Wakix® (pitolisant) – Expanded indication

- On October 13, 2020, Harmony Biosciences announced the FDA approval of Wakix (pitolisant), for the treatment of cataplexy in adult patients with narcolepsy.
    - Wakix is also approved for excessive daytime sleepiness (EDS) in adult patients with narcolepsy.
- The approval of Wakix for the expanded indication was based on two, randomized, double-blind, placebo-controlled studies in 154 adult patients with cataplexy. In the first study, which was conducted in patients with narcolepsy and cataplexy, the primary endpoint was the change in geometric mean number of cataplexy attacks per week from baseline to the average of the 4-week stable dosing period. The second study was conducted in patients with narcolepsy and included a subset of patients with cataplexy. A secondary endpoint in the study was the change from baseline in geometric mean daily rate of cataplexy at week 8.
    - In the first study, the weekly rate of cataplexy was 9.1 at baseline and the final rate was 2.3 for Wakix vs. 7.3 to 4.5 for placebo (rate ratio [RR] 0.51, 95% CI: 0.44, 0.60).
    - In the second study, the weekly rate of cataplexy was 0.4 at baseline and the final rate was 0.1 for Wakix vs. 0.3 to 0.2 for placebo (RR 0.07, 95% CI: 0.01, 0.36).
- The recommended dosage range for Wakix is 17.8 mg to 35.6 mg administered orally once daily in the morning upon wakening. The dosage should be titrated as follows:
    - Week 1: Initiate with a dosage of 8.9 mg (two 4.45 mg tablets) once daily
    - Week 2: Increase dosage to 17.8 mg (one 17.8 mg tablet) once daily
    - Week 3: May increase to the maximum recommended dosage of 35.6 mg (two 17.8 mg tablets) once daily.
    - The dose may be adjusted based on tolerability.
    - It may take up to 8 weeks for some patients to achieve a clinical response.