AHS 2018: Lilly Highlights Positive Phase 3 Results from the Largest Controlled Preventive Trial in Episodic Cluster Headache

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INDIANAPOLIS, June 27, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE:LLY) announced today full results from a positive Phase 3 study of patients with episodic cluster headache treated with Emgality ™(galcanezumab-gnlm). Detailed primary and secondary results will be presented Saturday, June 30 as a late-breaking presentation at the American Headache Society (AHS) annual meeting in San Francisco.

Lilly also announced today that the intended brand name, Emgality ™, has been conditionally accepted by the U.S. Food and Drug Administration (FDA).

In this study, patients with episodic cluster headache treated with Emgality (300 mg once-monthly) experienced statistically significant differences in the reduction of weekly cluster headache attacks compared to patients treated with placebo across Weeks 1 to 3 of the two-month, double-blind treatment period (-8.7 for Emgality compared to -5.2 for placebo, p=0.036), the primary endpoint of the study. Three out of four patients (76%) treated with Emgality (300 mg once-monthly) achieved at least a 50 percent reduction in weekly cluster headache attacks compared to 57 percent for placebo at Week 3 (p=0.04), the gated secondary endpoint. Additionally, 73 percent of patients treated with Emgality reported improvements based on the Patient Global Impression of Improvement (PGI-I) at Week 4, compared to 46 percent for placebo (p=0.016).

"Often confused with migraine, cluster headache is a neurological disease that has been characterized as 'beyond excruciating' by those who live with it," said Christi Shaw, president of Lilly Bio-Medicines. "We are proud to present full results of this data, which represents potential hope for a resilient community of people struggling to prevent episodic cluster headache."

Episodic Cluster Headache Study Results

The episodic cluster headache study included a two-month treatment period comparing Emgality to placebo. Patients with episodic cluster headache treated with Emgality (300 mg once-monthly) experienced statistically significant differences in the reduction of weekly cluster headache attacks compared to patients treated with placebo across Weeks 1 to 3 of the two-month, double-blind treatment period (-8.7 for Emgality compared to -5.2 for placebo, p=0.036), the primary endpoint of the study.

The observed safety and tolerability profile was consistent with previous studies that evaluated Emgality for the prevention of migraine. In this study, 8 percent of patients treated with Emgality discontinued treatment during the study compared to 21 percent of patients treated with placebo. Four percent of patients treated with Emgality discontinued treatment during the study due to adverse events compared to 2 percent of patients treated with placebo. Discontinuations due to lack of efficacy occurred in 2 percent of patients treated with Emgality, compared to 14 percent of patients treated with placebo (p=0.036).

Emgality is a once-monthly, self-administered calcitonin gene-related peptide (CGRP) antibody currently under review by the FDA for the prevention of migraine in adults. A decision is expected by the end of September 2018.

Based on results from the episodic cluster headache trial, Lilly is working with regulatory agencies around the world to determine the best path forward. Episodic cluster headache represents 85 to 90 percent of cluster headache cases.[1]

About the Phase 3 Study

The episodic cluster headache study was a two-month Phase 3, randomized, double-blind, placebo-controlled international trial evaluating the safety and efficacy of Emgality (300 mg once-monthly) administered subcutaneously compared with placebo in 106 patients with episodic cluster headache. Patients who participated in this trial had an average of 17.5 cluster headache attacks per week at baseline. The primary endpoint was the overall mean change from baseline in weekly cluster headache attack frequency across weeks one to three with Emgality compared with placebo.

The key (gated) secondary endpoint was the proportion of patients achieving a response, defined as a reduction from baseline of at least 50 percent in the weekly cluster headache attack frequency at Week 3. Other secondary endpoints included proportion of participants very much or much better based on (PGI-I) at Weeks 4 and 8.

About Cluster Headache

Cluster headache is a disabling headache disorder composed of recurrent "attacks" of intense headaches on one side of the head, frequently associated with pain behind or around one eye, restlessness and agitation.[1,2] Cluster headache attacks typically last between 15 to 180 minutes, occurring near daily to multiple times daily during a cluster period.[1] It is estimated that 85 to 90 percent of cluster headache cases are classified as "episodic" with attacks occurring in periods that last from seven days to one year, separated by pain-free remission periods of three months or longer.[2] The remaining 10 to 15 percent are classified as "chronic" with attacks occurring for more than one year without a remission period, or with remission lasting less than three months.[1]

About Emgality ™

Emgality ™(galcanezumab-gnlm) is a monoclonal antibody specifically designed to bind to and reduce the overactivity of calcitonin gene-related peptide (CGRP), which is believed to play a role in migraine and cluster headache. Emgality is an investigational once-monthly, self-administered injection under evaluation for the prevention of migraine and cluster headache.

About Lilly's Commitment to Headache Disorders

For over 25 years, Lilly has been committed to helping people suffering from headache disorders, investigating more than a dozen different

compounds for the treatment of migraine, cluster headache and other disabling headache disorders. These research programs have accelerated the understanding of these diseases and furthered the advancement of Lilly's comprehensive late-stage development programs studying Emgality for prevention of migraine and cluster headache, and lasmiditan for the acute treatment of migraine. Our goal is to make life better for people with headache disorders by offering comprehensive solutions to prevent or stop these disabling diseases. The combined clinical, academic and professional experience of our experts helps us to build our research portfolio, identify challenges for healthcare providers and pinpoint the needs of patients living with migraine and cluster headache.

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 as a potential treatment for patients with cluster headache and 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 future study results will be consistent with the results to date or that Emgality will receive regulatory approvals. 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.

[1] Matharu M, Goadsby P. Trigeminal autonomic cephalgias. *Journal of Neurology, Neurosurgery, and Psychiatry*. 2002;72(Suppl II):ii19-ii26.

[2] Headache Classification Committee of the International Headache Society (IHS). The international classification of headache disorders, 3rd edition. *Cephalalgia.* 2018;38(1):1–211.

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