Wakix® (pitolisant) – Expanded indication

- On June 24, 2024, Harmony Biosciences announced the FDA approval of Wakix (pitolisant), for the treatment of excessive daytime sleepiness (EDS) in pediatric patients 6 years of age and older with narcolepsy.
- Wakix is also approved for the treatment of EDS or cataplexy in adult patients with narcolepsy.
- The approval of Wakix for the expanded indication was based on a randomized, double-blind, placebo-controlled study in 110 pediatric patients 6 years of age and older with narcolepsy. Patients were randomized to Wakix or placebo.
    - Wakix demonstrated statistically significantly greater improvement on the least square mean change from baseline to the end of treatment in final Pediatric Daytime Sleepiness Scale (PDSS) total score compared to placebo, of -3.41 points (95% CI: -5.52, -1.31).
- The most common adverse reactions (≥ 5% and greater than placebo) with Wakix use in pediatric patients were headache and insomnia.
- The recommended starting dosage of Wakix for the treatment of EDS in pediatric patients 6 years and older is 4.45 mg administered orally once daily in the morning upon wakening. The dose should be titrated as follows:
    - Week 1: Initiate with a dosage of 4.45 mg (one 4.45 mg tablet) once daily
    - Week 2: Increase dosage to 8.9 mg (two 4.45 mg tablets) once daily
    - Week 3: Increase dosage to 17.8 mg (one 17.8 mg tablet) once daily, which is the maximum recommended dosage for patients weighing < 40 kg
    - Week 4: For patients weighing ≥ 40 kg, may increase to the maximum recommended dosage of 35.6 mg (two 17.8 mg tablets) once daily.
- Refer to the Wakix drug label for adult dosing.