INTRODUCTION

OMAC (OMADACYCLINE) is a 20-µg/mL crystalline, water-insoluble semisynthetic tetracycline antibiotic that was discovered in the late 1990s. It has a broad spectrum of activity against aerobic, anaerobic, and atypical bacterial pathogens. OMAC is structurally related to doxycycline, but it has been modified to overcome the two main mechanisms of tetracycline resistance: efflux pumps and ribosomal protection. These modifications allow OMAC to overcome the efflux pumps of Gram-negative bacteria such as Pseudomonas aeruginosa, which are responsible for the relative resistance of these organisms to many tetracyclines. OMAC also has a long half-life, which improves its ability to achieve high tissue levels in chronic infections. A phase 3 study, OASIS, compared OMAC with linezolid for the treatment of skin and skin structure infections (SSSIs) caused by Gram-negative and Gram-positive bacteria.

METHODS

Subjects were randomized 1:1 to receive OMAC 100 mg IV q12h × 2 doses then 100 mg OASIS was a global, randomized (1:1), double-blind, multicenter, phase 3 study comparing OMC 300 mg q24h or oral LZD 600 mg q12h based on investigator assessment. Total treatment ≥ 7 days IV treatment, a primary lesion ≥ 75 cm² in total surface area of contiguous involved tissue, and at least two of four clinical signs (redness, warmth, induration, fluctuation) or ≥ 3 of the four clinical signs. Subjects were excluded for use of any systemic or topical antibacterial treatment within 72 hours before the first dose of study drug.

RESULTS

Table 1: Microbiology recovery in global, randomized (1:1), double-blind, multicenter, phase 3 study comparing OMC 300 mg q24h or oral LZD 600 mg q12h based on investigator assessment. Pathogens were determined by investigator assessment and subsequent verification at a central laboratory. This definition included only pathogens determined to be involved in the lesion.

<table>
<thead>
<tr>
<th>Geographic Region</th>
<th>Pathogen</th>
<th>OMC</th>
<th>LZD</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMW</td>
<td>S. aureus (MRSA)</td>
<td>28 (17.9)</td>
<td>2 (3.9)</td>
</tr>
<tr>
<td>BMW</td>
<td>S. aureus (NSA)</td>
<td>95 (59.4)</td>
<td>7 (13.0)</td>
</tr>
<tr>
<td>BMW</td>
<td>S. pneumoniae</td>
<td>47 (29.6)</td>
<td>10 (19.2)</td>
</tr>
</tbody>
</table>

REFERENCES

4. OASIS global, randomized (1:1), double-blind, multicenter, phase 3 study comparing OMC 300 mg q24h or oral LZD 600 mg q12h based on investigator assessment. Total treatment ≥ 7 days IV treatment, a primary lesion ≥ 75 cm² in total surface area of contiguous involved tissue, and at least two of four clinical signs (redness, warmth, induration, fluctuation) or ≥ 3 of the four clinical signs.

ACKNOWLEDGMENTS

This work was supported by a grant from Phathom Pharmaceuticals, Inc. (see provisory, Pharmaceutical Group). The authors thank the subjects and investigators involved in the clinical study.