BACKGROUND

• Omadacycline (OMC) is a novel, tetracycline-like antibiotic with a broad spectrum of activity.

• OMC has completed phase 3 clinical development as an intravenous (IV) to oral monotherapy for acute bacterial skin and skin structure infections (ABSSSI) and as oral only monotherapy for ABSSSI.

• Additionally, modifications in the chemical structure of OMC allow it to overcome the 2 main mechanisms of resistance to tetracyclines: bacterial efflux and 7-position substituent.

• OMC demonstrates potent target-spectrum benefit over comparator antimicrobials for a broad range of Gram-negative and Gram-positive pathogens.

METHODS

Study Design and Analysis Population

• OPTIC was a randomized (1:1), double-blind, global, phase 3 clinical study comparing OMC and moxifloxacin (MOX) for the treatment of adult patients with CABP (ESPGH Class 4: severe CAP) or pneumonia (ESPGH Class 2: mild to moderate CAP) [1].

• Patient Population

  - Monomicrobial Gram-positive infections

    - Baseline pathogens from blood and/or respiratory cultures:

      - Staphylococcus aureus
      - Streptococcus pneumoniae

  - Baseline Gram-negative infecting pathogens

    - Baseline pathogens from blood and/or respiratory cultures:

      - Haemophilus influenzae
      - Pseudomonas aeruginosa

RESULTS

Table 1. Omadacycline and Moxifloxacin MIC Summary Statistics for Baseline Pathogens From Blood and/or Respiratory Cultures (microITT Population)

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Baseline MIC50 (µg/mL)</th>
<th>Baseline MIC90 (µg/mL)</th>
<th>Baseline MIC50 (µg/mL)</th>
<th>Baseline MIC90 (µg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. aureus</td>
<td>1</td>
<td>4</td>
<td>0.008</td>
<td>0.12</td>
</tr>
<tr>
<td>S. pneumoniae</td>
<td>0.015</td>
<td>0.12</td>
<td>0.03/0.06</td>
<td>0.12/0.12</td>
</tr>
<tr>
<td>H. influenzae</td>
<td>6</td>
<td>32</td>
<td>2/4</td>
<td>65</td>
</tr>
<tr>
<td>P. aeruginosa</td>
<td>32</td>
<td>&gt;16</td>
<td>0.008 - &gt;4</td>
<td>0.03 - &gt;4</td>
</tr>
</tbody>
</table>

Table 2. Clinical Success at PTE Based on Investigator Assessments by Baseline Pathogen and Study Drug (µg/mL; microITT Population)

<table>
<thead>
<tr>
<th>Baseline Pathogen</th>
<th>Baseline MIC50 (µg/mL)</th>
<th>Baseline MIC90 (µg/mL)</th>
<th>Baseline MIC50 (µg/mL)</th>
<th>Baseline MIC90 (µg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. pneumoniae</td>
<td>0.12</td>
<td>0.12</td>
<td>0.03 - 4</td>
<td>0.12/0.12</td>
</tr>
</tbody>
</table>

CONCLUSIONS

• OMC demonstrated significant activity against a broad range of Gram-negative and Gram-positive pathogens.

• OMC achieved high clinical success rates in comparison with moxifloxacin.

• OMC demonstrated a favorable safety profile.

REFERENCES