



FDA Accepts Biologics License Application (BLA) to Review Galcanezumab for the Prevention of Migraine in Adults

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Galcanezumab is the first of three investigational, non-opioid treatments in Lilly's pain portfolio

INDIANAPOLIS, Dec. 11, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the U.S. Food and Drug Administration (FDA) has accepted a Biologics License Application (BLA) to review galcanezumab for the prevention of migraine in adults. Galcanezumab has been submitted for use as a once-monthly, self-administered injection via auto-injector pen or prefilled syringe.

Lilly announced the submission of the BLA on its third-quarter earnings call in October 2017.

The application includes positive data from three Phase 3 studies (EVOLVE-1, EVOLVE-2 and REGAIN), which evaluated 2,901 patients. In these studies, patients treated with galcanezumab experienced a statistically significantly greater decrease in the average number of monthly migraine headache days compared to placebo. The most commonly-reported adverse events were injection site reactions, including pain.

"Migraine is more than a headache. It is a debilitating disease affecting one in eight Americans and may cause days of lost productivity each month," said Christi Shaw, president of Lilly Bio-Medicines. "We have worked for more than 25 years to develop innovative migraine therapies, and we are truly pleased to be one step closer to potentially providing a new self-administered and effective preventive treatment option that may help people experience fewer migraine days."

Galcanezumab represents the first of three investigational, non-opioid treatments in development as part of Lilly's overall pain portfolio. The portfolio also includes lasmiditan for the acute treatment of migraine and tanezumab, developed in partnership with Pfizer, for the treatment of osteoarthritis, chronic low back pain and cancer pain.

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 Migraine

Migraine is a disabling neurological disease characterized by recurrent episodes of severe headache accompanied by other symptoms including nausea, vomiting, sensitivity to light and sound, and changes in vision.^{1,2} More than 36 million Americans have migraine, with three times more women affected by migraine compared to men.³ 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.^{4,5}

About Lilly in Migraine

For over 25 years, Lilly has been committed to helping people suffering from migraine, investigating more than a dozen different compounds for the treatment of migraine and disabling 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 cluster headache, 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 people 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.

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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 preventive 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 future study results will be consistent with the results to date, or that galcanezumab will receive 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.

¹ Headache disorders. World Health Organization website. <http://www.who.int/mediacentre/factsheets/fs277/en/>. Accessed December 5, 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 Identifying and treating migraine. American Migraine Foundation website. <https://americanmigrainefoundation.org/understanding-migraine/identifying-treating-migraine/>. Last accessed December 5, 2017.

⁴ Migraine facts. Migraine Research Foundation website. <http://migraineresearchfoundation.org/about-migraine/migraine-facts/>. Accessed December 5, 2017.

⁵ 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 rendered in a vibrant red, cursive script. The letters are thick and fluid, with the 'L' starting with a large, sweeping loop that extends upwards and then curves back down to form the base of the letter. The 'i' is a simple dot above a short vertical stroke. The 'l' is a tall, thin vertical stroke. The 'lly' part of the word is more compact and rounded, with the final 'y' ending in a long, sweeping tail that curves downwards and to the right.

SOURCE Eli Lilly and Company