



Lilly Receives FDA Priority Review Designation for Emgality® (galcanezumab-gnlm) Injection for the Preventive Treatment of Episodic Cluster Headache in Adults

March 5, 2019

INDIANAPOLIS, March 5, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the U.S. Food and Drug Administration (FDA) has granted Priority Review for its supplemental Biologics License Application (sBLA) for Emgality® (galcanezumab-gnlm) injection for the preventive treatment of episodic cluster headache in adults. Priority Review aims to expedite the review of applications for drugs that, if approved, could potentially represent a significant advancement in treatment for a serious condition.

The sBLA is based on data from a Phase 3 study that evaluated the safety and efficacy of Emgality (galcanezumab-gnlm) injection 300mg in 106 adult patients with episodic cluster headache. Emgality was previously granted Breakthrough Therapy Designation by the FDA in September 2018 for the preventive treatment of episodic cluster headache, indicating the significant unmet need for this debilitating condition for which there are currently no approved preventive medications.

"Cluster headache is a severely disabling and excruciatingly painful neurological disorder. Few treatment options are available, and only a limited body of research from rigorous clinical trials exists. We are pleased the FDA has granted Priority Review for our sBLA, acknowledging the need for new treatments for this devastating disease and bringing us closer to potentially offering a preventive treatment option for these patients," said Gudarz Davar, M.D., vice president, Neurology Development, Lilly Bio-Medicines.

Cluster headache belongs to the group of primary headache disorders called trigeminal autonomic cephalalgias, and people with episodic cluster headache represent 85 to 90 percent of cluster headache sufferers, a disabling disorder with a prevalence of approximately 124 per 100,000 adults.¹ Cluster headache is under-recognized and often misdiagnosed. Currently, there are no approved preventive medications for episodic cluster headache in the U.S.

"The pain associated with cluster headache can be agonizing and crippling, with deep searing, burning, and stabbing pain, leaving people feeling desperate for new preventive treatment options. On behalf of the patient community, we are grateful to Lilly for their commitment to researching and working with regulatory authorities to potentially deliver a preventive treatment option for those living with episodic cluster headache," said Bob Wold, a person living with cluster headache and the founder of Clusterbusters, Inc.

Emgality was approved by the FDA in September 2018 for the preventive treatment of migraine in adults. Migraine is a neurologic disease characterized by recurrent episodes of severe headache.^{2,3} More than 30 million American adults suffer from migraine.^{4,5,6} Lilly is recruiting for Phase 3 studies evaluating Emgality for the prevention of migraine in children and adolescents (ages six to 17).⁷

Emgality represents the first of three investigational treatments in development as part of Lilly's overall pain portfolio. The portfolio also includes lasmiditan for the acute treatment of migraine in adults and tanezumab, developed in partnership with Pfizer, which is being investigated for the treatment of osteoarthritis pain, chronic low back pain and cancer pain in adults.

Indications and Usage for Emgality

Emgality (galcanezumab-gnlm) 120 mg injection is a calcitonin gene-related peptide (CGRP) antagonist indicated for the preventive treatment of migraine in adults.

Important Safety Information for Emgality

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 (e.g., rash, urticaria, and dyspnea) have been reported with Emgality in clinical studies. 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 $\geq 2\%$ 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 [pen](#) and [prefilled syringe](#).

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About Cluster Headache

Cluster headache is a disabling primary headache disorder characterized by severe pain with recurrent "attacks" of intense headaches which occur in cyclical patterns on one side of the head, frequently associated with pain behind or around one eye, restlessness and agitation.⁸ Cluster headache attacks typically last between 15 to 180 minutes, occurring near daily to multiple times daily during a cluster period.⁸ It is estimated that 85 to 90 percent of cluster headache cases are classified as "episodic."⁹

About Lilly's Commitment to Headache Disorders

For over 25 years, Lilly has been committed to helping people suffering from headache disorders, investigating more than a dozen different compounds for the treatment of migraine, cluster headache and other disabling headache disorders. These research programs have accelerated our understanding of these diseases and furthered the advancement of our comprehensive late-stage development programs studying galcanezumab-gnlm for the preventive treatment of migraine and cluster headache and lasmiditan for the acute treatment of migraine. Our goal is to make life better for people with headache disorders by offering comprehensive solutions to prevent or stop these disabling diseases. The combined clinical, academic and professional experience of our experts helps us build our research portfolio, identify challenges for healthcare providers and pinpoint the needs of patients living with migraine and cluster headache.

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. P-LLY

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 treatment for patients with migraine and potential treatment for patients with episodic cluster headaches; lasmiditan as a potential treatment for patients with migraine; and tanezumab, being developed in partnership with Pfizer, as a potential treatment for patients with osteoarthritis, chronic low back pain and cancer pain 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 or that lasmiditan or tanezumab will receive regulatory approval. 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.

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¹ Fischera M, Marziniak M, Gralow I & Evers S. The incidence and prevalence of cluster headache: a meta-analysis of population-based studies. *Cephalalgia* 2008; 614–618.

² Katsarava Z, Buse D, Manack A, et al. Defining the differences between episodic migraine and chronic migraine. *Current Pain Headache Reports*. 2012;16:86.

³ Blumenfeld AM, Varon SF, Wilcox TK, et al. Disability, HRQOL, and resource use amongst chronic and episodic migraineurs. Results from the International Burden of Migraine Study (IBMS). *Cephalalgia*.2011;31:301.

⁴ Lipton RB, Bigal ME, Diamond M, et al. Migraine prevalence, disease burden, and the need for preventive therapy. *Neurology*. 2007;68:343-349.

⁵ Data on File. Lilly USA, LLC. DOF-GZ-US-0028.

⁶ US Census Bureau. Quick Facts. <https://www.census.gov/quickfacts/fact/table/US/PST045217> . Updated September 23, 2018. Last accessed September 24, 2018.

⁷ A Study of Galcanezumab (LY2951742) in Participants 6 to 17 Years of Age With Episodic Migraine (REBUILD). <https://clinicaltrials.gov/ct2/show/NCT03432286>. Accessed February 1, 2019.

⁸ Headache Classification Committee of the International Headache Society (IHS). The international classification of headache disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1-211.

⁹ Hoffman J, May A. Diagnosis, pathology, and management of cluster headache. *Lancet Neurol*. 2018;17(1):75-83.

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