Kimyrsa™ (oritavancin) – New drug approval

- On March 15, 2021, Melinta Therapeutics announced the FDA approval of Kimyrsa (oritavancin), for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms:
    - Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus group (includes S. anginosus, S. intermedius, and S. constellatus), and Enterococcus faecalis (vancomycin-susceptible isolates only).
- Kimyrsa is a single-dose, long-acting lipoglycopeptide intravenous (IV) antibiotic. It is infused over 1 hour. IV oritavancin is also available under the brand name Orbactiv®, but that formulation requires an infusion over 3 hours. Orbactiv and Kimyrsa share the same indication.
- The efficacy and safety of Kimyrsa were established in the SOLO clinical studies with Orbactiv. The approval of Kimyrsa is based on the results of an open-label, pharmacokinetics study, which compared Kimyrsa administered over 1 hour to Orbactiv administered over 3 hours for the treatment of adult patients with ABSSSI.
- Contraindications for Kimyrsa include:
    - Use of IV unfractionated heparin sodium is contraindicated for 120 hours (5 days) after Kimyrsa administration because the activated partial thromboplastin time test results may remain falsely elevated for up to 120 hours (5 days) after Kimyrsa administration.
    - In patients with known hypersensitivity to oritavancin products.
- Warnings and precautions for Kimyrsa include coagulation test interference, hypersensitivity, infusion related reactions, *Clostridioides difficile*-associated diarrhea, potential risk of bleeding with concomitant use of warfarin, osteomyelitis, and development of drug resistant bacteria.
- The most common adverse reactions (≥ 3%) in patients treated with oritavancin products were headache, nausea, vomiting, limb and subcutaneous abscesses, and diarrhea. The adverse reactions occurring in ≥ 2 patients receiving Kimyrsa were hypersensitivity, pruritus, chills and pyrexia.
- The recommended dosage of Kimyrsa is 1,200 mg administered as a single dose by IV infusion over 1 hour in patients 18 years and older.
- Melinta Therapeutics plans to launch Kimyrsa in summer 2021. Kimyrsa will be available as a 1,200 mg lyophilized powder in a single-dose vial for reconstitution.