Effects of IV/oral omadacycline versus IV/oral linezolid on lesion size and local signs of ABSSSI in the phase 3 OASIS trial

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Background: OASIS (Omadacycline in Acute Bacterial Skin and Skin Structure Infections [ABSSSI] Study) was a phase 3 trial comparing safety and efficacy of IV/oral omadacycline (OMC) to IV/oral linezolid (LZD) in adults with ABSSSI known or suspected to be caused by a gram-positive pathogen(s). OMC was well-tolerated and met the primary efficacy endpoints, Early Clinical Response (ECR) based on ≥20% lesion size reduction 48-72h after first dose and investigator-assessed Clinical Response (CR) at Posttreatment Evaluation (PTE; 7-14 days after last dose). OMC was noninferior to LZD in this trial, with an ECR of 84.8% in the modified intent-to-treat (mITT) population and a CR at PTE of 86.1% and 96.3% in the mIT and clinically evaluable (CE) populations, respectively. Here we provide trial data for treatment effects on lesion size and specific local clinical signs of ABSSSI.

Material/methods: Eligible patients were randomised 1:1 to receive OMC 100 mg IV q12h x 2 doses then 100 mg IV q24h, or LZD 600 mg IV q12h. After ≥3 days’ IV therapy, patients could transition to oral therapy (OMC 300 mg q24h or LZD 600 mg q12h); total treatment duration was 7-14 days. Local tenderness, oedema, erythema, and induration were graded (none, mild, moderate, severe) at screening, on D2-7 and D10, and at end of treatment (EOT) and PTE. At the same timepoints, lesion surface area was calculated based on the largest of either erythema, oedema, and/or induration area.

Results: In the mITT population, median baseline lesion area was 299.5 cm² (OMC) and 315.0 cm² (LZD); ≥50% reduction in lesion area was seen in 14% (OMC) and 11% (LZD) of patients on D2, 95% (OMC) and 98% (LZD) on D10, 97% (both) at EOT, and 99% (both) at PTE. Comparable results were
seen in the CE population. For both mITT (see Figure) and CE populations, OMC and LZD groups showed similar presence and severity of signs of infection at baseline, with >90% of patients having moderate or severe tenderness, oedema, erythema, and induration. Both drugs caused rapid and continual improvement in all evaluated signs and achieved similar levels of improvement (<2% of patients graded moderate or severe at PTE).

**Conclusions:** Treatment of ABSSSI with OMC and LZD led to similar and rapid reductions in skin lesion size and local signs of ABSSSI.