Nurtec® ODT (rimegepant) – New indication

- On May 27, 2021, Biohaven announced the FDA approval of Nurtec ODT (rimegepant), for the preventive treatment of episodic migraine in adults.
- Nurtec ODT is also approved for the acute treatment of migraine with or without aura in adults.
- Nurtec ODT is the first oral calcitonin gene-related peptide (CGRP) antagonist approved to prevent migraine.
- The drug label was also expanded to include the use of Nurtec ODT up to 18 doses/month, allowing for both acute and preventive therapy in the same patient.
- The approval of Nurtec ODT for the new indication was based on a randomized, double-blind, placebo-controlled study in adult patients with at least a 1-year history of migraine (with or without aura). In the study, a different oral dosage formulation of rimegepant was used. Patients were randomized to rimegepant or placebo and were allowed to use acute headache treatments as needed. The primary efficacy endpoint was the change from baseline in the mean number of monthly migraine days (MMDs) during weeks 9 through 12 of the double-blind treatment phase.
    - The change from baseline in MMDs was -4.3 with rimegepant vs. -3.5 with placebo (difference of -0.8, p-value = 0.010).
- The most common adverse reactions (≥ 2% and ≥ 1% higher than placebo) with Nurtec ODT use for preventative treatment of episodic migraine were nausea and abdominal pain/dyspepsia.
- The recommended dose of Nurtec ODT for preventive treatment of episodic migraine is 75 mg orally every other day.
- The recommended dose of Nurtec ODT for acute treatment of migraine is 75 mg, as needed. The maximum dose in a 24-hour period is 75 mg.