FDA Approves Emgality® (galcanezumab-gnlm) as the First and Only Medication for the Treatment of Episodic Cluster Headache that Reduces the Frequency of Attacks

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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[1]

INDIANAPOLIS, June 4, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today 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.[1] 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.[1] 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.[1] 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.

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"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," said Christi Shaw, president, Lilly Bio-Medicines.

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.[2] 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.[3] 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.[2] 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. [2,4]

"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," said Bob Wold, founder, Clusterbusters, Inc. "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."

The efficacy of Emgality was evaluated for the treatment of episodic cluster headache in a randomized, 8-week, double-blind, placebo-controlled study.[1] In the study, 106 patients were randomized 1:1 to receive once-monthly injections of Emgality 300 mg (N=49) or placebo (N=57), with a baseline number of weekly cluster headache attacks of 17.8 for Emgality and 17.3 for placebo. Patients on Emgality experienced an average of 8.7 fewer weekly cluster headache attacks over Weeks 1 to 3 vs. 5.2 fewer weekly attacks for patients on placebo (p=0.036).[1] With Emgality, 71.4% of patients had their weekly cluster headache attacks cut in half or more from baseline at Week 3 vs. 52.6% of patients with placebo (p=0.046).[1]

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.[1] Two Emgality-treated patients discontinued double-blind treatment during the episodic cluster headache study because of adverse events.[1]

"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," said David Kudrow, M.D., director, California Medical Clinic for Headache.

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.[1]

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.

Patients and healthcare professionals with questions about Emgality should contact 1-833-EMGALITY (1-833-364-2548) or visit www.emgality.com. Patients can also text ACTIVATE to 54559 to receive helpful resources delivered straight to their phone.

Indications and Usage
Emgality is a calcitonin gene-related peptide (CGRP) antagonist indicated in adults for the:

- preventive treatment of migraine
- treatment of episodic cluster headache

Important Safety Information

Contraindications
Emgality is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients.

Warnings and Precautions
Hypersensitivity Reactions
Hypersensitivity reactions, including anaphylaxis, angioedema, dyspnea, urticaria, and rash, have been reported with Emgality. If a serious or severe hypersensitivity reaction occurs, discontinue administration of Emgality and initiate appropriate therapy. Hypersensitivity reactions can occur days after administration and may be prolonged.

Adverse Reactions
The most common adverse reactions (incidence ≥2% and at least 2% greater than placebo) in Emgality clinical studies were injection site reactions.

Please see Full Prescribing Information, including Patient Information, for Emgality. See Instructions for Use included with the device.

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About the Episodic Cluster Headache Study
The efficacy and safety of Emgality were evaluated for the treatment of episodic cluster headache in a randomized, 8-week, double-blind, placebo-controlled study. The study included 106 adults who met the International Classification of Headache Disorders 3rd edition (beta version) diagnostic criteria for episodic cluster headache and had a maximum of 8 attacks per day, a minimum of one attack every other day, and at least 4 attacks during the prospective 7-day baseline period. All patients were randomized in a 1:1 ratio to receive once-monthly subcutaneous injections of Emgality 300 mg or placebo. Patients were allowed to use certain specified acute/abortive cluster headache treatments, including triptans, oxygen, acetaminophen, and nonsteroidal anti-inflammatory drugs (NSAIDs) during the study. The study excluded patients on other treatments intended to reduce the frequency of cluster headache attacks; patients with medication overuse headache; patients with electrocardiogram (ECG) abnormalities compatible with an acute cardiovascular event or conduction delay; and patients with a history of myocardial infarction, unstable angina, percutaneous coronary intervention, coronary artery bypass grafting, deep vein thrombosis, or pulmonary embolism within 6 months of screening. In addition, patients with any history of stroke, intracranial or carotid aneurysm, intracranial hemorrhage, or vasospastic angina; clinical evidence of peripheral vascular disease; or diagnosis of Raynaud's disease were excluded. The primary efficacy endpoint was the mean change from baseline in weekly cluster headache attack frequency across Weeks 1 to 3.[1] 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.[1]

About Eli Lilly and Company
Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and www.lilly.com/newsroom/social-channels.

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This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Emgality (galcanezumab-gnlm) as a preventive treatment for patients with migraine and as a treatment for patients with episodic cluster headache, and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that Emgality will receive additional regulatory approvals or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

References

1. Emgality [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC.
2. Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1-211.
3. Rozen TD, Fishman RS. Cluster headache in the United States of America: demographics, clinical characteristics, triggers, suicidality, and personal burden. *Headache.* 2012;52(1):99-113.
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Refer to: Jen Dial; dial_jennifer_kay@lilly.com; 317-220-1172 (Lilly Bio-Medicines)
Kevin Hern; hern_kevin_r@lilly.com; 317-277-1838 (Investor Relations)