## Ajovy™ (fremanezumab-vfrm) – New drug approval

- On September 14, 2018, Teva announced the FDA approval of Ajovy (fremanezumab-vfrm) for the preventive treatment of migraine in adults.

- Ajovy is the second FDA-approved preventive migraine treatment in a new class of drugs that work by blocking the activity of calcitonin gene-related peptide (CGRP), a molecule that is involved in migraine attacks.

    — The first CGRP antagonist, Aimovig™ (erenumab-aooe), was approved in May 2018.

- The 2016 Global Burden of Disease Study ranks migraine among the top 10 causes of years lived with disability worldwide. Migraine is three times more common in women than in men and affects more than 10% of people worldwide.

- Patients often describe migraine headache pain as an intense pulsing or throbbing pain in one area of the head. Additional symptoms include nausea and/or vomiting and sensitivity to light and sound. About one-third of affected individuals can predict the onset of a migraine because it is preceded by an aura. People with migraine tend to have recurring attacks triggered by a number of different factors (eg, stress, hormonal changes, bright or flashing lights, lack of sleep or food, and diet).

- The efficacy of Ajovy for the preventive treatment of episodic or chronic migraine was evaluated in two 3-month studies. In the first study, 875 patients with episodic migraine were enrolled. In the second study, 1,130 patients with chronic migraine were enrolled. In both studies, patients were randomized to monthly or quarterly Ajovy or placebo.

    — In the first study, patients treated with quarterly or monthly dosing regimens of Ajovy experienced 1.2 and 1.5 fewer monthly migraine days, respectively vs. those receiving placebo ($p < 0.001$ for quarterly and monthly Ajovy vs. placebo).
    — In the second study, patients treated with quarterly and monthly dosing regimens of Ajovy experienced 1.8 and 2.1 fewer monthly headache days of at least moderate severity, respectively vs. those receiving placebo ($p < 0.001$ for quarterly and monthly Ajovy vs. placebo).

- A warning and precaution of Ajovy includes hypersensitivity reactions.

- The most common adverse reaction (≥ 5% and > placebo) with Ajovy use was injection site reactions.

- The recommended dosage of Ajovy is 225 mg administered subcutaneously (SC) monthly or 675 mg SC every 3 months (quarterly), which is administered as three consecutive SC injections of 225 mg each.

    — Ajovy may be administered by healthcare professionals, patients, and/or caregivers.
    — The SC injections should be administered in the abdomen, thigh, or upper arm.

- The wholesale acquisition cost (WAC) of Ajovy is $575 per monthly dose and $1,725 per quarterly dose (ie, $6,900 annually for either dose).

    — Teva will also launch Teva Shared Solutions®, which may be able to help reduce out of pocket costs for eligible patients with commercial insurance.
    — Aimovig has the same annual WAC as Ajovy.

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- Teva plans to launch Ajovy within the next two weeks. Ajovy will be available as a 225 mg/1.5 mL solution in single-dose prefilled syringes.