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Lilly's investigational medicine for prevention of migraine met primary endpoint in a Phase 2b study

INDIANAPOLIS, June 17, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that its investigational medicine for prevention of migraine (LY2951742, a CGRP neutralizing antibody) met the primary endpoint in a Phase 2b study in episodic migraine.

The randomized, double-blind, placebo-controlled study evaluated the efficacy and safety of four different doses of LY2951742 given in a once-monthly, subcutaneous injection in more than 400 patients with episodic migraine (people who experience between four and 14 migraine headache days per month).

The primary objective was to assess whether at least one dose of LY2951742 was superior to placebo in the prevention of migraine headache. LY2951742 demonstrated a statistically significant reduction in migraine headache days and a safety and tolerability profile confirming the previous results seen in a Phase 2a study.

Lilly will present data from this trial in a late-breaking session at the 57th Annual American Headache Society meeting on June 20 in Washington D.C., and will submit data from the study for additional disclosure at scientific meetings and in peer-reviewed journals.

"We're encouraged by the results from this positive Phase 2b study that confirms the safety and efficacy profile of LY2951742," said David Ricks, Lilly senior vice president, and president of Lilly Bio-Medicines. "These results reinforce our confidence in the potential of this medicine to be a significant option for the preventive treatment of debilitating headache disorders like migraine and cluster headache."

In addition to the migraine program, Lilly has initiated two Phase 3 trials with LY2951742 in patients suffering from cluster headache. Based on the unmet medical need and significance of this disorder for patients, Lilly has been granted Fast Track Designation from the U.S. Food and Drug Administration (FDA) for cluster headache.

About LY2951742

LY2951742 is a once-monthly subcutaneously injected calcitonin gene-related peptide (CGRP) antibody currently being studied as a potential treatment for the prevention of chronic and episodic migraine and cluster headache. Lilly's CGRP antibody is a biologic entity that binds and inhibits the activity of CGRP, a sensory neuropeptide thought to be associated with vasodilation, pro-inflammatory effects and pain signaling, all thought to be implicated in the pathophysiology of migraine and cluster headache.

About Migraine

Migraine is a neurological disorder characterized by recurrent episodes of severe headache, often accompanied by a variety of other symptoms including nausea, vomiting, sensitivity to light and sound and changes in vision. Thirty-six million Americans, about 12 percent of the population, suffer from migraines at least periodically. It is estimated that 38 percent of migraine sufferers -- people with between four and 30 headache days per month -- could benefit from preventive treatment, yet only 13 percent report using a daily preventive migraine medication, resulting in a significant unmet medical need for patients. The World Health Organization places migraine as one of the 20 most disabling illnesses. People with migraine are more likely to have depression, anxiety, sleep disorders, other pain conditions and fatigue. It is estimated that each year, lost work time and diminished productivity from migraines cost American employers \$225.8 billion.^{1,2,3} There currently is no cure for migraine.

About Cluster Headache

Cluster headache is an excruciatingly painful condition characterized by recurrent, severe headaches (called "attacks") on one side of the head, usually behind or around the eye. These attacks can occur daily to multiple times daily for weeks or longer, followed by periods of times in which no attacks occur. Cluster headache is relatively uncommon, estimated to affect fewer than 200,000 people in the United States. There are no approved medicines for the prevention of cluster headache in the United States.

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 newsroom.lilly.com/social-channels. P-LLY

This press release contains certain forward-looking statements about LY2951742, a calcitonin gene-related peptide (CGRP) antibody currently being studied as a potential treatment for the prevention of migraine headaches and cluster headaches, and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that future study results and patient experience will be consistent with the study findings to date, that LY2951742 will receive regulatory approval or, if approved, would be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

1. Stewart WF, Ricci JA, Chee E, et al. Lost productive work time costs from health conditions in the United States: results from the American Productivity Audit. *J Occup Environ Med.* 2003 Dec;45(12):1234-46.
2. Hu XH, Markson LE, Lipton RB, et al. Burden of migraine in the United States: disability and economic costs. *Arch Intern Med.* 1999 Apr 26;159(8):813-8.
3. Burton WN, Landy SH, Downs KE, et al. The impact of migraine and the effect of migraine treatment on workplace productivity in the United States and suggestions for future research. *Mayo Clin Proc.* 2009 May;84(5):436-45.

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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/lillys-investigational-medicine-for-prevention-of-migraine-met-primary-endpoint-in-a-phase-2b-study-300100695.html>

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