Emgality® (galcanezumab-gnlm) – New indication, new strength

- On June 4, 2019, the FDA announced the approval of Eli Lilly's Emgality (galcanezumab-gnlm), for the treatment of episodic cluster headache in adults.

- Emgality is also approved for the preventive treatment of migraine in adults.

- Cluster headache is a form of headache that produces extreme pain and tends to occur in clusters, often at the same time(s) of the day, for several weeks to months. Cluster headache attacks may strike several times a day, generally lasting between 15 minutes and three hours.

    — People with episodic cluster headache represent 85 to 90% of cluster headache prevalence, with approximately 250,000 adults living with this disease in the U.S.

- Emgality is the first FDA-approved drug that reduces the frequency of attacks of episodic cluster headache.

- The approval of Emgality's new indication was based on a double-blind study in 106 patients with episodic cluster headache. Patients were randomized to once-monthly subcutaneous (SC) injections of Emgality or placebo. The primary efficacy endpoint was the mean change from baseline in weekly cluster headache attack frequency across weeks 1 to 3. A secondary endpoint was the percentage of patients who achieved a response (defined as a reduction from baseline of 50% or greater in the weekly cluster headache attack frequency) at week 3.

    — During the three-week period, patients taking Emgality experienced 8.7 fewer weekly cluster headache attacks than they did at baseline vs. 5.2 fewer attacks for patients on placebo (difference: -3.5; p = 0.036).
    — At week 3, 71.4% of patients receiving Emgality had a response vs. 52.6% of patients with placebo (difference: 18.8%; p = 0.046).

- The recommended dosage of Emgality for episodic cluster headache is 300 mg (three consecutive SC injections of 100 mg each) at the onset of the cluster period, and then monthly until the end of the cluster period.

    — Emgality is intended for self-administration.
    — Emgality should be administered in the abdomen, thigh, back of the upper arm, or buttocks.
    — Refer to the Emgality drug label for dosing recommendations for preventive treatment of migraine.

- Along with the new indication, the FDA approved a 100 mg/mL solution in a single-dose prefilled syringe formulation of Emgality. Eli Lilly plans to launch the new strength the week of June 17th.

    — Emgality was previously available as a 120 mg/mL solution in a single-dose prefilled pen and 120 mg/mL solution in a single-dose prefilled syringe.