Efficacy of omadacycline versus linezolid in treating ABSSSI patients from different geographic regions (OASIS trial)

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Background: The phase 3 OASIS (Omadacycline in Acute Bacterial Skin and Skin Structure Infections [ABSSSI] Study) trial evaluated safety and efficacy of IV/oral omadacycline (OMC) vs IV/oral linezolid (LZD) in adults with ABSSSI from 12 countries. OMC was well-tolerated and noninferior to LZD for primary efficacy endpoints of Early Clinical Response (ECR; ≥20% reduction in lesion size 48-72h after first dose) and investigator-assessed Clinical Response (CR) at Post-treatment Evaluation (PTE; 7-14 days after last dose). Overall, OMC clinical success was 85%-96% depending on endpoint/study population. Here we report efficacy outcomes by geographic region, which was a randomization stratification factor.

Material/methods: Eligible patients received OMC 100 mg IV q12h x 2 doses then 100 mg IV q24h, or LZD 600 mg IV q12h (1:1 randomization). After ≥3 days’ IV therapy, patients could switch to oral OMC 300 mg q24h or oral LZD 600 mg q12h. Treatment lasted 7-14 days. The proportion of OMC- or LZD-treated patients from each region (North America, Latin America, Eastern Europe, Western Europe) showing clinical success (ECR in the modified intent-to-treat [mITT] population and CR at PTE in the mITT and clinically evaluable [CE] populations) was determined.
Results: Among all patients with at least 1 gram-positive pathogen in each region, *Staphylococcus aureus* was the most commonly identified pathogen, although the percentage of patients with methicillin-resistant *S. aureus* (MRSA) varied (North America 31%, Eastern Europe 14%, Western Europe 0%). Clinical success by region is shown below.

Conclusions: Although statistical assessment is limited by sample sizes per region, the efficacy of OMC in treating ABSSSI was comparable to that of LZD across the geographic regions studied in the OASIS trial, with the exception of Western Europe where LZD treatment led to a higher rate of ECR.