December 5, 2013

Lilly Announces Edivoxetine Did Not Meet Primary Endpoint of Phase III Clinical Studies as Add-On Therapy for Major Depressive Disorder

INDIANAPOLIS, Dec. 5, 2013 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that results from three studies of edivoxetine did not meet the primary study objective of superior efficacy in depression after eight weeks of treatment. When added to a selective serotonin reuptake inhibitor (SSRI), edivoxetine did not separate from placebo on the Montgomery-Asberg Depression Rating Scale (MADRS) in three acute randomized placebo-controlled Phase III studies (LNBM, LNBQ and LNBR).

While the safety and tolerability of edivoxetine was consistent with previous studies, the efficacy results do not support a regulatory submission for adjunctive treatment in patients with Major Depressive Disorder (MDD). Data from all three studies will be disclosed in appropriate scientific forums in 2014.

In 2010, Lilly launched the Phase III program for edivoxetine — a potent and highly selective norepinephrine reuptake inhibitor — to assess the benefits and risks of edivoxetine as an add-on therapy in patients with MDD. The Phase III program specifically focused on meeting the unmet needs of patients with major depression who had achieved only a partial response to treatment with an SSRI. In these three trials, patients remained on SSRI treatment and additionally received either edivoxetine or placebo.

"Lilly undertook a robust Phase III program to address a significant unmet need for people suffering from depression," said David Ricks, senior vice president, and president, Lilly Bio-Medicines. "However, the lack of efficacy compared to SSRI alone in three separate clinical trials means that Lilly will not proceed with development of edivoxetine as an add-on treatment for depression." The ongoing clinical study evaluating the long-term maintenance effect of edivoxetine will continue to completion.

"While disappointing for people suffering from depression, their families and Lilly, negative studies are unfortunately a reality of biopharmaceutical innovation, and are particularly prevalent in the area of neuroscience given the historically high placebo response rate," said Jan Lundberg, Ph.D., executive vice president, science and technology, and president, Lilly Research Laboratories. "Lilly remains committed to our neuroscience legacy of discovering and delivering innovative medicines, as evidenced by our pipeline of nine potential new medicines and diagnostic imaging agents for neuroscience-related diseases and disorders, including Alzheimer's disease, Parkinson's disease, depression, bipolar disorder, migraine prevention and osteoarthritis pain."

"Despite this news, we remain focused on implementing our innovation-based strategy," said Derica Rice, executive vice president, global services and chief financial officer, Eli Lilly and Company. "We've made substantial progress on our number one priority - advancing our pipeline. This year alone, we submitted four potential new medicines to regulatory authorities with more anticipated next year. In addition, we expect to begin launching new products in 2014 and are on track to return to revenue growth and margin expansion in 2015 and beyond."

The decision not to proceed with development of edivoxetine as adjunctive treatment for MDD is expected to result in a fourth-quarter charge to R&D expense of approximately $15 million (pre-tax), or approximately $0.01 per share (after-tax). The company's previously-issued financial guidance for 2013 remains unchanged.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers — through medicines and information — for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

This press release contains forward-looking statements about edivoxetine and reflects Lilly's current beliefs. As with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. 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.

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