Zonisade™ (zonisamide) – New drug approval

- On July 18, 2022, Azurity Pharmaceuticals announced the FDA approval of Zonisade (zonisamide), as adjunctive therapy for the treatment of partial-onset seizures in adults and pediatric patients 16 years and older.

- Zonisamide is currently available generically as an oral capsule as an adjunctive therapy in the treatment of partial seizures in adults with epilepsy.

- The efficacy of Zonisade is based upon a bioavailability study comparing Zonisade oral suspension to zonisamide capsules in healthy subjects.

- Warnings and precautions for Zonisade include potentially fatal reactions to sulfonamides; serious skin reactions; serious hematologic events; drug reaction with eosinophilia and systemic symptoms/multi-organ hypersensitivity; oligohidrosis and hyperthermia in pediatric patients; acute myopia and secondary angle closure glaucoma; suicidal behavior and ideation; metabolic acidosis; seizures on withdrawal of antiepileptic drugs; teratogenicity; cognitive/neuropsychiatric adverse reactions; hyperammonemia and encephalopathy; kidney stones; effect on renal function; and status epilepticus.

- The most common adverse reactions (an incidence at least 4% greater than placebo) with Zonisade use were somnolence, anorexia, dizziness, ataxia, agitation/irritability, and difficulty with memory and/or concentration.

- The recommended initial dosage of Zonisade is 100 mg orally daily given once or twice per day. The dosage may be increased by 100 mg daily every two weeks, based on clinical response and tolerability, to 400 mg daily. Patients who are tolerating Zonisade at 400 mg daily and require further reduction of seizures may be increased up to a maximum dosage of 600 mg daily. However, evidence from controlled trials shows no suggestion of increasing response above 400 mg/day,

- Azurity Pharmaceuticals' launch plans for Zonisade are pending. Zonisade will be available as a 100 mg/ 5 mL oral suspension.