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Lilly to Present Data for Galcanezumab for the Prevention of Migraine at the American Academy of Neurology (AAN) Annual Meeting

INDIANAPOLIS, April 20, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) will highlight Phase 2 data evaluating galcanezumab for the prevention of migraine at the American Academy of Neurology (AAN) annual meeting, which will take place April 22-28, 2017, in Boston.

Lilly will present four abstracts at AAN, including safety and patient outcomes data for galcanezumab in patients with migraine and factors associated with a reduction in monthly migraine headache days among patients with episodic migraine. Lilly will also highlight findings from U.S. healthcare claims data identifying clinical characteristics and treatment patterns among patients with cluster headache.

Galcanezumab is a once-monthly, subcutaneously injected calcitonin gene-related peptide (CGRP) antibody currently being studied as a potential treatment for the prevention of episodic and chronic migraine and cluster headache. Galcanezumab is a monoclonal antibody specifically designed to bind to and inhibit the activity of CGRP that may prevent or significantly reduce the frequency of monthly migraine headache days in patients with episodic and chronic migraine and cluster headache.

"Migraine and cluster headaches are serious, neurological diseases that have a significant physical and emotional impact on not only people affected, but those with whom they interact at home and at work," said Sheena Aurora, M.D., medical fellow and global launch leader, galcanezumab, Eli Lilly and Company. "Lilly is excited to present these galcanezumab data, which further our understanding of these diseases and support our decades-long effort to develop a targeted, preventive therapy that can bring significant value to patients, including a meaningful reduction in the number of days lost to migraine."

Studies, as well as the dates and times of the data sessions, are highlighted below.

Sunday, April 23 - 4:00-5:30 p.m. ET

- | **P1.181:** Clinical Characteristics and Treatment Patterns among Patients with Diagnostic Codes for Cluster Headache in the U.S. Healthcare Claims Data
 - | Presenter: Casey Choong, associate consultant, Eli Lilly & Company, Indianapolis, IN

Monday, April 24 - 5:30-7:00 p.m. ET

- | **P2.164:** Hepatic Safety of Galcanezumab in Patients with Migraine: Results of Three Phase 2 Double-Blind Placebo-Controlled Trials
 - | Presenter: Vladimir Skljarevski, M.D., medical fellow, Eli Lilly & Company, Indianapolis, IN
- | **P2.177:** Factors Associated with Significant Reduction in Migraine Headache Days: A Post-Hoc Analysis of a Phase 2 Placebo-Controlled Trial in Patients Treated with Galcanezumab
 - | Presenter: Sheena Aurora, M.D., medical fellow and global launch leader, galcanezumab, Eli Lilly & Company, Indianapolis, IN
- | **P2.179:** Measures of Functioning Using MSQ v2.1 in Patients with a History of Episodic Migraine and Treated with Galcanezumab or Placebo Injections in a Phase 2 Clinical Trial
 - | Presenter: David Ayer, senior research scientist, Eli Lilly & Company, Indianapolis, IN

Top-line results for galcanezumab for the treatment of migraine are expected in 2017. Lilly plans to submit galcanezumab for regulatory approval for migraine in the second half of 2017.

About Galcanezumab

Galcanezumab is a once-monthly, subcutaneously injected calcitonin gene-related peptide (CGRP) antibody currently being studied as a potential treatment for the prevention of episodic and chronic migraine and cluster headache. Galcanezumab is a monoclonal antibody specifically designed to bind to and inhibit the activity of CGRP that may prevent or significantly reduce the frequency of monthly migraine headache days in patients with episodic and chronic migraine.

About Migraine

Migraine is a painful, 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.^{1,3} 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 United States,¹ yet it remains under-recognized and under-treated, with more than 40 percent of people going undiagnosed.⁴

About Cluster Headache

Cluster headache, often characterized as the most painful of all headaches, is a neurological disease characterized by recurrent, severe headaches on one side of the head, usually behind or around one eye.^{2,5} Cluster headaches - commonly known as "attacks" - typically last between 15 minutes to more than two hours and can recur on the same day and occur daily to multiple times a day for weeks or longer, followed by periods of time in which no attacks occur.⁵ Cluster headache is classified as "chronic" when attacks occur for more than one year without a remission period, or with remission lasting less than one month.⁵

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 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 or 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 April 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/>. Accessed April 19, 2017.

⁴ 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.

⁵ Treatment for cluster headache. American Migraine Foundation website. <https://americanmigrainefoundation.org/understanding-migraine/treatment-of-cluster-headache/>. Accessed April 19, 2017.

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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/lilly-to-present-data-for-galcanezumab-for-the-prevention-of-migraine-at-the-american-academy-of-neurology-aan-annual-meeting-300442793.html>

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