Lilly Announces Head-to-Head Study Comparing Once-Monthly Emgality® with Every-Other-Day Nurtec® ODT for the Preventive Treatment of Migraine

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- First clinical trial comparing anti-CGRP migraine preventive medicines

INDIANAPOLIS, June 15, 2021 /PRNewswire/ -- To advance the science of migraine treatment and aid the understanding of calcitonin gene-related peptide (CGRP) monoclonal antibodies (mAbs) compared to oral CGRP receptor antagonists in the prevention of migraine, Eli Lilly and Company (NYSE: LLY) will be conducting a head-to-head study comparing once-monthly injectable Emgality® (galcanezumab-gnlm) with Nurtec® ODT (rimegepant), an orally disintegrating tablet patients take every other day. CGRP is a protein in the brain thought to play a key role in migraine. Emgality binds to this protein, preventing it from attaching to the CGRP receptors, whereas Nurtec ODT blocks the receptor for this protein.[1-3] This study aims to answer important questions that will help clinicians and patients make more informed treatment decisions on the path to more migraine-free days.

The study, which is the first head-to-head clinical trial comparing two medications targeting CGRP, is a multi-site, randomized, double-blind, double-dummy, parallel-group Phase 4 study in patients who meet the International Classification of Headache Disorders (ICHD) criteria for a diagnosis of episodic migraine with or without aura. There will be two treatment arms: Emgality 120 mg once-monthly injection, with an initial 240 mg loading dose, and Nurtec ODT 75 mg, taken every other day. The study's primary endpoint is 50% reduction in monthly migraine headache days. Enrollment is expected to begin later this year.

"Migraine is a painful, burdensome and complex neurologic disease. Every person's experience is different. Providing patients with options and individualized treatment plans is vitally important," said Ilya Yuffa, senior vice president and president, Lilly Bio-Medicines. "We are confident in Emgality's efficacy profile and that our head-to-head clinical trial against Nurtec ODT will yield valuable insights for patients and their healthcare providers."

Emgality is the only CGRP therapy that includes ≥50%, ≥75% and 100% reduction in monthly migraine headache days for the duration of the treatment period for episodic migraine patients, in its FDA-approved labeling. Emgality's adherence and persistence findings were recently presented at AHS, and insights about interictal burden (impact of migraine between migraine attacks) were shared previously.

"The American Headache Society and the National Headache Foundation have endorsed several goals that raise the treatment outcomes bar for preventive migraine medications. Patients tell us they want an easy and convenient migraine treatment that can help them be productive and free to focus on what matters most to them. In order for patients to manage their own disease and have a sense of personal control, they need to find treatments that work for them that they can stay on. Reducing the number of days patients experience migraine is possible and it's important that patients and their HCPs talk about this as a goal," said Dr. Merle Diamond, managing director of the Diamond Headache Clinic and longstanding board member of the National Headache Foundation. "Undertaking this head-to-head study signals Lilly's confidence in Emgality, a once-monthly injectable monoclonal antibody CGRP antagonist (CGRP mAb), as it compares to Nurtec ODT, a small molecule oral CGRP receptor antagonist (gepant), for the prevention of migraine."

"This year, we are proud to help more than 700,000 Emgality patients. We encourage HCPs and patients to talk about the preventive treatment goal of freedom from migraine through reduced frequency of attacks, which can also result in greater quality of life and functional improvements. We believe people should expect more and get more from their migraine medications," said Yuffa. "We're looking forward to commencing the study later this year and sharing our results."

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.[4,5] More than 30 million American adults have migraine, with three times more women than men affected by migraine.[6] 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.[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 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. P-LLY

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 can be no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with the results to date, or 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.

Emgality® is a registered trademark owned or licensed by Eli Lilly and Company, its subsidiaries, or affiliates. All non-Lilly products referenced are the trademarks of their respective owners.

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Refer to: Jen Dial; dial_jennifer_kay@lilly.com; 317-220-1172 (Lilly Bio-Medicines)
Kevin Hern; hern_kevin_r@lilly.com; 317-277-1838 (Investor Relations)

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