Clinical Experience with Telavancin for the Treatment of Patients with Bone and Joint Infections: Preliminary Results from the Telavancin Observational Use Registry (TOUR™)

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INTRODUCTION

• Bone and joint infections, commonly caused by Gram-positive pathogens, including Staphylococcus aureus, are frequently difficult to treat with existing antimicrobial therapies (1–3).
• Treatment failures have been associated with Gram-positive pathogens, including methicillin-resistant Staphylococcus aureus (MRSA), methicillin-resistant S. epidermidis (MRSE), and vancomycin-resistant enterococci (VRE) (4).
• Inactive or insufficient concentrations of antibiotics reaching the site of infection reduce the probability of successful antimicrobial therapy (5).
• Telavancin (VOYAGER®; TheraVance Biopharma US, Inc.) is a novel, synthetic peptide–lipid conjugate that directly inhibits bacterial cell wall synthesis via a mechanism that is distinct from that of currently available antibiotics (6).
• Approval for the use of telavancin was based on clinical experience with chronic osteomyelitis and uncomplicated skin and skin structure infections (7).

METHODS

TOUR™ Design and Methodology

• TOUR™ is an open-label, prospective, observational study of cases identified in patients treated at 1000 sites across the U.S.
• Any patient who received at least one dose of IV telavancin from January 1, 2008, to December 31, 2008, was eligible for inclusion.
• Participants had community-acquired infections and could be from any age and any setting.
• Telavancin clinical study was included.
• All treatment decisions and clinical assessments were at the discretion of the treating physician.
• Data were collected on demographics, primary infection type, baseline characteristics, disease course, and outcomes.

RESULTS

• At a preliminary cut-off date of September 14, 2009, 43 sites with at least 1000 patients (Days 14 to 28) and 94 sites with at least 1000 patients (6–12 weeks) were collected.
• Tour™ database contains 12,083 patients with a median age of 57 years, 67% male, and 11% (n = 1394) pediatric patients.
• Characteristics: 36% Staphylococcus aureus, 28% Staphylococcus epidermidis (29% MRSE), and 19% Streptococcus spp.
• MRSA was 38% in S. aureus and 14% in S. epidermidis (Table 2).
• Mean age was 57 years, median of 26 days (range, 1–201 days), and patients were treated for 21 days (range, 1–187 days).
• Infectious disease consults were obtained in only 12% of cases.
• Proportion of patients who received telavancin for at least 14 days was 52%.
• The majority of patients (64% in 237/1394) were treated as outpatients.
• Infections were classifiable as ECTDI ≥72% (2008 patients had positive clinical diagnosis, 8.3% were ≤50 treated), ECTDI ≤50 or ≥72% treated or ≥50 treated with a positive clinical diagnosis, ≥72% treated or ≥50 treated with a negative clinical diagnosis, ≥50 treated or ≥72% treated.
• Clinical diagnosis was made in 58% of cases.
• A sign of the 36% of patients were treated 14 days or longer, 0.0% of patients were treated 14 days or longer for 14 days or longer, and 0.0% of patients were treated ≥72% treated for 14 days or longer.
• Median days to cure was 21 days, and 95% of patients were cured at 21 days.
• Outcomes: 31% failure, 8% end of therapy clinical failure, 10% clinical failure, 50% clinical cure.
• In the event that clinical failure was defined as cure.

CONCLUSIONS

• Telavancin, administered once daily, produced positive clinical outcomes in the majority of patients treated for bone and joint infections with response assessment of ECTDI ≥72%, 78%.
• Most patients received telavancin as a single-agent therapy, which was mainly administered in an outpatient setting.
• Telavancin was administered at a median daily dose of 8.2 mg/kg, median total daily dose of 750 mg, and for a median of 26 days.
• No new safety signals were identified in this patient subset.
• These preliminary, real-world data suggest that once-daily IV Telavancin may represent an alternative treatment option for patients with bone and joint infections (completed TOUR™ data will be available and reported at a later date).

REFERENCES

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ACKNOWLEDGMENTS

The research and publication of this report was supported by TheraVance Biopharma US, Inc. Data collection and quality control was provided by Phamaris, LLC, Seattle, WA (now part of TheraVance Biopharma US, Inc.), and Medidata Solutions, Inc., London, UK (now part of TheraVance Biopharma US, Inc.).