First-Of-Its-Kind Head-to-Head Clinical Trial Reaffirms the Efficacy of Emgality in Episodic Migraine Prevention

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Emgality demonstrated robust efficacy for patients consistent with previous studies, although it did not achieve statistical superiority versus active comparator on the primary endpoint

Emgality performed numerically better than the active comparator on key secondary endpoints of the CHALLENGE-MIG trial

The CHALLENGE-MIG study demonstrates Lilly's commitment to migraine research and results underscore that people living with episodic migraine deserve broad access to effective treatments

INDIANAPOLIS, June 16, 2023 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced results of the CHALLENGE-MIG clinical trial of Emgality® (galcanezumab-gnlm) and Nurtec® ODT (rimegepant orally disintegrating tablet), the first and only trial of its kind comparing two calcitonin gene-related peptide (CGRP) antagonist therapies. Emgality did not meet the study's primary endpoint, defined as statistical superiority to Nurtec ODT on the percentage of participants achieving a 50% or greater reduction in monthly migraine headache days. Response rates were similar. However, it demonstrated clinically meaningful efficacy and safety in this 3-month study consistent with Emgality's previous 6-month studies. And, Emgality performed numerically better on key secondary endpoints of the 3-month trial.

"These results bolster our knowledge of Emgality's ability to work quickly and help patients improve their quality of life with less frequent dosing," said Anne White, executive vice president of Eli Lilly and Company and president of Lilly Neuroscience. "Reducing the frequency of migraine headache days can help people experience more freedom from the burden of this debilitating neurological disease and get back to participating in the daily activities that matter most to them."

Emgality is a monoclonal antibody (mAb) that inhibits the effects of CGRP by binding directly to CGRP, while gepants like Nurtec ODT bind to and block the CGRP receptor. Emgality is administered via injection, and Nurtec ODT is administered orally.

CHALLENGE-MIG was a 3-month, double-blind clinical study that assessed the efficacy and safety of Emgality compared to Nurtec ODT in the prevention of episodic migraine in adults. The study randomized 580 participants to either four injections of Emgality 120 mg (a loading dose of two injections followed by two additional monthly injections) or 45 doses of Nurtec ODT 75 mg (one oral tablet every other day), both of which are the regulatory approved doses. Also, patients assigned to Emgality received placebo ODT and patients assigned to Nurtec ODT received placebo injections.

"Despite being the third most common disease worldwide, migraine remains largely under-diagnosed and under-treated," said Peter Goadsby, MBBS, M.D., Ph.D., King's College London and University of California, Los Angeles, CA. "I applaud Lilly for embarking on this bold study and their continued investment in the migraine community to better inform care. These results reinforce the impact that innovative medicines can have in the prevention of migraine."

In CHALLENGE-MIG, the safety profiles of Emgality and Nurtec ODT were consistent with those previously reported for both treatments. There were no new safety findings.

Lilly will disclose the full results of the CHALLENGE-MIG trial later this year.

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/300 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 (galcanezumab-gnlm)

Emgality is **contraindicated** in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients.

Hypersensitivity reactions, including dyspnea, urticaria, and rash, have occurred with Emgality in clinical studies and the post marketing setting. Cases of anaphylaxis and angioedema have also been reported in the post marketing 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.

The **most common adverse reactions (incidence ≥2% and at least 2% greater than placebo)** in Emgality clinical studies were injection site reactions.

For more information about Emgality, please see Full Prescribing Information. See Instructions for Use included with the device.

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About Lilly
Lilly unites caring with discovery to create medicines that make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 51 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges, redefining diabetes care, treating obesity and curtailing its most devastating long-term effects, advancing the fight against Alzheimer's disease, providing solutions to some of the most debilitating immune system disorders, and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit lilly.com and lilly.com/newsroom or follow us on Facebook, Instagram, Twitter and LinkedIn. 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 is no guarantee that patient and future study results will be consistent with study findings to date, that the CHALLENGE-MIG clinical trial results will achieve Lilly's objectives, or that Lilly will execute its strategy as planned. 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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