Emgality™ (galcanezumab-gnlm) – New drug approval

- On September 27, 2018, Elli Lilly announced the FDA approval of Emgality (galcanezumab-gnlm) for the preventive treatment of migraine in adults.

- Emgality is the third 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.

    — Aimovig™ (erenumab-aooe) was approved in May 2018 and Ajovy™ (fremanezumab-vfrm) was approved earlier this month.

- 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 Emgality was evaluated in three studies: two 6-month studies in patients with episodic migraine (studies 1 and 2) and one 3-month study in patients with chronic migraine (study 3). Patients were randomized to receive once-monthly injections of Emgality 120 mg, Emgality 240 mg, or placebo. The primary endpoint was mean change from baseline in the number of monthly migraine headache days.

    — In study 1 (n = 858) and study 2 (n = 915), patients treated with Emgality 120 mg experienced, on average, 1.9 and 2.0 fewer monthly migraine headache days, respectively, vs. those receiving placebo.
    — In study 3 (n = 1,113), patients treated with Emgality 120 mg experienced, on average, 2.1 fewer monthly migraine headache days vs. those receiving placebo.
    — In all three studies, treatment with Emgality 240 mg demonstrated no additional benefit over the 120 mg dose.

- A warning and precaution of Emgality includes hypersensitivity reactions.

- The most common adverse reaction (≥ 2% and ≥ 2% vs. placebo) with Emgality use was injection site reactions.

- The recommended dose of Emgality is 240 mg (two consecutive subcutaneous [SC] injections of 120 mg each) once as a loading dose, followed by monthly SC doses of 120 mg.

    — Emgality is intended for patient self-administration.
    — The SC injections should be administered in the abdomen, thigh, back of the upper arm, or buttocks.

- The wholesale acquisition cost (WAC) of Emgality is $575 per monthly dose (ie, $6,900 annually).

    — Eli Lilly will also launch an Emgality Savings Card, which may be able to help reduce out of pocket costs for eligible patients with commercial insurance.

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— Aimovig and Ajovy have the same annual WAC as Emgality.

Eli Lilly plans to launch Emgality immediately. Emgality will be available as a 120 mg/mL solution in a single-dose prefilled pen and a prefilled syringe.