Elepsia™ XR (levetiracetam) – New drug approval

- On December 20, 2018, the FDA approved Sun Pharma's Elepsia XR (levetiracetam) extended-release tablets, as adjunctive therapy for the treatment of partial onset seizures in patients 12 years of age and older.
- Elepsia XR was originally approved in 2015; however, the FDA rescinded the approval, citing that the compliance status of the manufacturing facility was not acceptable on the date of approval.
- Extended-release levetiracetam is also available generically as a tablet (500 mg and 750 mg) and approved for the same indication as Elepsia XR.
- The approval of Elepsia XR was based upon bioavailability studies comparing levetiracetam extended-release tablets to Elepsia XR extended-release tablets and the clinical studies using immediate-release and extended-release levetiracetam tablets as adjunctive therapy for the treatment of partial onset seizures.
- Elepsia XR is contraindicated in patients with known hypersensitivity to levetiracetam; angioedema and anaphylaxis have occurred.
- Warnings and precautions of Elepsia XR include behavioral abnormalities and psychotic symptoms, suicidal behavior and ideation, somnolence and fatigue, anaphylaxis and angioedema, serious dermatological reactions, coordination difficulties, withdrawal seizures, hematologic abnormalities, and seizure control during pregnancy.
- The most common adverse reactions (≥ 5% and > placebo) of Elepsia XR use were somnolence and irritability.
- The recommended initial dose of Elepsia XR is 1000 mg orally once daily. The once daily dosage may be adjusted in increments of 1000 mg every 2 weeks, to a maximum recommended daily dose of 3000 mg/day.
- Sun Pharma's launch plans for Elepsia XR are pending. Elepsia XR will be available as 1000 mg and 1500 mg extended-release tablets.