

## FDA approves Elli Lilly's Emgality® (galcanezumab-gnlm) for Episodic Cluster Headache

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**With this approval, Emgality is the only calcitonin gene-related peptide (CGRP) antibody indicated for the preventive treatment of migraine and the treatment of episodic cluster headache**



Eli Lilly and Company has announced that the U.S. Food and Drug Administration (FDA) has approved Emgality®(galcanezumab-gnlm) injection (300 mg) for the treatment of episodic cluster headache in adults.

Emgality is an innovative therapeutic approach for this neurologic disease and the first and only calcitonin gene-related peptide (CGRP) antibody approved by the FDA for two distinct headache disorders.<sup>1</sup> After training by a healthcare professional, patients can administer Emgality at home through subcutaneous injections at the onset of a cluster headache period, and then monthly until the end of a cluster period.

Emgality was first approved by the FDA in September 2018 for the preventive treatment of migraine in adults and is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients.

Christi Shaw, president, Lilly Bio-Medicines said, "Episodic cluster headache can be devastating. The approval of Emgality for the treatment of episodic cluster headache is an important milestone as it provides a new treatment option, which has been long-awaited by those impacted by this disease."

Cluster headache is characterized by the abrupt onset of severe to very severe pain on one side of the head. Pain is felt in the orbital, supraorbital, and/or temporal regions (around or above the eye and/or temple) and can be accompanied by symptoms on the same side of the body: conjunctival injection (eye redness), lacrimation (tearing), nasal congestion, rhinorrhea (runny nose), forehead and facial sweating, miosis (constriction of the pupil), ptosis (drooping eyelid) and/or eyelid edema (swollen eyelid), and/or restlessness or agitation.

Cluster headache, although severely crippling, is challenging to diagnose because of limited awareness and, for some, may take five years or more to diagnose on average. It has been historically challenging to conduct clinical trials that identify treatment options that help reduce the frequency of attacks for those with episodic cluster headache. During a cluster period, which usually spans two weeks to three months, attacks last 15 to 180 minutes and can occur from once every other day to eight times per day.<sup>2</sup> People with episodic cluster headache represent 85 to 90 percent of cluster headache prevalence, with approximately 250,000 adults living with this disease in the U.S.

Bob Wold, founder, Clusterbusters, Inc said, "As someone impacted by cluster headache and an advocate for others living with this disease, I know firsthand the desperation that we have felt for additional treatment options that can reduce the frequency of these attacks that have such a debilitating impact on our lives. The approval of Emgality for the treatment of episodic cluster headache is a cause for celebration and hope. On behalf of this community, we thank the FDA, Lilly, the researchers and the patients who helped to usher forward this innovative treatment."

Overall, the safety profile observed in patients with episodic cluster headache treated with Emgality 300 mg monthly is consistent with the safety profile in patients with migraine treated with Emgality 120 mg monthly. Two Emgality-treated patients discontinued double-blind treatment during the episodic cluster headache study because of adverse events.

David Kudrow, M.D., director, California Medical Clinic for Headache said, "For years, there have been few therapeutic options to offer patients for the treatment of episodic cluster headache. With today's approval, physicians are now armed with an FDA-approved medication that has the potential to help patients living with this condition by reducing the frequency of cluster attacks."

For episodic cluster headache, the recommended dosage of Emgality is 300 mg (administered as three consecutive subcutaneous injections of 100 mg each) at the onset of the cluster period, and then monthly until the end of the cluster period.

Emgality will be available to patients for pickup at retail pharmacies. The U.S. list price of Emgality for the treatment of episodic cluster headache is the same per milligram as the migraine indication.