Efficacy and Safety of Omadacycline in Chronic Kidney Disease (CKD) Patients With Acute Bacterial Skin and Skin Structure Infections (ABSSSI): A Subgroup Analysis From the OASIS Trial

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BACKGROUND

- The incidence and severity of acute bacterial skin and skin structure infections (ABSSSI) have increased in recent years.
- Nearly 5 million hospital admissions from 2005 to 2011 were due to a primary diagnosis of skin and soft tissue infections (SSTIs).
- SSTIs can be complicated by diabetes, chronic kidney disease (CKD), or chronic obstructive pulmonary disease.

METHODS

- Omadacycline (OMC), a fixed-dose minocycline/polymyxin B lipid-A antibiotic, is a semi-synthetic derivative of minocycline that maintains activity against Gram-negative bacteria and Gram-positive bacteria, as well as against vancomycin-resistant enterococci.
- OMC has a long terminal half-life, an important attribute for the treatment of serious and complicated infections.
- Baseline infections were generally similar between OMC- and LZD-treated patients in both CKD subgroups.
- There were no drug-related serious TEAEs between regimens across subgroups.

RESULTS

- Overall, 3.6% difference (95% CI, −7.0, 16.2) in ECR rates was observed between OMC and LZD.
- There were minor variations in liver chemistry TEAEs between regimens across subgroups.
- No differences in efficacy, oradacycline or LZD were observed between in-hospital and outpatient treatment settings.

CONCLUSIONS

- Taken together with data from a phase 1 renal impairment study, this subgroup analysis supports the use of omadacycline in patients with renal impairment and ABSSSI.

REFERENCES