Emgality® Versus Nurtec® ODT Head-to-Head Migraine Preventive Treatment Study Now Enrolling Patients

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- CHALLENGE-MIG is the first and only clinical trial comparing two anti-calcitonin gene-related peptide (CGRP) medicines, Emgality and Nurtec ODT, which work differently

- The study's primary endpoint is the percentage of patients with ≥50% reduction from baseline in monthly migraine headache days

- The study's secondary endpoints include quality of life improvements and the percentage of patients with ≥75% and 100% reductions from baseline in monthly migraine headache days

INDIANAPOLIS, Nov. 18, 2021 /PRNewswire/ -- Today, Eli Lilly and Company (NYSE: LLY) announced that enrollment is now open for the CHALLENGE-MIG clinical trial, the first and only head-to-head trial comparing two anti-calcitonin gene-related peptide (CGRP) medicines for the preventive treatment of episodic migraine in adults.[1] The study is evaluating once-monthly Emgality® (galcanezumab-gnlm) injection compared to Nurtec® ODT (rimegepant), a tablet patients take every other day, on patient-centric measures, including reductions in monthly migraine headache days and quality of life improvement.

While Nurtec ODT and Emgality are both medications that target CGRP, because Emgality is a monoclonal antibody (mAb) that binds to CGRP (a protein found in the brain thought to play a key role in migraine), it works differently than gepants like Nurtec ODT, that bind to and block the CGRP receptor.[2-4] Emgality is the only CGRP medication with ≥50%, ≥75% and 100% reductions of monthly migraine headache days in its label for people with episodic migraine experiencing 4 to 14 migraine headache days per month. Lilly's CHALLENGE-MIG study aims to deepen the understanding of CGRP monoclonal antibodies (mAbs) compared to oral gepants in the preventive treatment of migraine and answer important questions that will help physicians and patients make informed treatment decisions.

"Migraine can greatly impact day-to-day activities, robbing people of their routines and their everyday and special occasions in life. Reducing the frequency of migraine attacks can help people achieve more migraine-free days and enjoy an improved quality of life; both of which are essential treatment goals," said Shivang Joshi, a trial investigator and neurologist at Dent Neurologic Institute. "Lilly's CHALLENGE-MIG study will help us understand how different types of preventive medications (CGRP mAbs vs. gepants) may help people achieve the goals that matter most to them. It's exciting that insights generated in this first-of-its-kind head-to-head trial will be able to spark treatment plan discussions between people with migraine and their health care providers."

The CHALLENGE-MIG clinical trial is expected to enroll approximately 700 adults across the U.S. with episodic migraine, and individual participation in the study can last up to 6 months. For more information about the CHALLENGE-MIG trial, contact The Lilly Answers Center at 1-800-LillyRx (1-800-545-5979). Information about the CHALLENGE-MIG study is also available at the Lilly booth at the American Headache Society's annual education symposium taking place in Scottsdale, AZ, November 18-21, 2021.

"Lilly has been deeply committed to neuroscience research across a spectrum of diseases for over 30 years," said Anne White, senior vice president of Eli Lilly and Company and president of Lilly Neuroscience. "We believe patients should expect more and get more from medications that can help prevent migraine. Therefore, we look forward to sharing the findings from our Emgality versus Nurtec ODT head-to-head trial."

About the CHALLENGE-MIG Study

In the first head-to-head clinical trial comparing two medications targeting calcitonin gene-related peptide (CGRP), the CHALLENGE-MIG is a randomized, double-blind, placebo-controlled Phase 4 study in adult patients who meet the International Classification of Headache Disorders-3 (ICHD-3) criteria for a diagnosis of migraine with or without aura and experiencing 4-14 migraine headache days per month. The study aims to evaluate the efficacy and safety of once-monthly injectable Emgality® (galcanezumab-gnlm) compared to every-other-day Nurtec® ODT (rimegepant) taken orally. The primary endpoint is ≥50% reduction from baseline in monthly migraine headache days across the 3-month double-blind treatment period. Secondary endpoints include ≥75% and 100% reduction from baseline in monthly migraine headache days and improvements in the Migraine-Specific Quality of Life (MSQ), a 14-item questionnaire designed to measure migraine-specific health-related quality of life by assessing the limitation of daily performance, and the Migraine Disability Assessment (MIDAS), a five-item questionnaire used to assess headache-related disability in the past three months.

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 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, 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 severely disabling neurologic disease characterized by recurrent episodes of moderate to severe headache accompanied by other symptoms including nausea, sensitivity to light, and sensitivity to sound.[5,6] More than 30 million American adults have migraine, with three times more women than men affected by migraine.[7] Migraine is often incapacitating, leading to high personal, societal and economic burden. According to the Medical Expenditures Panel Survey, total annual healthcare costs associated with migraine are estimated to be as high as $56 billion in the United States, yet it remains under-recognized and under-treated.[8]

About Lilly's Commitment to Headache Disorders
For more than 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 treatments for headache disorders. Our goal is to apply our combined clinical, academic and professional experience to build a research portfolio that delivers broad 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.

Lilly Forward-Looking Statement
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 beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with study findings to date, that Emgality will receive any additional regulatory approvals, or that Emgality will 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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