# AHS 2019: Post-Hoc Analyses of Phase 3 Pivotal Studies of Emgality® (galcanezumab-gnlm) Show Improvements in Daily Functioning and Reductions in Disability in Patients with Chronic and Episodic Migraine

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**-Results showed that treatment with Emgality, when compared to placebo, resulted in lower levels of migraine-related disability and fewer restrictions on daily activities that are limited by migraine, such as relationships with family and friends, leisure time, productivity, concentration, energy and fatigue(1)**

INDIANAPOLIS, July 12, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced the presentation of post-hoc analyses showing improvements in daily functioning and reductions in disability in patients with chronic and episodic migraine treated with Emgality® (galcanezumab-gnlm) compared to placebo.[1] The analyses are based on data from three double-blind, placebo-controlled, Phase 3 pivotal studies of Emgality in chronic (REGAIN) and episodic migraine (EVOLVE-1 & EVOLVE-2).[1] The data will be presented today at the 61st Annual Scientific Meeting of the American Headache Society (AHS) in Philadelphia.

"Migraine is the second leading cause of disability in the U.S. and can severely impact people's lives," said Gudarz Davar, M.D., vice president, Neurology Development, Lilly Bio-Medicines.[2] "Emgality gives people a chance to reduce their monthly migraine headache days. Given the diverse disability and restrictions imposed by migraine, it is important to understand whether treatments like Emgality can lead to improvements in people's migraine-related disability and restrictions imposed on their daily activities, relationships, productivity and free-time."

Based on the post-hoc analyses:

- Greater and statistically significant proportions of patients treated with Emgality showed reductions in disability due to migraine, as measured by the Migraine Disability Assessment (MIDAS), when compared to placebo.[1] The MIDAS questionnaire measures headache-related disability as lost time due to headache from paid work or school, household work and nonwork activities.[3] The MIDAS disability categories correspond to different levels of limitation and medical need.[3]
  - Among patients in the chronic migraine pivotal study (REGAIN), a statistically significant increase of 46.2% was seen in the proportion of patients with "little/no disability" after three months of treatment with Emgality compared to placebo (Emgality 20.3% vs. placebo 13.9%), regardless of baseline disability.[1]
  - In the pooled analysis of the pivotal studies for episodic migraine (EVOLVE-1 and EVOLVE-2), patients with "moderate to very severe disability" at baseline were 66.1% more likely to shift to "little/no disability" after six months of treatment with Emgality compared with placebo, with the difference achieving statistical significance (Emgality 44.0% vs. placebo 26.5%).[1]
- Treatment with Emgality was associated with improvements across all seven items of the Migraine-Specific Quality of Life Questionnaire Role Function-Restrictive Domain (MSQ-RFR).[1] The MSQ-RFR questionnaire measures the degree to which migraine limits a person's daily social and work-related activities, including: feeling more energetic; feeling less tired for work or daily activities; concentrating better on work/daily activities; able to get more done at work and home; less difficulty performing work/daily activities; less interference in leisure activities; and less interference dealing with family and friends.[4]
  - In the REGAIN pivotal study for chronic migraine, patient gains in daily functioning were greater among patients treated with Emgality compared to placebo, for all items of the MSQ-RFR, with most reaching statistical significance.[1]
  - In the pooled analysis of the pivotal studies for episodic migraine (EVOLVE-1 and EVOLVE-2) patient gains in daily functioning were statistically significantly greater among patients treated with Emgality as compared to placebo across all seven items of MSQ-RFR.[1]

Overall, the analyses showed that patients treated with Emgality for the prevention of chronic or episodic migraine showed improvements in migraine-related disability and functional gains in the performance of daily activities that are limited by migraine.[1]

**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 and in June 2019 for the treatment of episodic cluster headache in adults. Emgality was also approved in Europe in November 2018 for the prophylaxis of migraine in adults who have at least four migraine days per month.

**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 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 Migraine**
Migraine is a neurologic disease characterized by recurrent episodes of severe headache accompanied by other symptoms including nausea, vomiting, sensitivity to light and sound and changes in vision.[5,6] More than 30 million U.S. adults have migraine, with three times more women affected by migraine compared to men.[7] 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.[8]

**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 our comprehensive late-stage development programs studying galcanezumab-gnlm, 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, and lasmiditan, an investigational drug currently under review by the U.S. Food and Drug Administration for the acute treatment of migraine with or without aura 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 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 upon 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 preventive treatment for patients with migraine and as a treatment for patients with episodic cluster headache and lasmiditan as a potential acute treatment for patients with migraine, 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.

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