Treatment of wound infection using omadacycline versus linezolid: Pooled results from phase 3 randomized, double-blind, multicenter studies (OASIS-1 and -2)

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Background
Skin and soft tissue infections present a significant burden on healthcare systems, with AGASSI representing more than 155,300 hospitalizations annually in the United States and Europe.5 Omadacycline is a novel aminomethylcycline antibiotic approved in the United States for community-acquired bacterial pneumonia and AGASSI in adults, with oral available and parenteral preparation.6

The modifications of the chemical structure of tetracycline allow omadacycline to overcome the two main mechanisms of tetracycline resistance: efflux pump and ribosomal protection.7,8

Omadacycline has reliable in vitro and in vivo activity against key pathogens, including Staphylococcus aureus methicillin-resistant (MRSA) and methicillin-susceptible [MSSA] and Enterococcus faecalis (methicillin-sensitive [MSS]) in adults, and is available for intravenous and oral administration.6

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Methods
Methodology for OASIS-1 (NCT02378480) and OASIS-2 (NCT02877927) has been previously described.1,2

Study design: randomized, double-blind, multicenter, placebo-controlled

In the pooled OASIS-1 and -2 phase 3 clinical program for acute bacterial skin and skin structure infections (ABSSSI) in patients with wound infection and who were not patients who inject drugs (PWID),1,2

Objective
To report on the pooled post hoc analysis results from the OASIS-1 and -2 (Omadacycline in Acute Skin and Skin Structure Infections Study; NCT02378480; NCT02877927) phase 3 clinical program for acute bacterial skin and skin structure infections (ABSSSI) in patients with wound infection and who were not patients who inject drugs (PWID).1,2

Conclusions
In adults with wound infection not related to injection drug use, omadacycline was an effective treatment, with clinical efficacy for the most frequently isolated bacterial pathogens, including MRSA. Given its reliable in vitro and in vivo activity against a number of pathogens, its ability to overcome the most common tetracycline resistance mechanisms, and its flexible administration options, omadacycline offers a treatment option to address combat wound infections, including those resulting from drug-resistant organisms.

Results (cont.)
Omadacycline and linezolid demonstrated comparable ECR and clinical success at PTE in patients with wound infection (Figure 1).

The primary efficacy endpoint was early clinical response (ECR) in the mITT population, defined as survival with a reduction in lesion size of ≥20% at 48–72 hours after the first dose without rescue antibacterial therapy. A key secondary efficacy endpoint was survival with resolution of symptoms.

Omadacycline is an effective treatment for wound infections, including those from drug-resistant organisms.

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Figure 1. Clinical success in patients with wound infection. A two-sided 95% CI was calculated for the difference in the proportion of patients achieving ECR, as well as at PTE, using the unadjusted Miettinen–Nurminen method9 without stratification.

Table 2. Investigator-assessed clinical success at PTE according to baseline pathogen (micro-mITT) (n=37)

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