Wound infection

- Stage 0/1 chronic kidney disease (CKD-0/1): Glomerular filtration rate (GFR) ≥ 90 mL/min
- OASIS-1 was a randomized (1:1), double-blind, phase 3 study comparing OMC to linezolid (LZD) for the treatment of ABSSSI with comparable safety in the general population.
- In OASIS-1, omadacycline (OMC), a first-in-class aminomethylcycline antibiotic, is a semisynthetic derivative of the tetracyclines that exhibits activity against Gram-positive and Gram-negative aerobes, anaerobes, and atypical bacteria.
- Nearly 5 million hospital admissions from 2005 to 2011 were due to a primary diagnosis of skin and soft tissue infections.
- OMC is predominantly eliminated in the feces, but an appreciable portion of OMC is eliminated via the kidneys.
- In the OASIS-1 study (NCT02877927), oral-only treatment with OMC was compared to intravenous to oral linezolid (LZD) for the treatment of ABSSSI with comparable safety in the general population. In the OASIS-2 study (NCT02877927), oral-only treatment with OMC was compared to intravenous to oral linezolid (LZD) for the treatment of ABSSSI with comparable safety in the general population.
- In wound infections, CKD-2/3 patients had a higher proportion of mixed pathogens (≥ 2 pathogens identified).
- Differences in clinical success rates between OMC- and LZD-treated patients were not statistically significant in either CKD subgroup.
- Overall success rates and most drug-related adverse events were comparable between OMC and LZD.
- Clinical success at ECR endpoint was slightly higher for both OMC and LZD in comparison to placebo.
- The safety and efficacy of omadacycline in patients with CKD-0/1 and CKD-2/3 are generally similar between OMC and LZD treated across both subgroups Table 1.
- These results compare favorably with those reported in other studies that between groups across subgroups.
- 5% of patients in each treatment group had ABSSSI-related manifestations for drug exposure. All other baseline characteristics were similar and typically due to the study design, leading the authors to conclude no significant differences.

REFERENCES

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