Effects of Oral Omadacycline versus Oral Linezolid on Lesion Size and Local Signs of ABSSSI in the Phase 3 OASIS-2 Study

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BACKGROUND

- Acute bacterial skin and skin structure infections (ABSSSI) represent a significant clinical and economic burden to health systems globally.
- Omadacycline (OMC) is the first tetracycline in late-stage clinical development. Amongst its unique mechanisms of action, OMC has anti-efflux properties attributed to the tetracycline-
- OMC is unique among the tetracyclines in its ability to inhibit efflux pumps and ribosomal protection.

METHODS

- The Eligibility study: 16 of 18 eligible subjects with ABSSSI and common lesions, 7.75 cm, and with evidence of systemic inflammatory response within 24 hours prior to randomization.
- Eligible subjects were randomized 1:1 to receive OMC 450 mg once every 12 hours or 300 mg every 12 hours for 7 days for cellulitis and erysipelas, and 1000 mg every 12 hours for 7 days for cellulitis/erysipelas, major abscess.
- Randomization was stratified by site of infection (dermatological, edema, and/or induration), as measured with a baseline of severe signs.
- In the OASIS-2 trial, OMC was non-inferior to iv linezolid (LZD) at 7 and 14 days after treatment, with a high degree of similarity in systemic inflammatory response.

RESULTS

- The median lesion size was 32.3 cm2 (OMC group) and 39.5 cm2 (LZD group) at baseline, for the ITT population.
- Median lesion size varied by infection type (MRSA), many variables were measured for each study visit as measures of systemic ABSSSI signs.
- The percentage of subjects with clinical signs of ABSSSI varies by socioeconomic status (SES).

CONCLUSIONS

- The kinetics and magnitude of improvement were similar for both treatments.
- The efficacy of OMC and LZD in the treatment of ABSSSI is comparable for both treatments.

The authors wish to thank the subjects and investigators involved in this study.

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