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Lilly Announces Positive Results for Three Phase 3 Studies of Galcanezumab for the Prevention of Episodic and Chronic Migraine

INDIANAPOLIS, May 12, 2017 /CNW/ -- Eli Lilly and Company (NYSE: LLY) announced today that galcanezumab, an investigational treatment for the prevention of episodic and chronic migraine, met its primary endpoint in three Phase 3 studies (EVOLVE-1, EVOLVE-2 and REGAIN) demonstrating statistically significant reductions in the number of monthly migraine headache days compared to placebo at both studied doses.

"The robust results from these three studies bring us one step closer to helping people experience more migraine-free days, an important treatment goal for those living with this serious disease," said Christi Shaw, president of Lilly Bio-Medicines. "The impact of migraine is underestimated, with people who experience migraine attacks often missing work, family activities or social engagements. For patients with as few as one migraine headache day per week, this can mean more than 50 days of lost productivity a year."

In these three studies, the most commonly-reported adverse events were injection site reactions, including pain. The observed safety and tolerability profile was consistent with findings from previous studies of galcanezumab.

Based on these results, Lilly will submit a Biologics License Application to the U.S. Food and Drug Administration (FDA) for galcanezumab in the second half of 2017, followed by submissions to other regulatory agencies around the world.

EVOLVE-1 and EVOLVE-2 Study Results

In both studies, over the six-month treatment period, patients with episodic migraine treated with galcanezumab 120 mg and 240 mg doses experienced a significantly greater decrease in the average number of monthly migraine headache days compared to patients treated with placebo.

- ┆ EVOLVE-1: Average reduction of 4.7 days for 120 mg and 4.6 days for 240 mg compared to an average reduction of 2.8 days for placebo, $p < 0.001$ for both dosing groups.
- ┆ EVOLVE-2: Average reduction of 4.3 days for 120 mg and 4.2 days for 240 mg compared to an average reduction of 2.3 days for placebo, $p < 0.001$ for both dosing groups.

Additionally, patients treated with galcanezumab experienced statistically significant improvement compared to placebo on several pre-specified secondary endpoints, including response rates and measures of daily activities.

REGAIN Study Results

Over the three-month treatment period, patients with chronic migraine treated with galcanezumab 120 mg and 240 mg doses experienced a significantly greater decrease in the average number of monthly migraine headache days compared to patients treated with placebo (average reduction of 4.8 days for 120 mg and 4.6 days for 240 mg compared to an average reduction of 2.7 days for placebo, $p < 0.001$ for both dosing groups).

Additionally, patients treated with galcanezumab experienced statistically significant improvement compared to placebo on several pre-specified secondary endpoints, including response rates and measures of daily activities.

"Lilly's commitment to the development of new treatments for migraine has spanned more than 25 years, and in that time, we have played an important role in advancing the understanding of this serious disease," said Robert Conley, M.D., Distinguished Lilly Scholar and Lilly global development leader for migraine therapeutics. "The topline results from these Phase 3 data are encouraging and reaffirm the potential for galcanezumab to provide a new option for people living with migraine."

Lilly will present detailed data from these studies at scientific meetings later this year and submit the results to peer-reviewed journals.

Lilly also is evaluating galcanezumab for the treatment of cluster headache, with Phase 3 trial results expected in 2018. Based on the unmet medical need and significance of this disease for patients, Lilly has been granted Fast Track

Designation from the FDA.

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 evaluating the safety and efficacy of two doses of galcanezumab 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. The primary endpoint was the mean change from baseline in monthly migraine headache days over the six-month, double-blind treatment phase.

About the REGAIN Study

REGAIN is a three-month Phase 3, randomized, double-blind, placebo-controlled global trial evaluating the safety and efficacy of two doses of galcanezumab administered subcutaneously (120 mg or 240 mg once-monthly, following a 240 mg starting dose) compared with placebo in patients with chronic migraine. To be eligible for the trial, patients must have experienced at least 15 headache days per month, of which at least eight met criteria for migraine. Patients that participated in the trial had an average of 19.4 migraine headache days per month at baseline. The primary endpoint was the mean change from baseline in monthly migraine headache days over the three-month, double-blind treatment phase. In REGAIN, galcanezumab was further evaluated for an additional nine months of an open-label extension phase following the three-month, double-blind treatment phase.

About Migraine

Migraine is a disabling neurological disease characterized by recurrent episodes of severe headache, and is often accompanied by other symptoms including nausea, vomiting, sensitivity to light and sound, and changes in vision.^{1,2} More than 38 million Americans have migraine, with three times more women affected by migraine compared to men.³ Of the approximately 40 percent of patients suffering from migraine for whom prevention is appropriate, only 13 percent are currently receiving therapy.^{4,5,6} Results from the Second International Burden of Migraine study show that side effects of treatment play a role in this disconnect, with up to 53 percent of respondents discontinuing migraine prevention therapy because of side effects.⁷ According to the Migraine Research Foundation, healthcare and lost productivity costs associated with migraine are estimated to be as high as \$36 billion annually in the U.S., yet it remains under-recognized and under-treated.^{3,7}

About Lilly in Migraine

Lilly has been committed to helping people suffering from migraine for over 25 years, investigating more than a dozen different compounds for the treatment of headache disorders. These research programs have accelerated understanding of this disease and advanced the development of Lilly's comprehensive late-stage development programs studying galcanezumab for prevention of migraine and lasmiditan for the acute treatment of migraine. Our goal is to make life better for people with migraine by offering comprehensive solutions to prevent or stop this disabling disease. 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 Galcanezumab

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

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This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about galcanezumab as a potential treatment for patients with chronic and episodic migraine and 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 future study results will be consistent with the results to date, that galcanezumab will achieve its primary study endpoints or 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 Headache disorders. World Health Organization website. <http://www.who.int/mediacentre/factsheets/fs277/en/>. Accessed May 11, 2017.

² Russo AF. Calcitonin gene-related peptide (CGRP): a new target for migraine. *Annual Review of Pharmacology and Toxicology*. 2015;55:533-552.

³ Migraine facts. Migraine Research Foundation website. <http://migraineresearchfoundation.org/about-migraine/migraine-facts/>. Accessed May 11, 2017.

⁴ Lipton RB, Bigal ME, Diamond M, et al. Migraine prevalence, disease burden and the need for preventive therapy. *Neurology*. 2007;68(5):343-349.

⁵ Lafata, JE, Tuniceli O, Cerghet M, et al. The use of migraine preventive medications among patients with and without migraine headaches. *Cephalgia*. 2010;30(1):97-104.

⁶ Diamond S, Bigal ME, Silberstein S, et al. Patterns of diagnosis and acute and preventive treatment for migraine in the United States: results from the American Prevalence and Prevention study. *Headache*. 2007;47(3):355-363.

⁷ Blumenfeld AM, Bloudek LM, Becker WJ, et al. Patterns of use and reasons for discontinuation of prophylactic medications for episodic migraine and chronic migraine: results from the Second International Burden of Migraine Study (IBSM-II). *Headache*. 2013;53(4):644-655.

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The Lilly logo is a stylized, red, cursive script of the word "Lilly". The letters are thick and fluid, with a classic, elegant feel. The 'L' is particularly large and loops around the 'i', which is also large and loops around the 'l'. The 'y' has a long, sweeping tail that extends downwards and to the right.

To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/lilly-announces-positive-results-for-three-phase-3-studies-of-galcanezumab-for-the-prevention-of-episodic-and-chronic-migraine-300456628.html>

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