



Lilly Announces the Launch of TRIUMPH, the First, Long-Term, Real-World Evidence Study of Emgality® (galcanezumab-gnlm)

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-In TRIUMPH all treatment decisions will be determined exclusively by patients and physicians, providing important data about the comparative effectiveness of migraine preventive treatments in a real-world population - a current gap in the field of migraine research.

INDIANAPOLIS, Dec. 18, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today the launch of TRIUMPH, a long-term, real-world evidence study of Emgality® (galcanezumab-gnlm). The objective of the TRIUMPH study (Preventive **T**reatment of **M**igraine: **O**utcomes for **P**atients in Real-World **H**ealthcare Systems) is to evaluate the real-world effectiveness of Emgality, in comparison to other preventive treatments for migraine, among people receiving routine medical care who are switching or beginning a new prescription treatment for migraine prevention.

Migraine is the second leading cause of disability in the U.S. and affects more than 30 million adults.^{1,2,3,4} It affects three times more women than men and in the U.S. migraine attacks account for almost 35% of the approximately three million annual emergency department visits for headache.^{2,5} During a migraine attack, more than 90% of people are unable to function normally, and according to the Medical Expenditures Panel Survey, the total unadjusted cost associated with migraine in the U.S. is estimated to be as high as \$56 billion annually, yet migraine remains under-recognized and under-treated.^{2,6,7}

"The introduction of CGRP therapies, like Emgality, has provided physicians with valuable preventive treatment options for migraine. But historically and prior to this introduction, it's been estimated that more than 40% of people who use migraine preventive treatments have a history of failure or switching," said Gudarz Davar, M.D., vice president, neurology development, Lilly Bio-Medicines.⁸ "People with migraine deserve effective treatment options. The results from TRIUMPH will be enormously valuable to the migraine community in assessing the role of Emgality in long-term care and in comparison to other preventives."

The TRIUMPH study has a planned enrollment of approximately 2,850 patients from multiple sites across the U.S., Europe and Asia. The study will track prescribing and treatment choices related to migraine preventive treatment use over a two-year period and will include comparison of switching patterns and discontinuation rates between Emgality, other approved CGRP antibodies, oral migraine preventive treatments and botulinum toxin A or B. Patient-reported outcomes related to migraine burden, quality of life and overall-treatment satisfaction will be assessed. The study will also examine reduction in monthly migraine headache days, acute medication outcomes and other patterns of migraine treatment use over the two-year period. Throughout the study, treatment initiation or changes are solely at the discretion of the physician investigator and the patient.

"It's important for us to examine the real-world impact of our therapies outside of a formal, clinical trial setting," said Patrik Jonsson, senior vice president and president, Lilly Bio-Medicines. "By tracking physician and patient treatment decisions in the real-world, the results from TRIUMPH will contribute to a more comprehensive understanding of the real-world benefit of Emgality and its comparative effectiveness as a long-term treatment option."

For over 25 years, Lilly has been committed to helping people affected by disabling headache disorders, investigating more than a dozen different compounds. Lilly is also conducting ongoing observational studies to expand the breadth and depth of knowledge in the field of migraine. These studies include TRIUMPH, as well as OVERCOME. The OVERCOME study aims to be the largest U.S. study of its kind and is intended to further understanding of the burden and stigma experienced by people living with migraine, to identify barriers to appropriate treatment of migraine and to assess how the introduction of novel preventive and acute treatment options may influence delivery of migraine care.

About Emgality

Emgality is a monoclonal antibody that selectively binds to calcitonin gene-related peptide (CGRP) and was approved by the FDA in September 2018 for the preventive treatment of migraine in adults. Emgality is the only CGRP monoclonal antibody with response rates in the episodic migraine headache population on $\geq 50\%$, $\geq 75\%$ and 100% reduction from baseline in monthly migraine headache days over Months 1 to 6 included in its Full Prescribing Information. In June 2019 Emgality was approved by the FDA for the treatment of episodic cluster headache in adults.

Indications and Usage for Emgality (galcanezumab-gnlm) Injection

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 dyspnea, urticaria, and rash, have occurred with Emgality in clinical studies and the postmarketing setting. Cases of anaphylaxis and angioedema have also been reported in the postmarketing setting. 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 device.

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About Migraine

Migraine is a neurologic disease characterized by recurrent episodes of moderate-to-severe headache accompanied by other symptoms including nausea, sensitivity to light and sensitivity to sound.^{9,10,11} More than 30 million American adults have migraine, with three times more women affected by migraine compared to men.^{2,3,4} According to the Medical Expenditures Panel Survey, total annual healthcare costs associated with migraine are estimated to be as high as \$56 billion annually in the United States, yet it remains under-recognized and under-treated.^{2,6,7}

About Lilly's Commitment to Headache Disorders

For over 25 years, Lilly has been committed to helping people affected by headache disorders, investigating more than a dozen different compounds for the treatment of migraine and cluster headache. These research programs have accelerated our understanding of these diseases and furthered the advancement of Emgality, approved by the U.S. Food and Drug Administration for the preventive treatment of migraine in adults and the treatment of episodic cluster headache in adults. Our goal is to apply our combined clinical, academic and professional experience to build a research portfolio that delivers comprehensive solutions and addresses the needs of people affected by these disabling neurologic diseases.

About Eli Lilly and Company

Lilly is a global health care leader that unites caring with discovery to create medicines that 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 lilly.com and lilly.com/newsroom. 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 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 any 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. GBD 2016 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet*. 2017;390:1220.
2. Lipton RB, Bigal ME, Diamond M, et al; on behalf of the AMPP Advisory Group. Migraine prevalence, disease burden, and the need for preventive therapy. *Neurology*. 2007;68:343-349.
3. Data on file. Indianapolis, IN:Lilly USA, LLC.
4. US Census Bureau Quick Facts. <https://www.census.gov/quickfacts/fact/table/US/PST045217>. Updated July 1, 2018. Last accessed September 10, 2019.
5. Lucado J, Paez K, Elixhauser A. Headaches in U.S. hospitals and emergency departments, 2008. Agency for Healthcare Research and Quality website. Healthcare Cost and Utilization Project. (HCUP) Statistical Brief #111. <https://hcup-us.ahrq.gov/reports/statbriefs/sb111.pdf>. Published May 2011. Accessed September 13, 2019.
6. Raval AD, Shah A. National trends in direct health care expenditures among US adults with migraine: 2004 to 2013. *J Pain*. 2017;18:96-107.
7. Diamond S, Bigal ME, Silberstein S, et al. Patterns of diagnosis and acute and preventive treatment for migraine in the United States: results from the American Migraine Prevalence and Prevention Study. *Headache*. 2007;47:355-363.
8. Pike J, Mutebi A, Shah N, Jackson J, Cotton S, Desai PR, Sapra S. Factors associated with a history of failure and switching migraine prophylaxis treatment: an analysis of clinical practice data from the United States, Germany, France,

and Japan. *Value Health*. 2016;19(3):A68.

9. Blumenfeld AM, Payne KA, Varon SF, 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.

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

11. Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1-211.

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The Lilly logo is rendered in a vibrant red, cursive script font. The letters are fluid and interconnected, with a prominent 'L' at the beginning and a long, sweeping tail on the 'y'.

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