Lumryz™ (sodium oxybate) – New orphan drug approval

- On May 1, 2023, Avadel announced the FDA approval of Lumryz (sodium oxybate), for the treatment of cataplexy or excessive daytime sleepiness in adults with narcolepsy.
    - Lumryz was previously granted tentative approval in July 2022.
- Lumryz is the first once nightly sodium oxybate medication. Other sodium oxybate products, Xyrem® and generics and Xywav™ require twice-nightly dosing.
- The efficacy of Lumryz was established in a double-blind, randomized, placebo-controlled, two-arm study in 212 patients with narcolepsy. There was a three-week screening period, a 13-week treatment period including up-titration over a period of eight weeks, five weeks of stable dosing at 9 g/night, and a one-week follow-up period. The three co-primary endpoints were the Maintenance of Wakefulness Test (MWT), Clinical Global Impression-Improvement (CGI-I), and mean change in weekly cataplexy attacks.
    - A statistically significant improvement was seen on the MWT, CGI-I, and mean weekly cataplexy attacks, for the 6 g (week 3), 7.5 g (week 8), and 9 g (week 13) dose of Lumryz vs. placebo.
- Lumryz carries a boxed warning for central nervous system depression; abuse and misuse; and is available only through a restricted program called the Lumryz Risk Evaluation and Mitigation Strategy (REMS).
- Lumryz is contraindicated in combination with sedative hypnotics and alcohol and in patients with succinic semialdehyde dehydrogenase deficiency.
- Additional warnings and precautions for Lumryz include respiratory depression and sleep-disordered breathing; depression and suicidality; other behavioral or psychiatric adverse reactions; parasomnias; use in patients sensitive to high sodium intake.
- The most common adverse reactions (≥ 5% and greater than placebo) with Lumryz use were nausea, dizziness, enuresis, headache, and vomiting.
- The recommended starting dose of Lumryz is 4.5 grams (g) once per night orally. The dosage should be increased by 1.5 g per night at weekly intervals to the recommended dosage range of 6 g to 9 g once per night orally. The dosage may be gradually titrated based on efficacy and tolerability.
    - Doses higher than 9 g per night have not been studied and should not ordinarily be administered.
- Avadel plans to launch Lumryz in early June 2023. Lumryz will be available as a powder in packets of 4.5 g, 6 g, 7.5 g, or 9 g for extended-release oral suspension.