



IHC 2017: Lilly's Galcanezumab Demonstrates Positive Long-Term Safety Results for up to 12 Months in Patients with Migraine

September 8, 2017

INDIANAPOLIS, Sept. 8, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that treatment with self-administered galcanezumab for up to 12 months demonstrated a positive safety and tolerability profile in patients with migraine, consistent with previous studies. Detailed results from a 12-month, open-label Phase 3 study will be presented today at the 18th Congress of the International Headache Society (IHC) in Vancouver.

Over the 12-month treatment period, galcanezumab was also associated with a statistically significant reduction in the number of monthly migraine headache days with both doses (5.6 days for 120 mg and 6.5 days for 240 mg, $p < 0.001$ for both dosing groups). Notably, there was no clinically meaningful difference in the rate of adverse events between galcanezumab 120 mg and 240 mg dosing groups.

"These long-term results are significant for the millions of Americans with migraine. They reinforce the efficacy and safety profile of galcanezumab while supporting its potential use as a self-administered, monthly injection," said Christi Shaw, president of Lilly Bio-Medicines. "After more than two decades of research, Lilly is excited to submit galcanezumab to the FDA as a new potential treatment option that can provide more migraine-free days for people suffering with migraine."

Lilly plans to submit a Biologics License Application (BLA) 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.

Study Results

Patients were randomized to treatment with galcanezumab 120 mg or galcanezumab 240 mg once-monthly for 12 months. The initial dose of galcanezumab was administered by a healthcare provider, with subsequent doses self-administered by the patient via prefilled syringe or auto-injector pen.

The most commonly reported adverse events ($\geq 10\%$) in both dosing groups included injection site pain, nasopharyngitis and upper respiratory tract infection. Serious adverse events were reported by three patients in the 120 mg dosing group and seven patients in the 240 mg group.

In this study, 4.8 percent of patients discontinued treatment due to adverse events. The incidence of both treatment-emergent adverse events and adverse events leading to study discontinuation were not statistically significantly different between the two dosing groups.

Lilly will submit these findings for publication in a peer-reviewed journal in the coming year.

Study Design

This 12-month, randomized, open-label study evaluated the safety and effectiveness of two doses of galcanezumab administered subcutaneously (120 mg or 240 mg once-monthly, following a 240 mg starting dose) in 270 patients with episodic and chronic migraine. Patients that participated in the trial had an average of 10.6 migraine headache days per month at baseline. The primary endpoints included the percentage of patients who discontinued treatment with galcanezumab and additional safety measures.

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.^{3,4} 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

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 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.

P-LLY

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, 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 September 7, 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 September 7, 2017.

⁴ Migraine facts. Migraine Research Foundation website. <http://migraineresearchfoundation.org/about-migraine/migraine-facts/>. Accessed September 7, 2017.

Refer to:	Jen Dial; dial_jennifer_kay@lilly.com ; 317-220-1172 (Lilly Bio-Medicines)
	Phil Johnson; johnson_philip_j@lilly.com ; 317-655-6874 (Investor Relations)



View original content with multimedia: <http://www.prnewswire.com/news-releases/ihc-2017-lillys-galcanezumab-demonstrates-positive-long-term-safety-results-for-up-to-12-months-in-patients-with-migraine-300516207.html>

SOURCE Eli Lilly and Company