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Complicated skin and skin structure infections treated in the telavancin observational use registry (TOUR™)

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Background: Telavancin (TLV) is a lipoglycopeptide antibacterial active against a wide range of Gram-positive pathogens, including methicillin-sensitive and -resistant *Staphylococcus aureus* (MSSA and MRSA). TLV, administered intravenously once daily, is approved for treatment of complicated skin and skin structure infections (cSSSI) in the US, Canada, and Russia. TLV also demonstrated efficacy in treating patients with cSSSI who had concurrent *S. aureus* bacteraemia. Resistant Gram-positive organisms are a major issue when treating cSSSI, and it is important to characterise effective treatment options for these infections.

Methods: The Telavancin Observational Use Registry (TOUR™) is an ongoing multicentre, study designed to characterise infection types, pathogens, and outcomes of patients treated with TLV in

clinical practice through medical chart review. Thirty-seven US sites reported data from 593 patients between January 1, 2015 and September 30, 2016. Patient demographics, antibiotic treatments, pathogens, dosage, duration of therapy, clinical outcome, and adverse events (AEs) were analysed in the subset with cSSSI infections. Clinical success was defined by investigator assessment of information in the medical chart.

Results: There were 279 patients treated for cSSSI. Patients were a median age of 56 years (range 18−88), 153 (55.0%) were female, 241 (86.0%) were white, 30 (11.0%) were African American, and the median body mass index was 30.7 kg/m^2 (range 14.9−105.2 kg/m^2). Predominant subtypes of cSSSI included cellulitis (n = 141, 50.5%), abscess (n = 62, 22.2%), and surgical wound (n = 43, 15.4%). Of the 194 patients (69.5%) in whom an organism was identified, the most common pathogens were MRSA (n = 84, 30.1%), MSSA (n = 26, 9.3%), and coagulase-negative staphylococcus (n = 18, 6.5%). The median TLV dose was 750 mg/day at a median of 10.0 mg/kg, and median treatment duration was 10 days (range 1−185 days). Outpatient treatment was reported for 141 patients (50.5%). Overall, 210 (75.3%) patients had a positive clinical response (cured or improved to step-down oral therapy), 26 (9.3%) failed treatment, and 43 (15.4%) were not evaluable (non-evaluable, indeterminate, missing data, or undocumented). AEs were reported by 29 patients, 3 patients reported a serious AE, 20 patients discontinued TLV due to an AE, and there were no deaths.

Conclusions: Once-daily TLV treatment produced high clinical success rates in patients with cSSSI. These preliminary real-world data from TOUR™ reinforce TLV efficacy and safety results observed in US clinical trials, and validate ongoing use of TLV for patients with *S. aureus* cSSSI in both the inpatient and outpatient setting.