



Lilly to Present New Data for Galcanezumab and Lasmiditan at the 18th Congress of the International Headache Society (IHC)

September 6, 2017

INDIANAPOLIS, Sept. 6, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today it will present new data for galcanezumab and lasmiditan, two investigational treatments for migraine, at the 18th Congress of the International Headache Society (IHC) taking place Sept. 7-10 in Vancouver.

Lilly will highlight new, long-term data from an open-label study evaluating the safety and effectiveness of two doses of galcanezumab (120 mg and 240 mg) for the prevention of migraine. Galcanezumab is a once-monthly, subcutaneously injected calcitonin gene-related peptide (CGRP) antibody under evaluation for the prevention of episodic and chronic migraine and cluster headache.

Lilly will also present new data from SPARTAN, a Phase 3 study evaluating the safety and efficacy of lasmiditan for the acute treatment of migraine. Lasmiditan is an investigational, oral, first-in-class molecule that could represent the first significant innovation for the acute treatment of migraine in more than two decades.

"After more than 25 years of research in migraine, we are thrilled to help introduce a new era of treatment innovation not only for the prevention of migraine, but also the acute treatment of this disabling disease," said Robert Conley, M.D., Distinguished Lilly Scholar and Lilly global development leader for migraine therapeutics. "We are excited to have another opportunity this year to share new data for galcanezumab and lasmiditan, which if approved, may provide much-needed treatment options for the millions of Americans struggling to effectively manage migraine."

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

Oral Presentations:

Friday, Sept. 8, 2017 – 7:00-8:00 p.m. PT

- **PO-01-197: Phase 3 Studies (EVOLVE-1 & EVOLVE-2) of Galcanezumab in Episodic Migraine: Results of 6-Month Treatment Phase**
 - Presenter: Vlad Skljarevski, M.D., senior medical fellow, Eli Lilly and Company, Indianapolis, IN
- **PO-01-195: A Phase 3 Placebo-Controlled Study of Galcanezumab in Patients with Chronic Migraine: Results from the 3-Month Double-Blind Treatment Phase of the REGAIN Study**
 - Presenter: Sheena Aurora, M.D., medical fellow and global launch leader, galcanezumab and lasmiditan, Eli Lilly and Company, Indianapolis, IN

Poster Presentations:

Friday, Sept. 8, 2017 – 11:00 a.m.-12:00 p.m. PT

- **PO-01-197: Phase 3 Studies (EVOLVE-1 & EVOLVE-2) of Galcanezumab in Episodic Migraine: Results of 6-Month Treatment Phase**
 - Presenter: Katie Selzler, Ph.D., Scientific Communications, Eli Lilly and Company, Indianapolis, IN
- **PO-01-184: A Phase 3, Long-Term, Open-Label Safety Study of Self-Administered Galcanezumab Injections in Patients with Migraine**
 - Presenter: Qi Zhang, Ph.D., principal research scientist, Global Statistical Sciences and Bio-Medicines, Eli Lilly and Company, Indianapolis, IN
- **PO-01-195: A Phase 3 Placebo-Controlled Study of Galcanezumab in Patients with Chronic Migraine: Results from the 3-Month Double-Blind Treatment Phase of the REGAIN Study**
 - Presenter: Sheena Aurora, M.D., medical fellow and global launch leader, galcanezumab and lasmiditan, Eli Lilly and Company, Indianapolis, IN

Saturday, Sept. 9, 2017 – 10:00-10:45 a.m. PT

- **PO-02-0999: Cycling Through Migraine Prevention Treatments: Implications to All-Cause Total Direct Costs**
 - Presenter: Janet Ford, Ph.D., M.P.H., consultant scientist, Global Patient Outcomes and Real World Evidence, Bio-Medicines, Eli Lilly and Company, Indianapolis, IN
- **PO-02-180: Phase 3 Study (SPARTAN) of Lasmiditan Compared to Placebo for Acute Treatment of Migraine**
 - Presenter: Sheena Aurora, M.D., medical fellow and global launch leader, galcanezumab and lasmiditan, Eli Lilly and Company, Indianapolis, IN
- **PO-02-173: In Vitro Characterization of Agonist Binding and Functional Activity at a Panel of Serotonin Receptor Subtypes for Lasmiditan, Triptans and other 5-HT Receptor Ligands and Activity Relationships for Contraction of**

Human Isolated Coronary Artery

- Presenter: Eloísa Rubio-Beltrán, Division of Pharmacology, Department of Internal Medicine, Erasmus University Medical Center, Rotterdam, Netherlands

● PO-02-172: Lasmiditan Inhibits CGRP Release in the Mouse Trigeminal System

- Presenter: Alejandro Labastida-Ramírez, Division of Vascular Medicine and Pharmacology, Erasmus University Medical Center, Rotterdam, Netherlands

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

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.^{1,5} 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 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 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 Lasmiditan

Lasmiditan is an investigational, first-in-class molecule under evaluation for the acute treatment of migraine. Lasmiditan selectively targets 5-HT_{1F} receptors expressed in the trigeminal pathway, and has been designed for the acute treatment of migraine without the vasoconstrictor activity associated with some migraine therapies. In March 2017, Lilly completed the acquisition of CoLucid Pharmaceuticals, including lasmiditan, which was originally discovered at Lilly.

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 and lasmiditan as potential treatments 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 or lasmiditan will achieve their 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 August 29, 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 August 29, 2017.

⁴ Migraine facts. Migraine Research Foundation website. <http://migraineresearchfoundation.org/about-migraine/migraine-facts/>. Accessed August 29, 2017.

⁵ Treatment for cluster headache. American Migraine Foundation website. <https://americanmigrainefoundation.org/understanding-migraine/treatment-of-cluster-headache/>. Accessed August 29, 2017.

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