**Effects of IV/Oromaclycline Versus IV/Oral Linezolid on Localized Size and Signs of ABSSSI in the Phase 3 OASIS Trial**

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**INTRODUCTION**

- Omadacycline (OMC) is the first antibiotic in a new class of compounds, the aminomethylcyclines, which are semi-synthetic antibiotics related to the tetracyclines.
- Modifications in the chemical structure of OMC allow it to overcome the two main mechanisms of tetracycline resistance: efflux pumps and ribosomal protection proteins. OMC demonstrates potent bactericidal activity against Gram-negative aerobes, anaerobes, and atypical bacterial pathogens.
- In the OASIS trial, demonstrated that OMC was well-tolerated and statistically superior to linezolid (LZD) for the treatment of adults with ABSSSI, acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia.
- Aminomethylcyclines are a class of oral and IV antibiotics for the treatment of skin infections, ABSSSI, and community-acquired bacterial pneumonia.
- The aim of the study was to assess the safety, tolerability, and clinical efficacy of a novel oral antibiotic, OMC, in comparison to LZD for the treatment of ABSSSI.

**METHODS**

- **Study Design:** This was a randomized, double-blind, active-controlled, 2:1 non-inferiority trial comparing OMC and LZD for the treatment of ABSSSI.
- **Participants:** The study included adults (≥18 years) with ABSSSI, as defined by the Clinical and Laboratory Standards Institute (CLSI) classification.
- **Randomization:** Participants were randomized 2:1 to receive OMC (150 mg twice daily for 3 days, then 300 mg twice daily for 12 days) or LZD (600 mg twice daily for 10 days).
- **Efficacy Endpoints:** The primary endpoint was the percentage of subjects with resolution of all signs of infection (erythema, edema, induration) at post-therapy evaluation (PTE).
- **Safety Endpoints:** Adverse events, laboratory evaluations, and vital signs were monitored throughout the study.

**RESULTS**

- **Safety and Tolerability:** No new safety concerns were observed with OMC compared to LZD. The incidence of adverse events was similar between the two groups.
- **Clinical Efficacy:** OMC and LZD showed comparable improvement in skin infection resolution, with >90% of subjects in the overall Modified Intent-to-Treat (mITT) populations having resolution of all signs of infection at baseline.
- **Microbiological Response:** Bacterial eradication was achieved in ≥90% of evaluable subjects at the end of treatment for both OMC and LZD.

**CONCLUSIONS**

- OMC showed non-inferiority in the primary and secondary endpoints compared to LZD for the treatment of ABSSSI.
- OMC was well-tolerated and demonstrated comparable clinical efficacy to LZD for the treatment of ABSSSI.

**REFERENCES**


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