• In CABP, DLX IV/oral monotherapy is comparable to moxifloxacin.

METHODS

Study Design and Inclusion/Exclusion Criteria:
- DLX was studied in one of three multicenter, stratified, randomized, double-blind trials designed using the guidelines of FDA.
- 450 patients with CABP were randomly assigned in a 1:1 ratio to receive either DLX IV/oral monotherapy or moxifloxacin IV/oral monotherapy for 7–14 days. However, due to significant mortality and significant healthcare expenditures due to common pathogens, we decided to continue the treatment with the same antibiotic for another 7–14 days.

Baseline pathogens were classified as:
- Pathogens that were definitively detected by a test method other than routine with a clinical assessment of success.
- Pathogens that were identified from multiple sources and showed the pathogen(s) present at enrollment was eradicated and there was no persistence/definitive

Pathogen Identification and Level of Microbiological Evidence by CABP Detection Method:
- For presumed eradicated: no respiratory and/or blood culture specimen was available at TOC with a clinical assessment of success.
- Pathogens were classified as:
  - Definitive or probable based on method of detection

Per-Patient Microbiological Response at TOC (ME-1 TOC):
- Pathogens were classified as:
  - Definitive or probable based on method of detection

Per-Patient Microbiological Response at TOC (ME-1 TOC):
- Pathogens were classified as:
  - Definitive or probable based on method of detection

Conclusions:
- There was a high degree of favorable microbiological response to TOC (acidification plus piperacillin sodium) or presumed eradication for delafloxacin treated patients.
- Delafloxacin retained potent activity against resistant phenotypes found in S. pneumoniae (PFSP, macrolide-resistant, MDR). Haemophilus species (macrolide-nonsusceptible) and S. aureus (including MRSA and PFQ-nonsusceptible MSSA).
- Like LEAP and OPTIC, no PFQ-nonsusceptible S. pneumoniae isolates were recovered from this trial. These data demonstrated the favorable microbiological efficacy of IV delafloxacin monotherapy in the treatment of adult patients with CABP.