AAN 2019: Pooled Analyses of Two Emgality® (galcanezumab-gnlm) Phase 3 Studies Show Reduction in Monthly Migraine Headache Days in Low- and High-Frequency Episodic Migraine Subgroups

May 6, 2019

INDIANAPOLIS, May 6, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced the upcoming presentation of results from pooled subgroup analyses of efficacy data from the Phase 3 EVOLVE-1 and EVOLVE-2 studies. These analyses demonstrate a reduction in monthly migraine headache days with Emgality® (galcanezumab-gnlm) versus placebo in patients with low- and high-frequency episodic migraine.[1] Detailed results will be presented in an oral platform presentation (**S17.003**) at the Annual Meeting of the American Academy of Neurology (AAN) taking place in Philadelphia from May 4-10, 2019.

"Migraine causes people to suffer from substantial pain and impairment, no matter how frequently they occur. These collective analyses of more than 1,700 patients with episodic migraine from our Phase 3 Emgality program reflect our continued commitment to aid people living with this serious neurologic disorder," said Gudarz Davar, M.D., vice president, Neurology Development, Lilly Bio-Medicines.

In these analyses of the EVOLVE-1 and EVOLVE-2 trials, patients were stratified by low-frequency (from four to less than eight monthly migraine headache days) and high-frequency (from eight to 14 monthly migraine headache days) subgroups. Emgality 120 mg and 240 mg demonstrated a statistically significant reduction in monthly migraine headache days in both the low- and high-frequency subgroups, when compared with placebo.[1] Analyses of a number of secondary endpoints demonstrated statistically significant improvements in both low- and high-frequency subgroups compared to placebo, including the mean percentage of patients with ≥50%, ≥75% and ≥100% reduction from baseline in overall monthly migraine headache days and the impact of Emgality on quality of life measurements.[1]

These data will be delivered via oral presentation (**S17.003**) today from 1:00 PM – 3:00 PM.

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 was also approved in Europe in November 2018 for the prophylaxis of migraine in adults who have at least four migraine days per month. Emgality is currently under Priority Review by the FDA as an investigational drug for the preventive treatment of episodic cluster headache in adults.

Indications and Usage for Emgality (galcanezumab-gnlm) injection
Emgality is indicated for the preventive treatment of migraine in adults.

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 (e.g., rash, urticaria, and dyspnea) have been reported with Emgality in clinical studies. 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 pen and prefilled syringe.

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About the EVOLVE-1 and EVOLVE-2 Studies
EVOLVE-1 and EVOLVE-2 are six-month Phase 3, randomized, double-blind, placebo-controlled global trials that evaluated the safety and efficacy of two doses of galcanezumab-gnlm administered subcutaneously (120 mg or 240 mg once-monthly, following a 240 mg starting dose) compared with placebo in patients with episodic migraine. To be eligible for the trials, patients must have experienced between four and 14 migraine headache days per month. Patients that participated in these trials had an average of 9.1 migraine headache days per month at baseline. Patients were allowed to use acute headache treatments, including migraine-specific medications (i.e., triptans, ergotamine derivatives), NSAIDs, and acetaminophen during the study. The primary endpoint was the mean change from baseline in monthly migraine headache days over the six-month, double-blind treatment phase.

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.[2,3] More than 30 million U.S. adults have migraine, with three times more women affected by migraine compared to men.[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.[5]

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 currently under Priority Review for 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 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 potential 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 or that lasmiditan will receive regulatory approval. 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:

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4. Lipton RB, Bigal ME, Diamond M, et al., Migraine prevalence, disease burden, and the need for preventive therapy. *Neurology*. 2007;68:343-349.
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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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