Qulipta™ (atogepant) – New drug approval

- On September 28, 2021, AbbVie announced the FDA approval of Qulipta (atogepant), for the preventive treatment of episodic migraine in adults.

- Qulipta is the second oral calcitonin gene-related peptide (CGRP) receptor antagonist approved for preventive treatment of episodic migraine in adults. Nurtec™ ODT (rimegepant) was also approved for this indication in May 2021.

- The efficacy of Qulipta was established in two randomized, double-blind, placebo-controlled studies in adults with episodic migraines. In both studies, patients were randomized to Qulipta 10 mg, Qulipta 30 mg, Qulipta 60 mg, or placebo, once daily for 12 weeks. Patients were allowed to use acute headache treatments as needed. Study 1 included 910 patients and study 2 included 652 patients. The primary endpoint was the change from baseline in mean monthly migraine days (MMD) across the 12-week treatment period.

Efficacy results: MMD across 12 weeks

	Qulipta 10 mg	Qulipta 30 mg	Qulipta 60 mg	Placebo
Study 1				
Baseline	7.5	7.9	7.8	7.5
Mean change from baseline	-3.7	-3.9	-4.2	-2.5
Difference from placebo	-1.2	-1.4	-1.7	--
p-value	< 0.001	< 0.001	< 0.001	
Study 2				
Baseline	7.6	7.6	7.7	7.8
Mean change from baseline	-4.0	-3.8	-3.6	-2.8
Difference from placebo	-1.1	-0.9	-0.7	--
p-value	0.024	0.039	0.039	

- The most common adverse reactions (≥ 4% and greater than placebo) with Qulipta use were nausea, constipation, and fatigue.

- The recommended dosage of Qulipta is 10 mg, 30 mg, or 60 mg taken orally once daily with or without food.

- AbbVie plans to launch Qulipta in early October 2021. Qulipta will be available as 10 mg, 30 mg, and 60 mg tablets.