Qulipta® (atogepant) – Expanded indication

- On April 17, 2023, AbbVie announced the FDA approval of Qulipta (atogepant), for the preventive treatment of migraine in adults.
    - Qulipta was previously only approved for the preventive treatment of episodic migraine in adults. The expanded indication broadens the use of Qulipta to include preventive treatment of chronic migraine.
- Qulipta is the first oral calcitonin gene-related peptide (CGRP) approved to prevent migraine across frequencies, including episodic and chronic.
- The approval of Qulipta for the expanded indication was based on a randomized, double-blind, placebo-controlled study in 502 adult patients with chronic migraine. Patients were randomized to Qulipta 60 mg once daily or placebo for 12 weeks. The primary endpoint was the change from baseline in mean monthly migraine days (MMD) across the 12-week treatment period.
    - The change from baseline in mean MMD was -6.9 with Qulipta vs. -5.1 with placebo (difference of -1.8, $p < 0.001$).
- The recommended dosage of Qulipta for the preventative treatment of chronic migraine is 60 mg taken orally once daily.
    - The recommended dosage of Qulipta for the preventative treatment of episodic migraine is 10 mg, 30 mg, or 60 mg taken orally once daily.