Eprontia™ (topiramate) – New drug approval

- On November 8, 2021, Azurity Pharmaceuticals announced the FDA approval of Eprontia (topiramate):
    - As initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older.
    - As adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older.
    - For the preventive treatment of migraine in patients 12 years and older.

- Eprontia is the first ready-to-use liquid formulation of topiramate.

- The safety and efficacy of Eprontia are based on the relative bioavailability of Eprontia compared to topiramate sprinkle capsules in healthy subjects.

- Warnings and precautions for Eprontia include acute myopia and secondary angle closure glaucoma syndrome; visual field defects; oligohidrosis and hyperthermia; metabolic acidosis; suicidal behavior and ideation; cognitive/neuropsychiatric adverse reactions; fetal toxicity; withdrawal of antiepileptic drugs; serious skin reactions; hyperammonemia and encephalopathy (without and with concomitant valproic acid use); kidney stones; and hypothermia with concomitant valproic acid use.

- The most common adverse reactions (≥ 10% more frequent than placebo or low-dose topiramate) with Eprontia use for epilepsy in adult and pediatric patients are paresthesia, anorexia, weight loss, speech disorders/related speech problems, fatigue, dizziness, somnolence, nervousness, psychomotor slowing, abnormal vision and fever.

- The most common adverse reactions (≥ 5% more frequent than placebo) with Eprontia use for migraine in adult and pediatric patients are paresthesia, anorexia, weight loss, difficulty with memory, taste perversion, diarrhea, hypoesthesia, nausea, abdominal pain and upper respiratory tract infection.

- Eprontia's initial dose, titration, and recommended maintenance dose varies by indication and age group. Refer to the Eprontia drug label for complete dosing and administration recommendations.

- Azurity Pharmaceuticals plans to launch Eprontia before year end. Eprontia will be available as a 25 mg/mL oral solution.