Background: Dalbavancin is a lipoglycopeptide antibiotic with activity against methicillin-resistant Staphylococcus aureus (MRSA), methicillin-susceptible S. aureus (MSSA), and many other Gram-positive pathogens. Several randomized, placebo-controlled clinical trials have been completed in MRSA ulcer disease, skin or catheter-associated infections. Over the last ten years, nine phase two or three clinical trials have been performed for the treatment of skin or catheter associated infections. The purpose of this analysis is to review the safety profile of dalbavancin from the phase 2/3 clinical trial programs.

Methods: We analyzed the safety data obtained from all phase 2 and phase 3 clinical trials of dalbavancin. The dalbavancin clinical development program was international in scope and included 2,555 patients. Diagnoses included MRSA skin and soft tissue infections, MRSA endocarditis, MRSA osteomyelitis, and catheter-related infections. The duration and time to onset of TEAE’s was similar in dalbavancin and comparator groups. The most common TEAEs in the dalbavancin and comparator groups were nausea, vomiting, headache, and diarrhea, all relatively self-limited adverse events. The incidences of subjects with death, SAEs, and premature discontinuation were similar in the dalbavancin and comparator regimens. The long half-life did not affect either duration or time of onset of adverse events, contrary to expectations. An infrequently dosed therapy such as dalbavancin might be predicted to result in fewer serious adverse events or deaths, versus a more frequently dosed comparator. dalbavancin is safe and well tolerated.

Results: There were 2,379 patients receiving dalbavancin, 1,518 (85.0%) patients receiving study medication and 861 (9.7%) patients discontinued due to TEAE’s. The most common TEAEs were nausea, vomiting, headache, and diarrhea.

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