Improvement in Quality of Life for Adults with Acute Bacterial Skin and Skin Structure Infections (ABSSSI) Following Treatment with Omadacycline or Linezolid

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ABSTRACT

Study Design: Phase 3 clinical study comparing omadacycline and linezolid for treatment of ABSSSI

RESULTS

In the omadacycline group, significant increases in SF-36v2 scores from baseline were observed in all eight domains of quality of life compared to linezolid. For physical functioning and role emotional, significant improvements were observed at the post-treatment evaluation (PTE) 7-14 days after last dose.

At baseline, the highest mean SF-36v2 scores were seen across both treatment groups in vitality role emotional, with lowest scores in vitality and bodily pain (Fig. 1A).

Of note, subjects receiving omadacycline showed greater improvements in all parameters compared to linezolid. For physical functioning, bodily pain, role physical, mental health, vitality, and social functioning, the mean improvement in overall physical health (p<0.001) and reported related quality of life, including impacts on physical health and mental well-being.

In the OASIS-2 study, omadacycline provided significant improvement in the physical health SF-36v2 domain compared to linezolid (p=0.021 point improvement for linezolid group) (Fig. 3).

Fig. 2

CONCLUSIONS

Although omadacycline achieved greater increases from baseline than linezolid in the physical health SF-36v2 domain, compared with baseline, for adult subjects with ABSSSI caused by a known or suspected Gram-positive pathogen.

Subjects receiving omadacycline showed greater improvements in all quality-of-life parameters measured, compared to linezolid, although the differences were not statistically significant.

As the OASIS-2 study was not specifically designed or powered to assess quality-of-life outcomes, the trends identified in this analysis merit further investigation.

ACKNOWLEDGMENTS

The authors wish to thank the subjects and investigators involved in the OASIS-2 study.

REFERENCES


Table 1. Subject Demographics and Baseline Characteristics (ITT population)

<table>
<thead>
<tr>
<th>Study Group</th>
<th>No. (%)</th>
<th>Age (yrs) Mean</th>
<th>Weight (kg) Mean (95% CI)</th>
<th>History of Diabetes, n (%)</th>
<th>History of Heart Disease, n (%)</th>
<th>History of Asthma, n (%)</th>
<th>History of COPD, n (%)</th>
<th>History of Hypertension, n (%)</th>
<th>History of Stroke, n (%)</th>
<th>History of Cancer, n (%)</th>
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</thead>
<tbody>
<tr>
<td>Omadacycline</td>
<td>368</td>
<td>77.4 (72.1-82.8)</td>
<td>79.6 (75.6-83.6)</td>
<td>16 (4.3)</td>
<td>10 (2.7)</td>
<td>3 (0.8)</td>
<td>2 (0.5)</td>
<td>25 (6.7)</td>
<td>1 (0.3)</td>
<td>4 (1.1)</td>
</tr>
<tr>
<td>Linezolid</td>
<td>366</td>
<td>77.4 (72.1-82.8)</td>
<td>79.6 (75.6-83.6)</td>
<td>16 (4.3)</td>
<td>10 (2.7)</td>
<td>3 (0.8)</td>
<td>2 (0.5)</td>
<td>25 (6.7)</td>
<td>1 (0.3)</td>
<td>4 (1.1)</td>
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