Vimpat® (lacosamide) – New indication

- On November 17, 2020, UCB announced the FDA approval of Vimpat (lacosamide), as adjunctive therapy in the treatment of primary generalized tonic-clonic (PGTC) seizures in patients 4 years of age and older.
    - Vimpat is a Schedule V controlled substance.
- The FDA also approved all three Vimpat formulations for treatment of partial-onset seizures in patients 4 years of age and older.
    - Vimpat tablets and oral solution were already approved to treat partial-onset seizures in adults and children four years and older. Vimpat injection was previously approved for the treatment of partial-onset seizures only in adult patients (17 years of age and older).
- The approval of Vimpat for the new indication was based on a 24-week, double blind, randomized, placebo-controlled study in 242 patients 4 years of age and older with idiopathic PGTC seizures. The study consisted of a 12-week historical baseline period, a 4-week prospective baseline period, and a 24-week treatment period (which included a 6-week titration period and an 18-week maintenance period). The primary efficacy endpoint was the time to second PGTC seizure during the 24-week treatment period.
    - The risk of developing a second PGTC seizure was statistically significantly lower in Vimpat group than in the placebo group during the 24-week treatment period (hazard ratio 0.548, 95% CI: 0.381, 0.788, p = 0.001), with the corresponding risk reduction being 45.2%.
- The recommended initial adult dosage for adjunctive therapy for PGTC seizures is 50 mg orally twice daily. The maximum recommended dosage is 200 mg twice daily. The recommended dosage for pediatric patients is based on body weight and is administered orally twice daily.
    - Dosage should be increased based on clinical response and tolerability, no more frequently than once per week.
    - Vimpat injection may be used when oral administration is temporarily not feasible. Vimpat injection can be administered intravenously with the same dosing regimens described for oral dosing. The clinical study experience of intravenous Vimpat is limited to 5 days of consecutive treatment.
    - Refer to the Vimpat drug label for complete dosing and administration information and recommendations for partial-onset seizures