Clinical Outcomes of Patients With Secondary Bacteremia in the Omacyclidine Phase 3 Acute Bacterial Skin and Skin Structure Infections and Community‐Acquired Bacterial Pneumonia Studies

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ABSTRACT

• The aminomethylcycline omacyclidine (OMC) is approved in the United States for the treatment of adults with acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP) after failure of initial antibiotic therapy.
• OMC is a 20S β-lactamase inhibitor and is active against β-lactamase-resistant pathogens.
• OMC is approved for the treatment of secondary bacteremia in CABP, defined as a positive blood culture result during treatment.
• All studies involved 7–14 days’ therapy with test article.

RESULTS

Demographic and Baseline Characteristics

• ABSSSI randomized patients without a sole Gram-negative pathogen at baseline.
• CABP randomized patients with ≥1 pathogen at baseline.
• All studies involved 7–14 days’ therapy with test article.

Modifications in the chemical structure of OMC allow it to overcome important characteristics of pathogen resistance against β-lactams.

• OMC minimum inhibitory concentration (MIC)90 = 0.50 μg/mL.
• – Median treatment duration
• – Patients with secondary bacteremia: 9 days (OMC) and 9 days (LZD).

• All treated patients (safety population): 9 days (OMC) and 9 days (LZD).

Microbiological Findings and Treatment Duration

• Streptococcus pneumoniae was the most frequent cause of secondary bacteremia in ABSSSI (Table 2). The OMC C10 concentration (MIC) was 0.06 μg/mL.
• – Median treatment duration
• – Patients with secondary bacteremia: 11 days (OMC) and 14 days (MOX).

• All patients (safety population): 10 days (OMC) and 10 days (MOX).

1. Omadacycline (NUZYRA®)
2.Aztreonam
3.Moxifloxacin
4.Methicillin-susceptible Staphylococcus aureus
5.Methicillin-resistant Staphylococcus aureus
6.Klebsiella pneumoniae
7.Aspergillus fumigatus
8.Pseudomonas aeruginosa
9.Anthrax bacillus
10.Capnocytophaga canimorsus
11.Clostridium difficile
12.Moraxella lacunata
13.Viridans streptococci
14.Streptococcus sanguinis
15.Rothia dentocariosa
16.Streptococcus pyogenes
17.E. coli
18.MSSA
19.MRSA
20.S. pneumoniae

RESULTS

• Clinical success rates in patients with secondary bacteremia were numerically lower in the OMC arm than in both the control arms at Day 9 and 10 with the test article at E2 and E–10% lower in E2 at both E in both treatment groups without any statistical difference.

Efficacy Findings

• Clinical success rates in patients with secondary bacteremia were numerically lower in the OMC arm than in both the control arms at Day 9 and 10 with the test article at E2 and E–10% lower in E2 at both E in both treatment groups without any statistical difference.

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REFERENCES


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No case of clinical failure was directly due to persistent bacteremia.

• Inadequate outcomes were due to missing data; in most cases due to introduction of rescue antibacterial therapy during study.

• Although these findings are limited by the small sample size, clinical success rates of PTE were similar in both comparative and noncomparative studies, in patients with secondary bacteremia.

• These findings provide preliminary measurement for use of omadacycline in patients with secondary bacteremia.

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