POSTER #E1005

DIAGNOSIS AND OUTCOMES IN PATIENTS WITH ATYPICAL PATHOGENS IN A PHASE 3 COMMUNITY ACQUIRED BACTERIAL PNEUMONIA TRIAL COMPARING DELAFLOXACIN (DLX) TO MOXIFLOXACIN (MOX)

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ECOPY

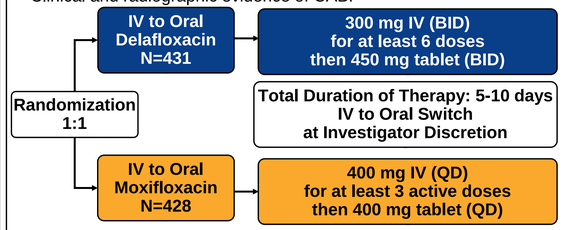
METHODS

BACKGROUND AND PURPOSE

- IDSA/ATS Guidelines recommend that empirical treatment for community-acquired bacterial pneumonia (CABP) cover atypical pathogens.
- Delafloxacin (DLX) is a novel fluoroquinolone (FQ), approved for IV/oral treatment of serious skin infections, that is active against many FQ-or macrolide- resistant strains including MRSA. DLX has FQ class warnings but no QT restrictions or phototoxicity liabilities, no food effect and no major drug-drug interactions.
- Clinical outcomes of patients with atypical pathogens are reported from a Phase 3 global, randomized, double-blind, active-controlled study of IV-to-oral DLX vs MOX in the treatment of CABP.

STUDY POPULATION (Planned N=860)

- 18+ years age, male and female
- Clinical and radiographic evidence of CABP



VISIT SCHEDULE

SCR/BASE	ECR	EOT	TOC	Follow Up
Day -1 to 1	96 h (±24) after first dose	24 h (±4) after last dose	5-10 days after last dose	Day 28 (±2)

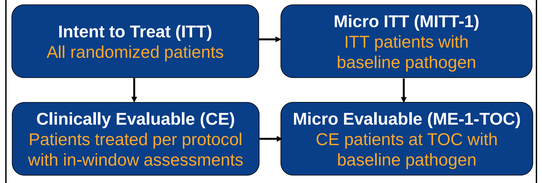
SCR/BASE=screening/baseline; ECR=early clinical response; EOT=end of treatment; TOC=test of cure

MATERIALS AND METHODS

DIAGNOSTIC METHODS FOR ATYPICAL PATHOGENS

- ***Legionella pneumophila*:**
  - Respiratory culture
  - Urinary antigen test (UAT)
  - Serology (acute versus convalescent titers; SCR vs TOC/FU)
- ***Mycoplasma pneumoniae*:**
  - Oropharyngeal swab culture
  - Serology (acute versus convalescent titers; SCR vs TOC/FU)
- ***Chlamydia pneumoniae*:**
  - Serology (acute versus convalescent titers; SCR vs TOC/FU)

ANALYSIS SETS



KEY ENDPOINTS

- **Primary: ECR at 96 h (±24) after first dose in ITT population (NI margin: 12.5%)**

  Responder = Improvement in ≥2 of the following: chest pain, frequency or severity of cough, sputum production, dyspnea, and no worsening of any.
- **Secondary: Investigator-assessed Clinical Outcome at TOC**

RESULTS

TABLE 1: DIAGNOSIS OF ATYPICAL PNEUMONIA (ITT)

	Total N=859
Any Pathogen Detected, MITT-1 (% ITT)	520 (60.5)
Any Atypical Pathogen, n (% MITT-1)	156 (30.0)

FIGURE 1: ATYPICAL PATHOGENS BY DETECTION METHOD (MITT-1)

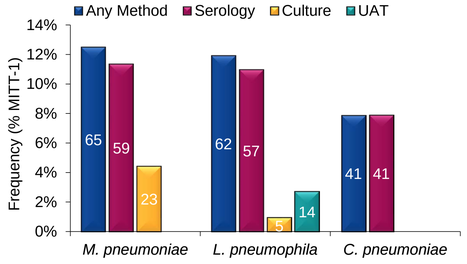


FIGURE 2: MONO/POLY-MICROBIAL INFECTIONS (MITT-1)

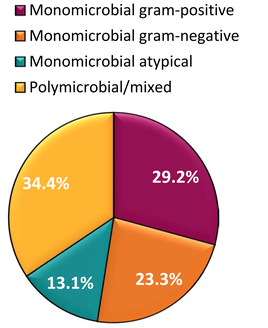
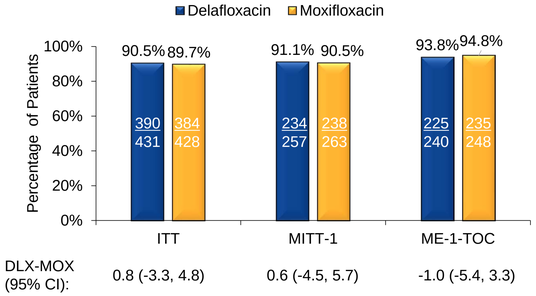


TABLE 2: SUSCEPTIBILITY OF ATYPICAL PATHOGENS AT BASELINE (MITT-1)

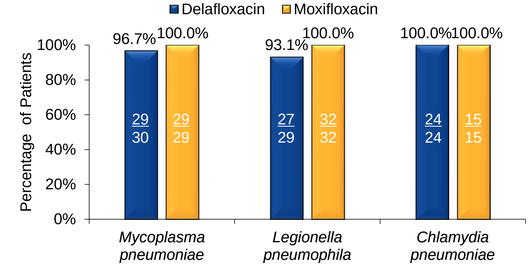
		Delafloxacin MIC (mcg/mL)			Moxifloxacin MIC (mcg/mL)		
	n	MIC_{50}	MIC_{90}	MIC Range	MIC_{50}	MIC_{90}	MIC Range
M. pneumoniae	19	0.25	0.5	0.125-0.5	0.125	0.25	0.125-0.25
L. pneumophila	5	-	-	0.00025-0.001	-	-	0.03-0.03

FIGURE 3: CLINICAL SUCCESS AT TOC BY SELECTED POPULATION



DLX-MOX (95% CI): 0.8 (-3.3, 4.8) | 0.6 (-4.5, 5.7) | -1.0 (-5.4, 3.3)

FIGURE 4: CLINICAL SUCCESS AT TOC BY ATYPICAL PATHOGEN (ME-1-TOC)



CONCLUSIONS AND CLINICAL IMPLICATIONS

Atypical pathogens were frequently identified as CABP pathogens, including as monomicrobial infections.

DLX monotherapy was confirmed as efficacious for treatment of CABP.

DLX treatment provided comparable outcomes to MOX among patients with atypical pathogens.

DLX may be a useful treatment option in CABP when empirical coverage of atypical pathogens is desired.