Sivextro® (tedizolid) – Expanded indication

- On June 19, 2020, the FDA approved Merck's Sivextro (tedizolid), in adult and pediatric patients 12 years of age and older, for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), and *Enterococcus faecalis*.
    - Sivextro was previously approved for this indication in adult patients.
- The approval of Sivextro for the expanded indication was based on a randomized, single blind, active-controlled study of 120 pediatric patients with clinically documented ABSSSI. Patients received Sivextro or a comparator therapy (selected by the investigator from a list of 5 intravenous and 4 oral comparators per local standard of care). Clinical success was assessed at the test of cure visit (day 18 to 25). Early clinical response, defined as at least a 20% reduction in lesion size at 48 to 72 hours after start of treatment, was also assessed.
    - Clinical success at test of cure was 96.7% (88/91) in the Sivextro group and 93.1% (27/29) in the comparator group (difference 3.6%; 95% CI: -6.3, 13.5).
    - Early clinical response at 48 to 72 hours was 92.3% in the Sivextro group and 96.6% in the comparator group (difference -4.2%; 95% CI: -12.9, 4.4).
- The most common adverse reactions (≥ 2%) with Sivextro use in pediatric patients were phlebitis and increased hepatic transaminases.
- The recommended dose of Sivextro for pediatric and adult patients is 200 mg administered once daily for six (6) days either orally (with or without food) or as an intravenous infusion.