Safety and Efficacy of Omadacycline for Treatment of Acute Bacterial Skin and Skin Structure Infections by Patient Body Mass Index

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BACKGROUND

- Omadacycline (OMC) is an intravenous (IV) and oral aminomethylcycline antibiotic in the tetracycline class recently approved in the USA to treat acute bacterial skin and skin structure infections (ABSSSIs) in adults.
- OMC, like linezolid (LZD), is administered on a fixed-dose basis in adults, without regard to body weight or composition.
- The pharmacokinetics of many antibacterial agents are altered in obese patients and may negatively impact the clinical outcomes of infections in this population.

METHODS

- OASIS-1 and OASIS-2 were randomized (1:1), double-blind, active comparator-controlled, Phase 3 studies evaluating OMC with LZD for the treatment of adults with ABSSSI (Fig. 1).

RESULTS

- Approximately two-thirds of patients were overweight (OCMC: 32.0%, LZD: 35.5%) or obese (OCMC: 30.4%, LZD: 29.5%) (Table 1).
- A small minority of patients (1.6%) were classified as underweight; because this group was so small, it was not shown in the efficacy and safety data by BMI.
- Baseline pathogens were similar across the BMI categories, with the most common being Staphylococcus aureus (present in ~70% of patients).
- Rates of hypertension, diabetes, and heart disease generally increased with increasing BMI.
- Clinical success at ECR and PTE was similar in healthy-weight, overweight, and obese patients, with no evidence of lower efficacy with increasing BMI (Fig. 2, 3).
- There were no differences in rates of treatment-emergent adverse events (TEAEs) and serious TEAEs across BMI categories in OMC- and LZD-treated patients (Table 2).
- No major differences in post-baseline liver transaminase changes, diarrhea or headache were noted across BMI categories or between treatment groups (Table 3).
- The rate of nausea and vomiting was approximately two- to four-fold higher in OMC-treated patients compared to LZD-treated patients, but was independent of BMI category.
- Changes in liver enzymes were similar across BMI categories (Table 4).

CONCLUSIONS

- Omadacycline showed similar efficacy and safety in obese, overweight and healthy-weight ABSSSI patients compared to linezolid.
- Observed adverse events were consistent with the known adverse effect profile of the tetracycline class.
- These data suggest that a fixed-dosing strategy, regardless of adult body size, did not impact the safety and efficacy of omadacycline used to treat ABSSSI in clinical studies.

REFERENCES


ACKNOWLEDGMENTS

The authors wish to thank the patients and investigators involved in the OASIS-1 and OASIS-2 studies.

FUNDING AND DISCLOSURES

Paratek Pharmaceuticals, Inc. Mark Wilcox has received consulting fees from Paratek Pharmaceuticals, Inc. Maria Curran, Lynne Garrity-Ryan and Paul C. McGovern are employees of Paratek Pharmaceuticals, Inc. Surya Chitra is a consultant to Paratek Pharmaceuticals, Inc. This study was sponsored by Paratek Pharmaceuticals, Inc. Medical editing assistance was provided by Paratek Pharmaceuticals, Inc., and was provided by Innovative Strategic Communications.

The authors declare no conflicts of interest.

Poster 00306
Abstract 1347