5%)
- Response = Improvement in ≥2 of the following: chest pain, frequency or severity of cough, production, dyspnea, and no worsening
- Investigator-assessed Clinical Outcome at TOC

RESULTS

- 859 patients were randomized. The outcomes were comparable between treatment groups with ECR 89.9% DLX and 89.0% MOX as well as clinical response at TOC 90.5% DLX and 89.7% MOX. 52% of patients had renal impairment calculated by CG.

- Level of Renal Impairment:
  - Normal function or mild or moderate renal impairment: CrCl 30-<60 mL/min
  - Severe (CrCl <30 mL/min)
  - ESRD: excluded from this study

- Moxifloxacin (MOX)
  - 300 mg IV q12h or 450 mg oral q12h

- DLX is well tolerated in CABP patients with renal impairment with low rates of treatment DC. The lack of QT restrictions or major DDIs may be a factor in antibiotic choice.

CONCLUSIONS AND CLINICAL IMPLICATIONS

DLX is well tolerated in CABP patients with renal impairment with low rates of treatment DC. The lack of QT restrictions or major DDIs may be a factor in antibiotic choice.

Vital oral DLX may be useful as a treatment option in CABP including patients with renal impairment and gram-positive, gram-negative or atypical pathogens.