Emgality® Demonstrates Reduction in Frequency, Duration, and Pain Severity in Patients with Episodic and Chronic Migraine

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INDIANAPOLIS, June 17, 2020 /PRNewswire/ -- Emgality® (galcanezumab-gnlm) reduces total pain burden in a recent analysis of patients with episodic and chronic migraine. Total pain burden is a patient-centric measure that combines the monthly frequency, duration, and pain severity of migraine. Additionally, total pain burden demonstrated significant associations with patient functioning and quality of life. Eli Lilly and Company's (NYSE: LLY) Emgality is the first and only migraine preventive CGRP medication to be assessed in this manner, providing a more complete picture of how Emgality reduced frequency, duration, and severity of migraine pain. These results were presented virtually at the 62nd American Headache Society Congress during National Migraine Awareness Month and at the 72nd American Academy of Neurology Annual Meeting in April (click here for the abstract).

"Total pain burden moves beyond the current and somewhat limited approach for describing migraine pain," said Gudarz Davar, M.D., vice president, neurology development, Lilly Bio-Medicines. "We're delighted that Emgality reduced the combined impact of migraine frequency, duration, and pain severity. We believe that viewing migraine through the lens of total pain burden provides a more holistic approach for people with migraine and doctors to discuss the personal pain experience."

This post hoc analysis of Emgality versus placebo used data from three randomized, double-blind studies in patients with episodic migraine (two pooled six-month studies – EVOLVE-1 and EVOLVE-2; Emgality n=435, placebo n=872) and chronic migraine (one three-month study – REGAIN; Emgality n=273, placebo n=535). Patients reported their headache frequency, duration, and severity using an electronic diary. Monthly total pain burden was calculated as severity-weighted duration by multiplying hours of migraine recorded and pain severity (0=none, 1=mild, 2=moderate, 3=severe) for each migraine day and summing these composite measurements over the migraine days in a month.

The mean change from baseline in monthly total pain burden was compared between Emgality and placebo groups. Patients on Emgality experienced statistically fewer severity-weighted hours of pain than at baseline at each month compared with patients on placebo ($p<0.0001$ for each comparison). In episodic migraine, patients on Emgality experienced 68.6 fewer severity-weighted hours of pain per month on average than at baseline and compared to those on placebo who experienced 36.2 fewer hours (mean difference = 32.3 fewer hours, 95% CI: 24.2 to 40.3). In chronic migraine, patients on Emgality experienced 102.6 fewer severity-weighted hours of pain per month on average than at baseline and compared to those on placebo who experienced 44.4 fewer hours of pain than at baseline (mean difference = 58.2 severity-weighted hours, 95% CI: 37.1 to 79.3).

"The impact of migraine is profound, and individualized management goes beyond how many days per month a person experiences migraine. Total pain burden serves as a more comprehensive measure and provides a deeper understanding for us and our patients to describe their pain," said Jessica Ailani, M.D., Director, MedStar Georgetown Headache Center, Professor of Clinical Neurology, Georgetown University Hospital. "As a clinician, I'm pleased that Emgality may help my patients achieve their preventive treatment goals. I am excited the results of this study show a positive impact on the cumulative burden of frequency, duration, and pain severity of migraine."

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 empowered us to offer new and novel medications to patients and healthcare professionals.

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 ≥50%, ≥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) 120 mg 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 ≥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. More than 30 million American adults have migraine, with three times more women affected by migraine compared to men. 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.

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.

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