Lilly to Present Phase 3 Data at AAN 2018 Reinforcing Commitment to New, Innovative Therapies in Migraine

April 20, 2018

INDIANAPOLIS, April 20, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today it will present Phase 3 data for galcanezumab and lasmiditan, two investigational treatments for migraine, at the American Academy of Neurology (AAN) annual meeting taking place April 21-27 in Los Angeles.

Lilly will highlight a new analysis from three Phase 3 studies (EVOLVE-1, EVOLVE-2 and REGAIN) evaluating galcanezumab in patients who previously failed two or more preventive therapies as part of the "Best in Headache" platform session on Tuesday, April 24. Lilly will also present data from two pivotal Phase 3 studies (SAMURAI and SPARTAN) side-by-side evaluating the safety and efficacy of lasmiditan for the acute treatment of migraine.

Galcanezumab is a once-monthly, self-administered calcitonin gene-related peptide (CGRP) antibody currently under review by the U.S. Food and Drug Administration (FDA) for the prevention of migraine in adults. 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.

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

"Like other recurrent and chronic pain conditions, migraine has a significant impact on a person's physical, social and economic well-being, yet there remains both a stigma and an unmet need for treatment options for this debilitating disease," said Robert Conley, M.D., Distinguished Lilly Scholar and Lilly global development leader for migraine therapeutics. "The data to be presented at AAN reflect Lilly's decades-long commitment to the development of new, innovative therapies in migraine, and reinforces the potential for galcanezumab and lasmiditan to address one of the biggest challenges in pain management today."

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

Oral Presentations:

Tuesday, April 24, 2018 – 8:24 – 8:32 a.m. PT

- **S20.004: Efficacy of Galcanezumab in Patients Who Failed to Respond to Preventives Previously: Results from EVOLVE-1, EVOLVE-2 and REGAIN Studies**
  - Presenter: Sheena Aurora , M.D., medical fellow and global launch leader, galcanezumab, Eli Lilly and Company, Indianapolis, IN

Wednesday, April 25, 2018 – 1:00 – 3:00 p.m. PT

- **S32.003: In Vitro Characterization of Agonist Binding and Function 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 Cornary Artery**
  - Presenter: Antoinette MaassenVanDenBrink, associate professor, Division of Vascular Medicine and Pharmacology, Department of Internal Medicine, Erasmus University Medical Center, Rotterdam, The Netherlands
- **S32.008: Lasmiditan Inhibits CGRP Release in the Mouse Trigeminovasular System**
  - Presenter: Antoinette MaassenVanDenBrink, associate professor, Division of Vascular Medicine and Pharmacology, Department of Internal Medicine, Erasmus University Medical Center, Rotterdam, The Netherlands

Friday, April 27, 2018 – 2:24 – 2:36 p.m. PT

- **S50.008: Phase 3 Studies (SAMURAI, SPARTAN) of Lasmiditan Compared to Placebo for Acute Treatment of Migraine**
  - Presenter: Eric Pearlman, M.D., medical fellow, Eli Lilly and Company, Indianapolis, IN

About Migraine

Migraine is a 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 Medical Expenditures Panel Survey, total annual healthcare costs associated with migraine are estimated to be as high as $56 billion annually in the United States, 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 disabling migraine attacks. 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. 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 treatment for patients with migraine and cluster headache; lasmiditan as a potential treatment for patients with migraine; and tanezumab as a potential treatment for patients with osteoarthritis pain, chronic low back pain, and cancer pain; 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.

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[1] Katsarava Z, Buse D, Manack A, et al. Defining the differences between episodic migraine and chronic migraine. *Current Pain Headache Reports.* 2012;16:86.

[2] Blumenfeld AM, Payne KA, Varon SF, et al. Disability, HRQOL, and resource use amongst chronic and episodic migraineurs. Results from the International Burden of Migraine Study (IBMS). *Cephalalgia* 2011;31:301..

[3] Identifying and treating migraine. American Migraine Foundation website. https://americanmigrainefoundation.org/understanding-migraine/identifying-treating-migraine/. Last accessed April 19, 2018.

[4] Raval AD, Shah A. National trends in direct health care expenditures among US adults with migraine: 2004 to 2013. *Journal of Pain.* 2017;57:60.

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