Dalvance® (dalbavancin) – Expanded indication

- On July 23, 2021, AbbVie announced the FDA approval of Dalvance (dalbavancin), for the treatment of adult and pediatric patients with acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and methicillin-resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus anginosus* group (including *S. anginosus*, *S. intermedius*, *S. constellatus*) and *Enterococcus faecalis* (vancomycin susceptible isolates).
    - Dalvance was previously approved in adults only.
- The approval of Dalvance for the expanded indication was based on an open-label, randomized, actively controlled study in 191 pediatric patients with ABSSSI, not known or expected to be caused exclusively by Gram-negative organisms. Patients were randomized to receive either Dalvance single-dose regimen, Dalvance two-dose regimen, or comparator. The comparator regimens included intravenous (IV) vancomycin for methicillin-resistant Gram-positive infections, or IV oxacillin or flucloxacillin for methicillin-susceptible Gram-positive infection. Primary endpoints included: (1) early clinical response at 48 to 72 hours, defined as ≥ 20% reduction in lesion size compared to baseline and no receipt of rescue antibacterial therapy; and (2) clinical cure, defined as resolution of the clinical signs and symptoms of infection, when compared to baseline, and no additional antibacterial treatment for the disease under study.
    - The proportion of patients with early clinical response was 97.3% in the Dalvance single-dose arm, 93.6% in the Dalvance two-dose arm, and 86.7% in the comparator arm. The difference in responder rates between the Dalvance single-dose and comparator arms was 10.7% (97.5% CI: -1.7, 31.6). The difference in responder rates between the Dalvance two-dose and comparator arms was 6.9% (97.5% CI: -6.4, 27.7).
    - The clinical cure rate at the test of cure visit was 94.7% in the Dalvance single-dose arm, 92.3% in the Dalvance two-dose arm and 100% in the comparator arm. The difference in cure rates between the Dalvance single-dose and comparator arms was -5.3% (97.5% CI: -15.1, 10.5). The difference in cure rates between the Dalvance two-dose and comparator arms was -7.7% (97.5% CI: -17.9, 8.3).
- The most common adverse reaction (> 1%) with Dalvance use in pediatric patients was pyrexia.
- The recommended dosage regimen of Dalvance in pediatric patients with estimated creatinine clearance (CLcr) 30 mL/min/1.73m^2 and above is a single dose regimen based on the age and weight of the pediatric patient. Dalvance is administered over 30 minutes by IV infusion.
    - In pediatric patients from birth to less than 6 years, the recommended dosage is 22.5 mg/kg (maximum 1500 mg). In pediatric patients 6 to less than 18 years of age, the recommended dosage is 18 mg/kg (maximum 1500 mg).
    - Refer to the Dalvance drug label for adult dosing.