Pooled Microbiological Outcomes from the Phase 3, Randomized OPTIC and OPTIC-2 Trials of Omadacycline vs Moxifloxacin in Community-Acquired Bacterial Pneumonia

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Background

Omadacycline (OMC) is an FDA-approved oral (PO) and intravenous (IV) treatment for adults with community-acquired bacterial pneumonia (CABP).[1]

In an initial trial (OPTIC), OMC was non-inferior to a standard-of-care respiratory fluoroquinolone, moxifloxacin (MOX), in adults with CABP.[2] An additional study in adults with CABP (OPTIC-2) was recently completed as part of a post-marketing commitment with the FDA.

Methods

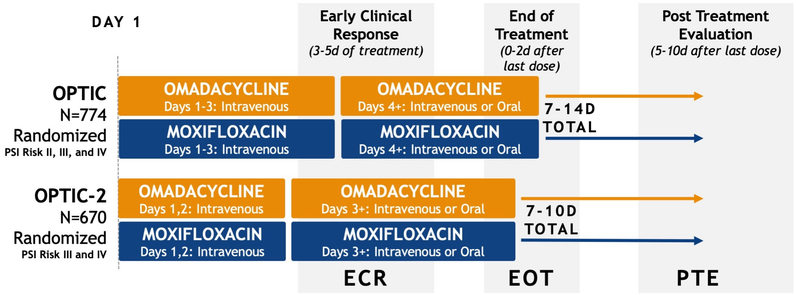
OPTIC: Treatment was OMC 100 mg IV twice daily (q12h) ×2 doses or 200 mg IV once on day 1, thereafter 100 mg IV once daily (q24h); or MOX 400 mg IV q24h, for 3 days (**Figure 1**). Thereafter, patients could transition to PO therapy (OMC 300 mg q24h or MOX 400 mg q24h), for a total of 7–14 days.

OPTIC-2: Treatment was OMC 100 mg IV q12h ×2 doses or 200 mg IV once per day, or MOX 400 mg IV q24h, on days 1–2. Thereafter, patients could transition to PO therapy (OMC 300 mg q24h or MOX 400 mg q24h), for a total of 7–10 days. Treatment could extend to 14 days if the participant had bacteremia at baseline.

Early clinical response (ECR; 72–120 hours after first dose) was defined as survival, no receipt of rescue antibacterial therapy, and improvement in at least two of four symptoms (cough, sputum production, pleuritic chest pain, dyspnea) without deterioration in any of these symptoms.

Secondary endpoints included investigator's assessment of clinical response at end of treatment (EOT; 0–2 days after last dose) and post-therapy evaluation (PTE; 5–10 days after last dose), defined as survival with resolution of signs and symptoms of infection such that further antibacterial therapy was unnecessary.

Figure 1: Study designs.



Results

762 participants (microbiological intent-to-treat population [microITT]) were included across both studies (n=406 OMC, n=356 MOX; **Table 1**). The five most common baseline pathogens in the OMC and MOX groups, respectively, were *Mycoplasma pneumoniae* (26.1% and 24.2%, respectively), *Legionella pneumophila* (18.7%, 19.4%), *Streptococcus pneumoniae* (17.0%, 15.2%), *Haemophilus influenzae* (14.8%, 10.1%), and *H. parainfluenzae* (14.5%, 15.7%).

Omadacycline showed high clinical success rates against common pathogens in two phase 3 trials in community-acquired bacterial pneumonia

Objectives

To present pooled efficacy and microbiological response data of omadacycline vs moxifloxacin from two CABP phase 3 trials (NCT02531438 and NCT04779242)

Conclusions

Pooled OPTIC and OPTIC-2 data for omadacycline in community-acquired bacterial pneumonia showed overall clinical success rates >86% for most baseline pathogens and favorable microbiological response rates at post-therapy evaluation

Outcomes for omadacycline were comparable to those for moxifloxacin

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Results, continued

Table 1: Demographic and Baseline Characteristics, Pooled microITT Population

Characteristics	Omadacycline (n=406)	Moxifloxacin (n=356)	All Participants (n=762)
Age, years; mean (SD)	61.2 (14.7)	61.1 (15.2)	61.2 (14.9)
Male; n (%)	220 (54.2)	204 (57.3)	424 (55.6)
PORT risk class (as randomized); n (%)			
III	284 (70.0)	249 (69.9)	533 (69.9)
IV	93 (22.9)	80 (22.5)	173 (22.7)
Baseline SIRS; n (%)	316 (77.8)	296 (83.1)	612 (80.3)
CURB 65 score; n (%)			
0	88 (21.7)	65 (18.3)	153 (20.1)
1	184 (45.3)	168 (47.2)	352 (46.2)
2	109 (26.8)	116 (32.6)	225 (29.5)
3	23 (5.7)	5 (1.4)	28 (3.7)
4	2 (0.5)	2 (0.6)	4 (0.5)
Bacteremia at baseline; n (%)	27 (6.7)	32 (9.0)	59 (7.7)

Abbreviations: CURB 65, confusion, uremia, respiratory rate, blood pressure, and age 65 or older; micro-ITT, microbiological intent-to-treat; PORT, Pneumonia Outcomes Research Team, PORT risk class (actual) was based on PORT score (derived) from the case report form; SD, standard deviation; SIRS, systemic inflammatory response syndrome.

Clinical success at ECR was ≥78% for the OMC group across the most common pathogens. At PTE, clinical success by baseline pathogen was similarly high (**Table 2**).

Table 2: Clinical Success for Most Frequent Baseline Pathogens, Pooled microITT Population

	Early Clinical Response		Post-Therapy Evaluation	
Participants with Clinical Success, % (n/N)	Omadacycline (n=406)	Moxifloxacin (n=356)	Omadacycline (n=406)	Moxifloxacin (n=356)
Gram-positive bacteria				
Streptococcus pneumoniae	87.0 (60/69)	83.3 (45/54)	84.1 (58/69)	87.0 (47/54)
Macrolide resistant	100 (18/18)	88.9 (8/9)	94.4 (17/18)	100 (9/9)
PSSP	83.8 (31/37)	88.8 (22/25)	86.5 (32/37)	96.0 (24/25)
PNSSP	100 (5/5)	100 (4/4)	100 (5/5)	100 (4/4)
MDRSP*	100 (14/14)	87.5 (7/8)	92.9 (13/14)	100 (8/8)
Staphylococcus aureus (MSSA)	87.8 (43/49)	90.2 (37/41)	75.5 (37/49)	92.7 (38/41)
Gram-negative bacteria				
Haemophilus influenzae	80.0 (48/60)	88.8 (32/36)	86.7 (52/60)	94.4 (34/36)
Haemophilus parainfluenzae	86.4 (51/59)	83.9 (47/56)	88.1 (52/59)	91.1 (51/56)
Klebsiella pneumoniae	89.7 (26/29)	81.3 (26/32)	89.7 (26/29)	84.4 (27/32)
Pseudomonas aeruginosa	85.0 (17/20)	100 (13/13)	65.0 (13/20)	100 (13/13)
Escherichia coli	83.3 (15/18)	78.9 (15/19)	66.7 (12/18)	68.4 (13/19)
Atypical pathogens				
Chlamydophila pneumoniae	78.4 (40/51)	81.0 (34/42)	88.2 (45/51)	90.5 (38/42)
Legionella pneumophila	84.2 (64/76)	87.0 (60/69)	89.5 (68/76)	95.7 (66/69)
Mycoplasma pneumoniae	82.1 (87/106)	86.0 (74/86)	95.3 (101/106)	88.4 (76/86)

Abbreviations: MDRSP, multi-drug–resistant *S. pneumoniae*; microITT, microbiological intent-to-treat; MSSA, methicillin-susceptible *S. aureus*; PNSSP, penicillin-nonsusceptible *S. pneumoniae*; PSSP, penicillin-susceptible *S. pneumoniae*.
*A pathogen was considered multidrug resistant if susceptibility testing showed resistance to at least one antibiotic within ≥3 different classes. For *Streptococcus* spp., isolates resistant to macrolides but susceptible to lincosamides and D-test positive (>4/0.5 µg/mL) were considered resistant to both macrolides and lincosamides.

At PTE, the per-participant microbiological response was favorable for both groups (**Table 3**).

Table 3: Per-participant Microbiological Response at Post-therapy Evaluation Visit

Participants with Microbiological Response at PTE Visit, n (%)	Omadacycline (n=406)	Moxifloxacin (n=356)
Favorable	356 (87.7)	312 (87.6)
Difference (95% CI)	0.1 (–4.6, 4.8)	
Unfavorable	34 (8.4)	30 (8.4)
Indeterminate	16 (3.9)	14 (3.9)

Abbreviations: CI, confidence interval; microITT, microbiological intent-to-treat; PTE, post-therapy evaluation (5–10 days after last dose).
Notes: 95% CI was constructed based on the Miettinen–Nurminen method with stratification. Percentages were based on the total number of participants at each visit in each treatment group.

References

1. Sakoulas G, et al. *Expert Rev Anti Infect Ther*. 2023;21:255-65. 2. Stets R, et al. *N Engl J Med* 2019;380:517-27.

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