Emgality® Shows Improvement in Work Productivity and Health and Well-Being Between Attacks in Patients with Migraine and a History of Preventive Treatment Failure

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INDIANAPOLIS, May 26, 2020 /PRNewswire/ -- Emgality® (galcanezumab-gnlm) significantly improved work productivity and reduced interictal burden, defined as health and well-being between migraine attacks, in an analysis of the 3-month double-blind period of the CONQUER study, which included patients with migraine from 12 different countries. The Phase 3 CONQUER study evaluated the efficacy and safety of Emgality for the preventive treatment of episodic and chronic migraine in patients with documented previous treatment failures on two to four different standard-of-care migraine preventive medication categories, due to inadequate efficacy or for safety/tolerability reasons.

"Migraine imposes a profoundly debilitating burden, including interference with work and compromises to social life, that extends beyond the duration of the attacks themselves. At Lilly, we believe that patients and practitioners should expect more from their preventive migraine treatments," said Gudarz Davar, M.D., vice president, neurology development, Lilly Bio-Medicines. "In this important analysis of the clinical trial data, patients reported that Emgality improved their day-to-day functioning and work productivity."

Absenteeism (unplanned absence from work), presenteeism (impairment while working), overall work productivity loss and activity impairment (non-work related) were measured using the migraine-specific Work Productivity and Activity Impairment Questionnaire (WPAI). The burden between headache attacks (interictal burden) in four key areas, including disruption at work and school, diminished family and social life, difficulty planning, and emotional difficulty, was measured using the Migraine Interictal Burden Scale (MIBS) which is a 12 point scale (categories: 0 none, 1-2 mild, 3-4 moderate and >5 severe).

Among the 462 patients randomized to Emgality (n=232) or placebo (n=230), there were statistically significant improvements in work productivity (WPAI) and reductions in overall work productivity loss for the Emgality group compared with placebo (-14.3% vs -3.5%; p<0.01). These gains in productivity appeared to be driven by statistically significant improvements in presenteeism (-12.5% vs -2.6%; p<0.01). Absenteeism was low and not significantly different between groups. Non-work-related activity impairment was also statistically significantly reduced in the Emgality group compared to placebo (-20.7% vs -8.6%; p<0.01). Results were similar in the subgroups of patients with episodic or chronic migraine.

Additionally, the average change in MIBS from a baseline of 5.5 (indicative of severe burden in the time between migraine attacks) was statistically significantly greater in patients receiving Emgality compared to placebo (-1.8 vs -0.8, respectively; p<0.0001). Among patients with episodic migraine, the most common categorization of MIBS at Month 3 was "none" for Emgality-treated patients versus "severe" for placebo-treated patients. Among patients with chronic migraine, fewer Emgality-treated patients had "severe" interictal burden per the MIBS at Month 3, with twice as many Emgality-treated patients reporting "mild" interictal burden in comparison to placebo.

"Migraine is the second leading cause of disability worldwide and one of the main causes of disability in people between 15 and 49 years old, robbing years of their lives when most people are fostering friendships, establishing their careers and caring for their family. In the U.S., 157 million workdays are lost each year due to migraine. Productivity losses are even greater among those who have tried numerous preventive treatments without finding an option that works for them," said David García-Azorín, M.D., MSci, Valladolid University Hospital Headache Clinic. "This study showed that Emgality improved workplace productivity and decreased impairment between attacks, both important outcomes for patients. Given the disabling effects of migraine, Emgality is an option that may help patients achieve the treatment goals that matter to them."

These results were presented virtually at the 6th European Academy of Neurology (EAN) Congress(see EPR1100). For over 25 years, Lilly has been committed to helping people affected by disabling headache disorders, investigating more than a dozen different compounds for the acute and preventive 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 (NYSE: LLY) 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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