Safety and efficacy of PTK 0796 (Omadacycline) as treatment of uncomplicated skin and soft tissue infection (cSSSI)

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ABSTRACT

Background: Having completed phase 1 and 2 clinical programs, PTK 0796, a broad-spectrum antibiotic active against most bacterial pathogens, including methicillin-resistant Staphylococcus aureus (MRSA), has begun phase 3 assessment in phase 3 trials.

Methods: PTK 0796 was administered in a single-blind Phase 3 study comparing PTK 0796 (600 mg/8-hr dosing) vs linezolid (600 mg QD) to linezolid-treated subjects. The study was designed to establish efficacy with a non-inferiority-based superior to linezolid. The study was designed with a two-sided significance level of 0.05 and 85% power for the primary endpoints.

Results: Enrolled 68/69 subjects treated with PTK 0796 and 68/69 subjects treated with linezolid. On an incident analysis, the primary efficacy endpoint was clinical success in the ITT population. The incidence of clinical success was 85.7% (58/68) and 88.9% (60/68) in the PTK 0796 and linezolid treatment arms, respectively. This difference was not statistically significant. The lower limit of the 95% confidence interval exceeded 0% then the study would have ~90% power for each of the co-primary endpoints.

CONCLUSIONS

Clinical success in patients in whom an infectious pathogen was identified was comparable across treatment arms. MRSA was frequently isolated in patients with both PTK 0796 and linezolid treatment success. This study was well tolerated.

Table 4. Clinical Response in the ITT (per-protocol) population at EOT and TOC

Patient population

| Treatment Group | Clinical Success | Clinical Failure | Clinical Improvement
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<tbody>
<tr>
<td>PTK 0796</td>
<td>85.7% (58/68)</td>
<td>3.6% (3/68)</td>
<td>9.7% (6/68)</td>
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<tr>
<td>Linezolid</td>
<td>88.9% (60/68)</td>
<td>2.9% (2/68)</td>
<td>8.4% (6/68)</td>
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SAFETY ANALYSES

The overall incidence of adverse events was similar in both treatment groups. The most common adverse event in both groups was headache, which occurred in ~15% of patients in both groups. The incidence of rash was ~5% in both groups.