



June 8, 2017

## **Lilly to Present Late-Breaking Data for Galcanezumab and Lasmiditan at the American Headache Society Annual Scientific Meeting**

INDIANAPOLIS, June 8, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) will present data from 14 abstracts, including late-breaking Phase 3 data for two investigational treatments for migraine, at the American Headache Society (AHS) annual scientific meeting, taking place June 8-11 in Boston.

Lilly will highlight new, Phase 3 primary and secondary endpoint data in three late-breaking presentations for galcanezumab for the prevention of episodic and chronic migraine. Galcanezumab is a once-monthly, subcutaneously injected calcitonin gene-related peptide (CGRP) antibody currently being studied as a potential treatment for the prevention of migraine and cluster headache.

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

"For more than 25 years, Lilly's expert clinicians and researchers have worked to develop innovative treatments that can improve the lives of patients with migraine and address the challenges healthcare providers face in treating this serious disease," said Robert Conley, M.D., Distinguished Lilly Scholar, neuroscience. "We are truly excited to present a range of new data from our migraine portfolio, which support the potential use of both galcanezumab and lasmiditan as much-needed, new treatment options for patients suffering from migraine."

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

### **Late-Breaking Oral Presentations:**

#### Saturday, June 10, 2017 - 9:40-9:50 a.m. ET

- | **IOR11B:** Lasmiditan (200 mg and 100 mg) Compared to Placebo for Acute Treatment of Migraine
  - | Presenter: Sheena Aurora, M.D., medical fellow and global launch leader, galcanezumab, Eli Lilly and Company, Indianapolis, IN

#### Saturday, June 10, 2017 - 9:50-10:00 a.m. ET

- | **IOR12LB:** Phase 3 Study (EVOLVE-2) of Galcanezumab in Episodic Migraine
  - | Presenter: Robert Conley, M.D., Distinguished Lilly Scholar, neuroscience, Eli Lilly and Company, Indianapolis, IN

### **Poster Presentations:**

#### Friday, June 9, 2017 - 1:15 p.m.-2:30 p.m. ET

- | **PF04:** Economics of Inhaled Oxygen Use as an Acute Therapy for Cluster Headache in the United States of America
  - | Presenter: Stewart Tepper, M.D., Geisel School of Medicine, Dartmouth College, Hanover, NH
- | **PF08:** Galcanezumab Administration Was Not Associated with Increase in Blood Pressure in Patients with Osteoarthritis
  - | Presenter: Sheena Aurora, M.D., medical fellow and global launch leader, galcanezumab, Eli Lilly and Company, Indianapolis, IN
- | **PF10:** Tolerability, Pharmacokinetics and Pharmacodynamics of Galcanezumab in Healthy Subjects Following a Subcutaneous Administration of a Lyophilized Formulation or a Solution Formulation
  - | Presenter: William Kielbasa, Ph.D., research advisor, Eli Lilly and Company, Indianapolis, IN
- | **PF14:** Medication Use among Patients Diagnosed with Headache and Migraine in a Large National Commercial Payer Database: A Retrospective Study
  - | Presenter: Paula Morrow, M.S.N., senior clinical research scientist, Eli Lilly and Company, Indianapolis, IN

Saturday, June 10, 2017 - 12:30-2:00 p.m. ET

- | **PS03:** Clinical Characteristics and Treatment Patterns among Patients with Diagnostic Codes for Cluster Headache in the U.S. Healthcare Claims Data
  - | Presenter: James Martinez, M.D., medical fellow, Eli Lilly and Company, Indianapolis, IN
- | **PS04:** 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: Sheena Aurora, M.D., medical fellow and global launch leader, galcanezumab, Eli Lilly and Company, Indianapolis, IN
- | **PS05:** Hepatic Safety of Galcanezumab in Patients with Migraine: Results of Three Phase 2 Double-Blind Placebo-controlled Trials
  - | Presenter: Vladimir Skljarevski, M.D., senior medical fellow, Eli Lilly and Company, Indianapolis, IN
- | **PS06:** 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 and Company, Indianapolis, IN
- | **PS18:** The Relationship between Headache Frequency and Illness Burden Prior to Treatment Randomization in Two Phase 3 Episodic Migraine Clinical Trials
  - | Presenter: Virginia Stauffer, Pharm.D., research advisor, Eli Lilly and Company, Indianapolis, IN
- | **PS19:** Safety and Tolerability of Galcanezumab in a Phase 2 Migraine Prevention Study
  - | Presenter: Tina Oakes, Ph.D., research advisor, Eli Lilly and Company, Indianapolis, IN
- | **PS88LB:** Phase 3 Study (EVOLVE-1) of Galcanezumab in Episodic Migraine
  - | Presenter: Virginia Stauffer, Pharm.D., research advisor, Eli Lilly and Company, Indianapolis, IN
- | **PS89LB:** 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: Holland Detke, Ph.D., research advisor, Eli Lilly and Company, Indianapolis, IN

### **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.<sup>[1],[2]</sup> More than 38 million Americans have migraine, with three times more women affected by migraine compared to men.<sup>[3]</sup> Of the approximately 40 percent of patients suffering from migraine for whom prevention is appropriate, only 13 percent are currently receiving therapy.<sup>[4],[5], [6]</sup> 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.<sup>[7]</sup> 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.<sup>[3],[7]</sup>

### **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.<sup>2,[8]</sup> 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.<sup>[5]</sup> 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.<sup>[5]</sup>

### **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.

### **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 5HT<sub>1F</sub> receptors expressed in the trigeminal pathway, and has been designed for the acute treatment of migraine without the vasoconstrictor activity associated with previous generations of migraine therapies. Data from the first of two Phase 3 studies was announced in 2016, with topline results from the second Phase 3 trial expected later this year. In January 2017, Lilly announced an agreement to acquire 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](http://www.lilly.com) and [www.lilly.com/newsroom/social-channels](http://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 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 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. *Cephalagia*. 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.

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

**Refer to:** Jen Dial; [dial\\_jennifer\\_kay@lilly.com](mailto:dial_jennifer_kay@lilly.com); 317-220-1172 (Media)  
Phil Johnson; [johnson\\_philip\\_l@lilly.com](mailto:johnson_philip_l@lilly.com); 317-655-6874 (Investors)



To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/lilly-to-present-late-breaking-data-for-galcanezumab-and-lasmiditan-at-the-american-headache-society-annual-scientific-meeting-300471313.html>

SOURCE Eli Lilly and Company

News Provided by Acquire Media