Fintepla® (fenfluramine) – New indication

- On March 28, 2022, UCB announced the FDA approval of Fintepla (fenfluramine), for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older.
    - Fintepla is a Schedule IV controlled substance.
- Fintepla is also approved for the treatment of seizures associated with Dravet syndrome.
- LGS is a severe childhood-onset developmental and epileptic encephalopathy characterized by drug-refractory seizures. LGS affects an estimated 30,000 to 50,000 patients in the U.S.
- The approval of Fintepla for the new indication was based on a randomized, double-blind, placebo-controlled study in 263 patients 2 to 35 years of age with LGS. Patients received Fintepla 0.7 mg/kg/day, Fintepla 0.2 mg/kg/day, or placebo. The primary endpoint was the median percent change from baseline in the frequency of drop seizures per 28 days during the combined 14-week titration and maintenance periods (ie, treatment period).
    - The median percent change from baseline in the frequency of drop seizures per 28 days was -23.7% with Fintepla 0.7 mg/kg/day vs. -8.7% with placebo (p = 0.0037).
    - The median percent reduction from baseline in drop seizure frequency per 28 days for Fintepla 0.2 mg/kg/day did not reach statistical significance vs. placebo.
- Fintepla carries a boxed warning for valvular heart disease and pulmonary arterial hypertension.
- The most common adverse reactions (≥ 10% and greater than placebo) with Fintepla use for LGS were diarrhea, decreased appetite, fatigue, somnolence, and vomiting.
- The initial starting dosage of Fintepla for patients with LGS is 0.1 mg/kg twice daily, which should be increased weekly based on tolerability. Refer to the drug label for the recommended titration schedule. Patients with LGS not on concomitant Diacomit® (stiripentol) who are tolerating Fintepla should be titrated to the recommended maintenance dosage of 0.35 mg/kg twice daily (maximum daily dosage of 26 mg). Patients with LGS taking concomitant Diacomit plus clobazam who are tolerating Fintepla should be titrated to the recommended maintenance dosage of 0.2 mg/kg twice daily (maximum daily dosage of 17 mg).
    - Refer to the Fintepla drug label for dosing for Dravet syndrome.

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