Inpefa® (sotagliflozin) – New drug approval

- On May 26, 2023, Lexicon Pharmaceuticals announced the FDA approval of Inpefa (sotagliflozin), to reduce the risk of cardiovascular (CV) death, hospitalization for heart failure, and urgent heart failure visit in adults with:
    - Heart failure; or
    - Type 2 diabetes mellitus (T2DM), chronic kidney disease (CKD), and other CV risk factors
- Inpefa is a sodium-glucose cotransporter 2 (SGLT2) inhibitor.
- The efficacy of Inpefa was established in SOLOIST, a randomized, double-blind, placebo-controlled study in 1,222 patients with T2DM who had been admitted to the hospital, a heart failure unit, infusion center, or emergency department. Patients were randomized to Inpefa or placebo and patients initiated treatment in the hospital or within a median of 2 days following hospital discharge. The primary endpoint was total occurrence of CV death, hospitalization for heart failure, and urgent heart failure visit.
    - The event rate per 100 patient-years for the primary endpoint was 51.3 and 76.4 for Inpefa and placebo, respectively (hazard ratio [HR] 0.67, 95% CI: 0.53, 0.85; p = 0.001).
- In addition, Inpefa was evaluated in SCORED, a randomized, double-blind, placebo-controlled study in 10,584 patients with T2DM, CKD, and additional CV risk factors. Patients were randomized to Inpefa and placebo. The primary endpoint was total occurrence of CV death, hospitalization for heart failure, and urgent heart failure visit.
    - The event rate per 100 patient-years for the primary endpoint was 5.6 and 7.5 for Inpefa and placebo, respectively (HR 0.75, 95% CI: 0.63, 0.88; p < 0.001).
- Warnings and precautions for Inpefa include diabetic ketoacidosis in patients with type 1 diabetes mellitus and other ketoacidosis; volume depletion; urosepsis and pyelonephritis; hypoglycemia with concomitant use with insulin and insulin secretagogues; necrotizing fasciitis of the perineum (Fournier's gangrene); genital mycotic infections; positive urine glucose test; and interference with 1,5 anhydroglucitol assay.
- The most common adverse reactions (≥ 5%) with Inpefa use were urinary tract infection, volume depletion, diarrhea, and hypoglycemia.
- The recommended starting dose of Inpefa is 200 mg orally once daily not more than one hour before the first meal of the day.
    - The dose should be up-titrated after at least 2 weeks to 400 mg orally once daily as tolerated. Down-titrate to 200 mg as necessary.
- Lexicon plans to set the wholesale acquisition cost for Inpefa comparable to existing branded heart failure medications.
- Lexicon plans to launch Inpefa by the end of June 2023. Inpefa will be available as a 200 mg and 400 mg tablet.