

PRESS RELEASE

QULIPTA™ (atogepant) Now Approved by Health Canada for the Preventive Treatment of Chronic Migraine in Adults

- *QULIPTA is now the first and only oral calcitonin gene-related peptide (CGRP) receptor antagonist (gepant) approved to prevent migraine across all frequencies, including episodic and chronic.*
- *Expanded indication provides an additional treatment option for those with chronic migraine whose frequent disabling attacks negatively impact performance of daily activities.*
- *Approval was based on a pivotal Phase 3 clinical trial that demonstrated statistically significant reduction from baseline in mean monthly migraine days.*
- *AbbVie is the only pharmaceutical company to offer three treatments across the full spectrum of migraine to help patients living with this debilitating disease.*

Montréal, Québec – May 8, 2024 – AbbVie (NYSE: ABBV) announced today that Health Canada has approved QULIPTA (atogepant) for the prevention of migraine in adults who have at least four migraine days per month.¹ QULIPTA is the first and only oral, small-molecule calcitonin gene-related peptide (CGRP) receptor antagonist (gepant) approved to prevent both episodic and chronic migraine.

"QULIPTA has been helping thousands of Canadians living with episodic migraine since December 2022. Now, QULIPTA offers a new option for those with the most challenging-to-treat chronic migraine," says Rami Fayed, Vice President and General Manager, AbbVie Canada. "With this approval, AbbVie is the only pharmaceutical company with three treatments across the entire migraine spectrum, including QULIPTA as a preventive treatment for both episodic and chronic migraine, BOTOX® (onabotulinumtoxinA) our foundational preventive treatment for chronic migraine, and UBRELVY® (ubrogepant), an acute treatment for migraine attacks."

QULIPTA's expanded chronic migraine indication is based on the pivotal Phase 3 PROGRESS trial evaluating QULIPTA 60 mg once daily in adult patients with chronic migraine, which met its primary endpoint of statistically significant reduction of -6.9 from baseline in mean monthly migraine days compared to placebo of -5.1 across the 12-week treatment period.² The average monthly migraine days (MMDs) for patients at baseline during the clinical trial was 19.2.

"Chronic migraine is incredibly debilitating for my patients. It makes day-to-day activities often unbearable, and isolates you from friends, family, and work," says Dr Ian Finkelstein, Medical Director of the Toronto Headache & Pain Clinic. "I have observed QULIPTA's ability to alleviate the challenges posed by episodic migraine in many of my patients, resulting in improved functionality, impressive response rates, and sustained efficacy. I'm excited to see Health Canada's approval of QULIPTA for chronic migraine and to be able to offer another treatment option to patients to help them successfully prevent their migraines."

QULIPTA blocks CGRP through a once-daily dose and is available in three strengths for the preventive treatment of episodic migraine – 10 mg, 30 mg and 60 mg. Only the 60 mg dose of QULIPTA is indicated for the preventive treatment of chronic migraine. The overall safety profile of QULIPTA is consistent with the episodic migraine patient population, with the most common adverse events including nausea, constipation, diarrhoea, and fatigue.¹

“Bringing new migraine-specific medications to Canadians living with migraine is critical as so many have yet to find the relief they seek,” says Wendy Gerhart, Executive Director of Migraine Canada. “Chronic migraine is a constant struggle for too many. We are pleased to see the approval of QULIPTA for this indication providing another safe and effective option and are confident it will have a positive impact on our community.”

About Migraine

Migraine is a complex neurological disease with recurrent attacks that lasts 4-72 hours. It can be defined by symptoms such as moderate to severe pain intensity, nausea, vomiting, photophobia and phonophobia.³ An estimated 2.7 million Canadians are reported diagnosed with migraine, however the number of people living with migraine is much higher.⁴ Episodic migraine is characterized as having less than 15 headache days per month, while 15 headache days or more per month, is considered chronic.⁵

About QULIPTA (atogepant)

QULIPTA (atogepant) is the first and only oral, small-molecule calcitonin gene-related peptide (CGRP) receptor antagonist (gepant) specifically developed for the preventive treatment of episodic and chronic migraine. QULIPTA is an orally administered, small-molecule, selective calcitonin gene-related peptide (CGRP) receptor antagonist that blocks the binding of the CGRP to its receptor. CGRP is a neuropeptide that may play a role in migraine pathophysiology.¹

For important safety information, please consult the [QULIPTA Product Monograph](#).

About AbbVie in Neuroscience

At AbbVie, our commitment to people around the world living with neurological and psychiatric disorders is unwavering. With more than three decades of experience in neuroscience, we are providing meaningful treatment options today and advancing innovation for the future. AbbVie's Neuroscience portfolio consists of approved treatments in neurological conditions, including migraine, movement disorders, and psychiatric disorders, along with a robust pipeline of transformative therapies. We have made a strong investment in research and are committed to building a deeper understanding of neurological and psychiatric disorders. Every challenge makes us more determined and drives us to discover and deliver advancements for those impacted by these conditions, their care partners, and clinicians. For more information, visit www.abbvie.ca.

About AbbVie

AbbVie's mission is to discover and deliver innovative medicines and solutions that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas – immunology, oncology, neuroscience, and eye care – and products and services in our Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.ca. Follow AbbVie Canada on [X](#), [Instagram](#), or [LinkedIn](#).

For more information on AbbVie's complete migraine portfolio, please visit www.abbvie.ca.

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¹ AbbVie Canada. QULIPTA Product Monograph. May 2024.

² AbbVie. Data on File: ABVRR173750

³ Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalgia. 2018;38(1):1-211. Accessed April 2024.

⁴ Ramage-Morin P., & Gilmour, H. (2014). Prevalence of migraine in the Canadian household population. Health Reports, 25(6): 10-16. <https://www150.statcan.gc.ca/n1/en/pub/82-003-x/2014006/article/14033-eng.pdf?st=CSyp19VF>. Accessed April 2024.

⁵ Migraine Canada. The Migraine Family: categories and groups. Retrieved from <https://migrainecanada.org/posts/the-migraine-tree/roots/migraine-categories/the-migraine-family-categories-and-groups/>. Accessed April 2024.