

New relief for Migraine sufferers as FDA approves AbbVie's QULIPTA (Atogepant)

KEYNOTE

Towards the end of September, Chicago-based biotechnology pharmaceutical giant AbbVie announced that the FDA had approved its QULIPTA (Atogepant) medication for the preventive treatment of episodic migraine in adults. The FDA has thus given the green light to the first and so far only oral CGRP (calcitonin gene-related peptide) receptor antagonist specifically formulated for the preventive treatment of migraine.

Peter J. Goadsby, professor at the University of California, Los Angeles, and at King's College London, described the FDA approval of QULIPTA as a milestone in the treatment of migraine. Goadsby, who was awarded the prestigious Brain Prize in 2021 for his research on the role of CGRP in migraine attacks, praised the drug's rapid onset of action and high patient response rate.

The approval is based on data from a clinical program that evaluated the efficacy, safety and tolerability of QULIPTA in a test involving just under 2,000 patients who experienced between 4 and 14 migraine days per month. The program included the pivotal Phase 3 ADVANCE study, the pivotal Phase 2b/3 study and the Phase 3 long-term safety study.

Over the full 12-week treatment period, QULIPTA showed a statistically significant, clinically meaningful, rapid and continuous reduction in average monthly migraine days in adults susceptible to episodic migraine compared to those receiving the placebo. In volunteers treated with 60 mg QULIPTA over a 12-week period, the number of migraine days decreased by 4.2 from baseline. In addition, the studies showed that 56%, 59% and 61% of patients in the 10 mg, 30 mg and 60 mg QULIPTA groups respectively achieved a 50-100% reduction, compared to 29% of patients in the placebo group.

According to Dr. Michael Severino, Vice Chairman and President of AbbVie, QULIPTA could be the game-changer millions of people living with migraine have been eagerly waiting for. With a once-daily oral dose that works quickly and continuously, QULIPTA could reduce the monthly number of migraine days and give sufferers back their quality of life as well as restoring their level of productivity.

AbbVie has thus become the only pharmaceutical company to offer three treatments for the full spectrum of migraine, including preventive therapies for chronic and episodic migraine and an acute treatment for migraine attacks.

QULIPTA will now complement the rest of AbbVie's migraine product line, which includes Botox, the "crown jewel" in its portfolio, and Ubrelvy (Ubrogepant), which has been approved by the FDA for the acute treatment in adults of migraine with or without aura (a sensory phenomenon or visual disturbance).

What exactly is QULIPTA (Atogepant)?

QULIPTA™ (Atogepant) is the first and so far only oral calcitonin gene-related peptide (CGRP) receptor antagonist specifically designed for the preventive treatment of episodic migraine in adults.

CGRP is one of the main messengers of the trigeminal nerve that mediates headache. CGRP and its receptors are expressed in regions of the nervous system associated with the pathophysiology of migraine. Previous studies have also shown that CGRP levels are elevated during migraine attacks. Consequently, resources have been directed towards discovering a CGRP blocker, and this research has now produced results. Atogepant not only reduces episodic migraine attacks; it also has the added benefit of not causing painkiller-induced headache, unlike almost all other acute migraine medications when taken over a long period of time. Once-daily administration of QULIPTA has been shown to block CGRP. It is available in three strengths – 10 mg, 30 mg and 60 mg.

QULIPTA became available as a prescription drug in the USA in early October 2021. So far, QULIPTA has only been approved in the United States, although further approvals are expected soon. We will keep you updated on developments in this regard and will be individually contacting our clients who suffer from episodic migraine.

SALVAGENE HQ
Université Paris Sorbonne
125 Rue Saint-Jacques, 75005 Paris

SALVAGENE UK
52 Grosvenor Gardens • SW1W 0AU London UF
Tel: 0044 20 3287 0644

SALVAGENE USA
101 Avenue of the Americas, 8th floor • 10013 New York
Tel: +1 646 583 0370

info@salvagene.com • www.salvagene.com