

P0272 Efficacy of omadacycline versus moxifloxacin in treating subjects from different geographic regions with community-acquired bacterial pneumonia (CABP)

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Background: Omadacycline (OMC) demonstrated non-inferiority to moxifloxacin (MOX) in the treatment of adults with CABP in the global Phase 3 OPTIC Study. Here we report the efficacy results by geographic region.

Materials/methods: Treatment randomization (1:1) was stratified by PORT Risk Class, receipt of a single dose of an allowed antibacterial therapy in the 72 hours prior to study treatment, and geographic region. Subjects received OMC or MOX intravenous treatment ≥ 3 days, then could transition to oral treatment if pre-defined clinical stability criteria were met; the total treatment duration was 7-14 days. Efficacy was evaluated at 5-10 days after last dose (Post Therapy Evaluation [PTE] based on Investigator's Assessment of Clinical Response [IACR]).

Results: A total of 774 subjects were randomized in Eastern Europe (EE: 64%), Western Europe/North America (WE/NA; 24%) and Rest of World (RW, including Latin America, Asia-Pacific, Israel, Turkey and South Africa; 12%). Efficacy results are shown in the table. A baseline pathogen was identified in 53.3% EE, 45.4% WE/NA and 39.4% RW subjects. *Streptococcus pneumoniae* (EE: 17.4%, WE/NA: 31.3%, RW: 13.5%) and *Haemophilus influenzae* (EE: 14.7%, WE/NA: 8.4%, RW: 5.4%) were the most common cultured pathogens and *Mycoplasma pneumoniae* (EE: 33.6%, WE/NA: 34.9%, RW: 24.3%) was the most common atypical pathogen identified.

Clinical Success by Region, IACR at PTE						
Region	Intent-to-treat			Clinically Evaluable		
	OMC n (%)	MOX n (%)	Difference	OMC n (%)	MOX n (%)	Difference
EE	N=249 225 (90.4)	N=248 212 (85.5)	4.9	N=218 210 (96.3)	N=225 203 (90.2)	6.1
WE/NA	N=91 78 (85.7)	N=92 74 (80.4)	5.3	N=83 74 (89.2)	N=79 69 (87.3)	1.8
RW	N=46 35 (76.1)	N=48 44 (91.7)	-15.6	N=39 32 (82.1)	N=41 40 (97.6)	-15.5

Conclusions: OMC showed comparable efficacy to MOX in the treatment of adults with CABP in the EE and WE/NA geographic regions where the majority of subjects were enrolled. MOX showed higher

clinical success rates than OMC in the RW region, however small sample sizes make it difficult to draw any conclusions from this numeric difference.