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Efficacy of Oral and IV Omadacycline vs. Linezolid for Treating Adult Subjects With ABSSSI: Analysis by Infection Type and Pathogen in the OASIS Study

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Background: Omadacycline, a novel aminomethylcycline antibiotic, is in clinical development as a 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 efficacy results by clinical infection type and pathogen for subjects in the Omadacycline in Acute Skin and Skin Structure Infections Study (OASIS).

Material/methods: OASIS was a global Phase 3 randomized (1:1), double-blind, multi-center study comparing omadacycline (OMC) and linezolid (LZD) for the treatment of adults with ABSSSI that was known or suspected to be caused by a Gram positive pathogen(s). Randomization was stratified by geographical region and by qualifying infection type. Use of antibiotics within 72 h prior to dosing was excluded and enrollment of subjects with major abscess was limited to 30%. In both OMC and LZD groups, subjects received a minimum of 3 days of IV therapy, after which they could be switched to oral therapy at the discretion of the investigator; total treatment duration was 7-14 days.

Results: In the modified intent-to-treat (mITT) population (randomized subjects without a sole Gram-negative pathogen at screening, N = 627), infection type overall was 33% wound infection, 38% cellulitis/erysipelas, and 29% major abscess. For OMC vs LZD, clinical success at Post Therapy Evaluation (PTE, 7-14 days after the last day of treatment) was: wound infection 81% vs 81%, cellulitis/erysipelas 91% vs 85%, major abscess 85% vs 85%. In the micro-mITT population (mITT

subjects with at least 1 Gram-positive pathogen at screening, N = 455), the most frequently identified pathogens included *Staphylococcus aureus* (68% overall; of which 61% were MSSA and 39% MRSA) and *Streptococcus anginosus* group (19%), with mixed Gram-positive and Gram-negative infections in 15%. In micro-mITT for OMC vs LZD, clinical success at PTE was: *S. aureus* overall 83% vs 83%, MSSA 84% vs 82%, MRSA 83% vs 86%, *S. anginosus* 75% vs 70%, mixed infections 81% vs 76%.

Conclusions: In the treatment of adults with ABSSSI, once-daily monotherapy with IV/oral omadacycline was effective across all infection types studied and across the most frequently isolated bacterial pathogens, including MRSA.