



Press release  
for immediate release

## Teva Canada Announces New Autoinjector for AJOVY® for the Preventive Treatment of Migraine in Adults

**AJOVY® now offers patients greater flexibility with two dosing options available in both an autoinjector and a prefilled syringe**

- *AJOVY® is the first and only subcutaneous anti-CGRP treatment with both quarterly (every three months) and monthly dosing options using either the autoinjector or prefilled syringe for the preventive treatment of migraine in adults.*
- *AJOVY® is supported by the [AJOVY® Teva Support Solutions® \(AJOVY® TSS\) Patient Support Program](#), whose services include reimbursement navigation, bridging/copay coverage, and injection training.*
- *AJOVY® has been studied in patients with either chronic or episodic migraine and was shown to significantly reduce patients' mean monthly migraine days—with some patients achieving a 50% reduction or more.<sup>1,2,3</sup>*

**Montréal, Québec (April 8, 2021)** – Teva Canada, a subsidiary of Teva Pharmaceutical Industries Ltd., today announced the launch and availability of a new autoinjector for AJOVY® (fremanezumab). AJOVY® is a subcutaneous injection for the preventive treatment of migraine in adults who have at least four migraine days per month. When launched in 2020, AJOVY® was available in a prefilled syringe only. The product is now available in two latex-free<sup>1</sup> formats: a new autoinjector and a prefilled syringe.

AJOVY® is the first and only product in its class that is available in multiple formats, providing two unique injection devices and two optional dosing regimens. It is also the first and only subcutaneous anti-CGRP (calcitonin gene-related peptide) drug approved in Canada, the European Union, and the United States that offers quarterly (225 mg) or monthly (675 mg) dosing regimens using either the autoinjector or prefilled syringe for the preventive treatment of migraine.<sup>1,2,3</sup> The new AJOVY® autoinjector also has several features that make it easy-to-use<sup>4</sup> including a button-free, push-down mechanism; audible cues that signal progress of administration; and, a window that displays when the dose has been delivered. Additionally, the autoinjector is for one-time use only and locks after use.

“Migraine patients are highly individual—not all want the same device. At Teva Canada, we believe in the power of choice and we believe that options are important for patients and prescribers,” says Christine Poulin, Teva Canada’s General Manager. “From the beginning, AJOVY® has offered flexible dosing options. With the launch of this new device, AJOVY® now also offers different injection options. I see AJOVY® as a complete package of care, with injection training and other support delivered through our AJOVY® Teva Support Solutions® (AJOVY® TSS) Patient Support Program.”

“For many Canadians, migraine is a debilitating regular occurrence that greatly impacts a patient’s ability to carry out day-to-day functions. Having another option in the AJOVY® family of treatments allows patients to manage their condition to suit their lifestyle,” said Dr. Elizabeth Leroux, President of the Canadian Headache Society and Founder of the websites Migraine Quebec and Migraine Canada. “Recent changes in the field of migraine treatment have opened a lot of doors; this new injection option with flexible dosing opens yet another one for patients and health care providers who manage migraine.”

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Migraine is a disabling chronic neurological disease that causes head pain so severe that sufferers often cannot function during an attack. Migraine reduces quality of life and disrupts migraineurs' ability to perform daily activities.<sup>5,6</sup> It is among the top 10 causes of disability worldwide and the seventh cause of years of life lost to disability.<sup>7,8,9</sup> In Canada, migraine is most common in women and most common between the ages of 30 and 49.<sup>10</sup> Migraine therefore reduces patients' quality of life, ability to work, and overall productivity right at the prime of their life. While acute treatment modalities are used to treat migraine attacks when they occur, they do not prevent them. Novel treatments like AJOVY<sup>®</sup> were specifically designed to actually prevent migraine from occurring.

AJOVY<sup>®</sup> was evaluated in two pivotal Phase III clinical trials that enrolled patients with disabling migraine and studied fremanezumab as a prophylactic treatment. For patients with chronic migraine, 40.8 per cent taking the monthly dose and 37.6 per cent taking the quarterly dose experienced more than a 50 per cent reduction in monthly average headache days of at least moderate severity.<sup>11</sup> For patients with episodic migraine, 47.7 per cent taking the monthly dose and 44.4 per cent taking the quarterly dose experienced more than a 50 per cent reduction in monthly average number of migraine days.<sup>12</sup> The safety profile was also assessed.<sup>1,2,3</sup> AJOVY<sup>®</sup> has been studied in patients with chronic or episodic migraine and was shown to significantly reduce patients' mean monthly migraine days—with some patients achieving a 50% reduction or more.<sup>1,2,3</sup>

### About AJOVY<sup>®</sup>

AJOVY<sup>®</sup> (fremanezumab) is indicated for the preventive treatment of migraine in adults who have at least four migraine days per month. AJOVY<sup>®</sup> is available as a 225 mg/1.5 mL single-dose injection in an autoinjector or prefilled syringe with two dosing options: 225 mg monthly, administered as one subcutaneous injection; or 675 mg every three months (quarterly), administered as three subcutaneous injections. AJOVY<sup>®</sup> is intended for patient self-administration after the patient or their caretaker has been trained to administer the product. AJOVY<sup>®</sup> patients and prescribers are supported by the AJOVY<sup>®</sup> Teva Support Solutions<sup>®</sup> Patient Support Program.

### About Teva Canada

Teva Canada, headquartered in Toronto, has provided affordable healthcare solutions to Canadians for over 50 years, building their trust one prescription at a time with now more than 192,000<sup>13</sup> prescriptions filled each day with our products, representing 1 of every 8 generic prescriptions in Canada<sup>14</sup>. Originally Novopharm Limited, Teva Canada specializes in the development, production, and marketing of high-quality generic prescription pharmaceuticals and, through our branded division, focuses on a diverse line of speciality and biopharmaceutical products in a variety of therapeutic areas such as central nervous system (CNS), respiratory, oncology and rheumatology. Teva Canada's commitment to helping improve the lives of Canadians also extends to the [Teva Caregiver](#) program – providing tools and resources for Canadians navigating the care journey. Teva Canada employs more than 900 professionals, had sales of nearly \$1.1 billion<sup>15</sup> in 2020, and markets more than 360<sup>16</sup> products in over 840 SKUs<sup>16</sup> in Canada. We are a proud subsidiary of Teva Pharmaceutical Industries Ltd. Learn more at [www.tevacanada.com](http://www.tevacanada.com).

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### About Teva Pharmaceutical Industries Ltd.

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) has been developing and producing medicines to improve people's lives for more than a century. We are a global leader in generic and specialty medicines with a portfolio consisting of over 3,500 products in nearly every therapeutic area. Around 200 million people around the world take a Teva medicine every day, and are served by one of the largest and most complex supply chains in the pharmaceutical industry. Along with our established presence in generics, we have significant innovative research and operations supporting our growing portfolio of specialty and biopharmaceutical products. Learn more at [www.tevapharm.com](http://www.tevapharm.com).



CGRP: calcitonin gene-related peptide; SKU: Stock Keeping Unit

1. AJOVY® Product Monograph. Teva Canada Limited, Montréal, Quebec. December 15, 2020.
2. Dodick DW et al. Effect of fremanezumab compared with placebo for prevention of episodic migraine. *JAMA*. 2018;319(19):1999–2008. doi: 10.1001/jama.2018.4853.
3. Silberstein SD et al. Fremanezumab for the preventive treatment of chronic migraine. *N Engl J Med*. 2017;377(22):2113–2122. doi: 10.1056/NEJMoa1709038.
4. Two Human Factor studies assessed evaluators' ability to complete critical tasks in order to demonstrate use of the AJOVY Autoinjector in simulated-use sessions. When asked "Was the autoinjector easy to use?", 97% in study 1 (N=30) and 98% in study 2 (N=47) answered "Yes." Data on file, Parsippany, NJ Teva Pharmaceuticals USA, Inc.
5. Buse DC, Rupnow MF, Lipton RB. Assessing and managing all aspects of migraine: migraine attacks, migraine-related functional impairment, common comorbidities, and quality of life. *Mayo Clin Proc*. 2009;84:422–435. doi: 10.1016/S0025-6196(11)60561-2.
6. Lipton RB, Liberman JN, Kolodner KB, et al. Migraine headache disability and health-related quality-of-life: a population-based case-control study from England. *Cephalalgia*. 2003;23:441–450. doi: 10.1046/j.1468-2982.2003.00546.x.
7. Steiner TJ, Stovner LJ, Birbeck GL. Migraine: the seventh disabler. *J Headache Pain*. 2013;14:1. doi: 10.1186/1129-2377-14-1.
8. Global Burden of Disease Study Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet*. 2015;386:743–800. doi: 10.1016/S0140-6736(15)60692-4.

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9. Institute for Health Metrics and Evaluation. Global burden of disease visualization tools. Available from: <http://vizhub.healthdata.org/gbd-compare/>. Accessed January 2016.
10. Ramage-Morin PL, Gilmour H. Prevalence of migraine in the Canadian household population. *Health Rep.* 2014;25(6):10–16.
11. Adapted from product monograph. Includes all randomized patients who received at least 1 dose of study drug and had at least 10 days of post-baseline efficacy assessments on the primary endpoint. A fixed-sequence (hierarchical) testing procedure was implemented to control the Type 1 error rate at 0.05. The p values were based on the Cochran-Mantel-Haenszel test stratified by baseline preventive medication use (yes/no). The early discontinued patients were considered as non-responders for overall analysis. Defined as a day in which headache pain lasted  $\geq 4$  consecutive hours and had a peak severity of at least a moderate level or days in which acute migraine-specific medication (triptans or ergots) was used to treat a headache of any severity or duration.<sup>2</sup>- Reference 2: Silberstein SD, Dodick DW, Bigal ME, et al. Fremanezumab for the preventive treatment of chronic migraine. *NEJM.* 2017;377(22):2113–2122.
12. Adapted from product monograph. Includes all randomized patients who received at least 1 dose of study drug and had at least 10 days of post-baseline efficacy assessments on the primary endpoint. A fixed-sequence (hierarchical) testing procedure was implemented to control the Type 1 error rate at 0.05. The p values were based on the Cochran-Mantel-Haenszel test stratified by baseline preventive medication use (yes/no). The early discontinued patients were considered as non-responders for overall analysis. Defined as a calendar day with either  $\geq 2$  consecutive hours of headache meeting criteria for migraine; probable migraine; or a day, regardless of duration, when acute migraine-specific medication (triptans or ergots) was used to treat a headache.<sup>3</sup> - Reference 3: Dodick DW, Silberstein SD, Bigal ME, et al. Effect of fremanezumab compared with placebo for prevention of episodic migraine. *JAMA.* 2018;319(19):1999–2008.
13. Source: IQVIA CDH Compuscript TRx MAT Dec 2020
14. Source: IQVIA Compuscript Trx MAT 2020.12
15. Source: IQVIA CDH & Compuscript MAT Dec 2020
16. Source: Teva Price list March 2, 2021

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