Sezaby™ (phenobarbital) – New orphan drug approval

- On November 18, 2022, Sun Pharma announced the FDA approval of Sezaby (phenobarbital), for the treatment of neonatal seizures in term and preterm infants.

- Sezaby is a benzyl alcohol-free and propylene glycol-free formulation of phenobarbital sodium powder for injection.

- The efficacy of Sezaby was established in a randomized, double-blind, active-controlled study in 94 neonates who were experiencing seizures. Patients who experienced electrographically-confirmed seizures were randomized to receive either intravenous phenobarbital or levetiracetam. The primary endpoint was the percentage of neonates whose seizures were terminated for at least 24 hours without the need for a second drug for the treatment of their seizures.

    — The primary endpoint was met in 73% of patients treated with phenobarbital vs. 25% with levetiracetam ($p < 0.001$).

- Sezaby carries boxed warnings for risks from concomitant use with opioids; dependence and withdrawal reactions after use of Sezaby for a longer duration than recommended; and abuse, misuse, and addiction with unapproved use in adolescents and adults.

- Sezaby is contraindicated in patients with acute porphyrias or a history of hypersensitivity reaction to phenobarbital or other barbiturates.

- Additional warnings and precautions for Sezaby include respiratory depression or insufficiency; serious dermatologic reactions; drug reaction with eosinophilia and systemic symptoms/ multiorgan hypersensitivity; hypersensitivity reactions; exacerbation of porphyria; infusion site reactions; QT prolongation; embryofetal toxicity with unapproved use in adolescents and adults; neonatal adverse reactions from unapproved maternal phenobarbital use; sedation, respiratory depression, and withdrawal in neonates exposed to phenobarbital through breast milk; and suicidal behavior and ideation with unapproved use in adolescents and adults.

- The most common adverse reactions (> 5%) with Sezaby use were abnormal respiration, sedation, feeding disorder, and hypotension.

- The recommended dosage of Sezaby in neonates consists of a loading dose(s) followed by maintenance dosage. Sezaby is administered by intravenous infusion (over 15 minutes) into a large peripheral vein to avoid local tissue toxicity.

    — Refer to the Sezaby drug label for complete dosing and administration recommendations.

- Sun Pharma plans to launch Sezaby in the fourth quarter of fiscal year 2023. Sezaby will be available as a 100 mg lyophilized powder in a single-dose vial for reconstitution.