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A phase 3 randomized, double-blind, multi-centre study to compare the safety and efficacy of oral and IV omadacycline to linezolid for treating adult subjects with ABSSSI (the OASIS study)

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Background: Omadacycline is a novel aminomethylcycline antibiotic currently in Phase 3 development as once daily oral and intravenous (IV) monotherapy for community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections (ABSSSI). Here we report the results of the first completed pivotal Phase 3 registration study, the Omadacycline in Acute Skin and Skin Structure Infections Study (OASIS).

Material/methods: OASIS was a global randomized (1:1), double-blind, multi-center study comparing omadacycline (OMC) and linezolid (LZD) for the treatment of adults with ABSSSI known or suspected to be caused by a Gram-positive pathogen(s). Use of antibiotics within the 72h prior to dosing was excluded and enrollment of subjects with major abscess was limited to 30%. Subjects received OMC 100 mg IV q12h x 2 doses then 100 mg IV q24h, or LZD 600 mg IV q12h. Subjects could be switched

to oral therapy (OMC 300 mg q24h or LZD 600 mg q12h) after a minimum of 3 days IV therapy; total treatment duration was 7-14 days. Efficacy was evaluated 48-72 h after the first dose (Early Clinical Response [ECR] based on a reduction of lesion size by ≥20%) and at 7-14 days after the last dose (Post Therapy Evaluation [PTE] based on Investigator Assessment of Clinical Response).

Results: In the modified intent-to-treat population (mITT, all randomized subjects without a sole Gram-negative pathogen(s) at screening; N = 316 OMC, N =311 LZD) results for OMC vs LZD were: ECR 84.8% vs 85.5% [95% confidence interval (CI): –6.3, 4.9]; clinical success at PTE 86.1% vs 83.6% [95% CI: –3.2, 8.2]. In the clinically evaluable population (N = 269 OMC, N = 260 LZD) clinical response at PTE was 96.3% vs 93.5%, [95% CI: –1.0, 6.9]. Treatment-emergent adverse events (TEAEs) were reported in 48.3% vs 45.7%; serious TEAEs in 3.4% vs 2.5% and discontinuation due to TEAE in 1.9% vs 2.2% of OMC and LZD treated subjects, respectively.

Conclusions: Monotherapy with once-daily IV/oral omadacycline was non-inferior to linezolid in the treatment of adults with ABSSSI and was well tolerated.