IHC 2017: Lilly's Lasmiditan Significantly Reduces Pain in Patients with Migraine

September 9, 2017

INDIANAPOLIS, Sept. 9, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) will present key primary and secondary endpoint data for lasmiditan, an investigational, oral, first-in-class molecule for the acute treatment of migraine, which demonstrated statistically significant improvements compared to placebo in the Phase 3 SPARTAN study. Detailed results will be highlighted today at the 18th Congress of the International Headache Society (IHC) in Vancouver.

"The data presented today demonstrate lasmiditan's potential to reduce pain and provide freedom from the most bothersome symptoms associated with migraine," said Christi Shaw, president of Lilly Bio-Medicines. "These results reflect Lilly's 25-year commitment to migraine research and to bringing first-in-class advancements to patients, including the use of a new clinical endpoint evaluating a patient's self-identified most bothersome symptom."

These findings are consistent with SAMURAI, the first pivotal Phase 3 study evaluating the safety and efficacy of lasmiditan for the acute treatment of migraine. The most commonly-reported adverse events after lasmiditan dosing were dizziness, paresthesia, somnolence, fatigue, nausea and lethargy.

Lilly plans to submit a New Drug Application for lasmiditan to the U.S. Food and Drug Administration (FDA) in the second half of 2018.

SPARTAN Study Results
At two hours following the first dose, a greater percentage of patients treated with lasmiditan were migraine pain-free compared to placebo. These results were statistically significant across all three studied doses (50 mg, 100 mg and 200 mg). A statistically significantly greater percentage of patients were also free of their most bothersome symptom (MBS) compared with placebo at two hours. In this study, patients chose their MBS from nausea, sensitivity to sound or sensitivity to light.

The majority of patients treated with lasmiditan also experienced relief from migraine pain—classified as mild or no pain—at two hours following the first dose (59 percent for 50 mg, 64.8 percent for 100 mg and 65 percent for 200 mg, $p<0.001$ for all dosing groups). These results were statistically significant compared to placebo (47.7 percent).

In this study, fewer patients treated with lasmiditan took a second, rescue dose of treatment compared to placebo (41 percent for 50 mg; 32.7 percent for 100 mg; 26.4 percent for 200 mg and 49.8 percent for placebo).

Lilly will submit the results to a peer-reviewed journal within the next year. An open-label Phase 3 study—GLADIATOR—is also underway evaluating the long-term safety of lasmiditan for the acute treatment of migraine.

About the SPARTAN Study
SPARTAN is a Phase 3 randomized, double-blind, placebo-controlled global trial evaluating the safety and efficacy of three doses of lasmiditan administered orally (50 mg, 100 mg or 200 mg) compared with placebo for the acute treatment of migraine. To be eligible for this trial, patients were required to have at least moderate migraine disability (as measured by a Migraine Disability Assessment Score (MIDAS) ≥ 11). Patients that participated in the trial had an average of more than five migraine attacks per month at baseline. SPARTAN did not exclude patients with one or more cardiovascular risk factors or known coronary artery disease. The primary endpoint of the study was comparison of the percentage of patients in the lasmiditan 200 mg and placebo groups who were migraine pain-free at two hours following the first dose. A key secondary endpoint of the study was comparison of the percentage of patients in each dosing group (200 mg, 100 mg and 50 mg) and placebo groups who were free of their MBS at two hours following the first dose. In these studies, MBS identified by patients included nausea, sensitivity to sound or sensitivity to light.

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 patients living with 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, including those 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 lasmiditan as a potential acute treatment for patients with migraine and the SPARTAN trial, 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 lasmiditan 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.

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