Omadacycline Outcomes in Community-Acquired Bacterial Pneumonia: Pooled Efficacy and Safety from the Phase 3 OPTIC and OPTIC-2 Trials

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Background

Omadacycline is a once-daily PO or IV aminomethylcycline antibiotic, approved in the United States for treating community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infection (ABSSSI) in adults caused by select micro-organisms[1]

Omadacycline has been studied in four pivotal phase 3 clinical trials: OASIS-1 and OASIS-2 in ABSSSI, and OPTIC and OPTIC-2 in CABP[2-5]

In the pivotal OPTIC trials, omadacycline was non-inferior to a standard-of-care respiratory fluoroquinolone, moxifloxacin, in adults with CABP[4,5]

Methods

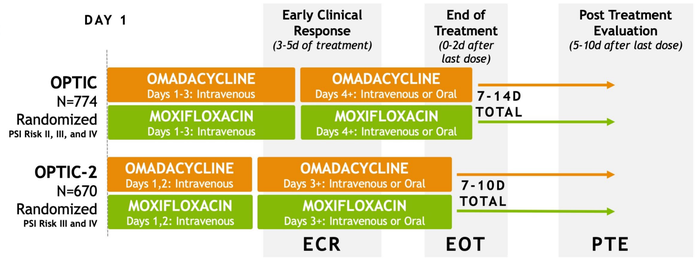
OPTIC (Global; NCT02531438) and OPTIC-2 (European; NCT04779242) were phase 3, randomized, double-blind trials of omadacycline versus moxifloxacin for the treatment of adults with CABP

Omadacycline 100 mg IV q12h ×2 doses (or 200 mg IV once) on day 1, thereafter 100 mg IV q24h; or moxifloxacin 400 mg IV q24h. Optional oral transition after ≥2 days (OPTIC-2) or ≥3 days (OPTIC) to omadacycline 300 mg PO q24h, or moxifloxacin 400 mg PO q24h

Primary endpoint ECR: survival, no receipt of rescue antibacterial therapy, and improvement in ≥2 of 4 symptoms (cough, sputum production, pleuritic chest pain, dyspnea) without deterioration

Secondary endpoints Investigator's assessment of clinical response at EOT and PTE: survival with resolution of signs and symptoms such that further antibacterial therapy was unnecessary

Figure 1: Study designs



Omadacycline demonstrated safety consistent with its established profile, and similar efficacy vs moxifloxacin

Objectives

To describe the pooled efficacy and safety of omadacycline versus moxifloxacin from two phase 3 trials in CABP

Conclusions and Clinical Implications

Omadacycline was as effective as moxifloxacin, a respiratory fluoroquinolone and standard-of-care antibiotic

As once-daily oral and IV monotherapy, omadacycline is an important treatment option for adults with CABP

Together, OPTIC and OPTIC-2 comprise the largest contemporary phase 3 dataset for treatment of CABP

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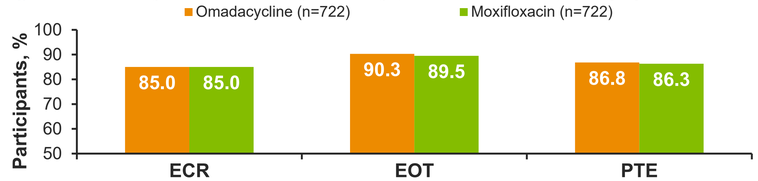
Abbreviations: CABP, community-acquired bacterial pneumonia; ECR, early clinical response; EOT, end of treatment; ITT, intent-to-treat population (all randomized participants); IV, intravenous; microITT, microbiological ITT (participants with baseline pathogen identified); PO, oral; PSI, Pneumonia Severity Index; PTE, post-therapy evaluation; q24h, every 24 hours; SD, standard deviation; TEAE, treatment-emergent adverse event

Results

1,444 participants (ITT population, n=722 each omadacycline and moxifloxacin) were randomized. Demographic and baseline characteristics were generally similar between the two treatment groups. Mean (SD) age was 62.1 (15.1) years, and 44.8% were >65 years

Figure 2: Primary and secondary efficacy (clinical success), ITT population



In the microITT population, clinical success at ECR was 84.7% (344/406) and 85.7% (305/356) in the omadacycline and moxifloxacin groups, respectively

For participants with baseline PSI class III or IV CABP, clinical success at ECR was 85.9% (572/666) for omadacycline and 85.7% (571/666) for moxifloxacin

Table 1: Clinical safety

Parameter / Category, n (%)	Omadacycline (n=718)	Moxifloxacin (n=720)
Participants with ≥1 TEAE	250 (34.8)	265 (36.8)
TEAEs reported in ≥2% of participants in either group		
Alanine aminotransferase increase	20 (2.8)	19 (2.6)
Headache	20 (2.8)	20 (2.8)
Hypertension	16 (2.2)	12 (1.7)
Aspartate aminotransferase increase	15 (2.1)	14 (1.9)
Insomnia	12 (1.7)	15 (2.1)
Nausea	11 (1.5)	26 (3.6)
Diarrhea*	4 (0.6)	41 (5.7)
Drug-related TEAE	48 (6.7)	91 (12.6)
Serious TEAE	40 (5.6)	41 (5.7)
TEAE leading to premature discontinuation of study	2 (0.3)	7 (1.0)
Death	14 (1.9)	10 (1.4)

*There were no cases of *Clostridioides difficile*–associated diarrhea reported in the omadacycline group; 8 cases reported in the moxifloxacin group

References

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