Rezzayo™ (rezafungin) – New drug approval

- On March 22, 2023, Cidara Therapeutics and Melinta Therapeutics announced the FDA approval of Rezzayo (rezafungin), in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis.
    - Approval of this indication is based on limited clinical safety and efficacy data for Rezzayo.
    - Rezzayo has not been studied in patients with endocarditis, osteomyelitis, and meningitis due to *Candida*.
- Rezzayo is a novel echinocandin antifungal.
- The efficacy of Rezzayo was established in a randomized, double-blind study in patients with candidemia and/or invasive candidiasis. Patients were randomized to receive Rezzayo or caspofungin. The modified intent-to-treat (mITT) population included 187 patients with a culture positive for *Candida* species within 4 days before randomization and who received at least one dose of study drug. Efficacy was assessed by all-cause mortality at day 30. Additional efficacy outcomes included global cure (mycological eradication/presumed eradication, clinical cure, and radiological cure) and investigator's assessment of clinical cure.
    - All-cause mortality at day 30 was 23.7% and 21.3% for Rezzayo and caspofungin, respectively (treatment difference 2.4, 95% CI: -9.7, 14.4).
    - Global cure at day 14 was achieved in 59.1% and 60.6% for Rezzayo and caspofungin, respectively (treatment difference -1.5, 95% CI: -15.4, 12.5).
    - Clinical cure at day 30 was achieved 54.8% and 55.3% for Rezzayo and caspofungin, respectively (treatment difference -0.5, 95% CI: -14.6, 13.7).
- Warnings and precautions for Rezzayo include infusion-related reactions, photosensitivity, and hepatic adverse reactions.
- The most common adverse reactions (≥ 5%) with Rezzayo use were hypokalemia, pyrexia, diarrhea, anemia, vomiting, nausea, hypomagnesemia, abdominal pain, constipation, and hypophosphatemia.
- The recommended dose of Rezzayo is once weekly by intravenous infusion, with an initial 400 mg loading dose, followed by a 200 mg dose once weekly thereafter.
    - The safety of Rezzayo has not been established beyond 4 weekly doses.
- Melinta Therapeutics plans to launch Rezzayo in Summer 2023. Rezzayo will be available as a 200 mg as a solid (cake or powder) in a single-dose vial for reconstitution.