/C O R R E C T I O N -- Eli Lilly and Company/

INDIANAPOLIS, Sept 11, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- In the news release, New Data Show Patients With Chronic Low Back Pain Maintained Pain Reduction on Cymbalta(R), issued 11-Sep-2009 by Eli Lilly and Company over PR Newswire, the third paragraph, third sentence should read "A total of 18 patients in the study discontinued due to adverse events during the extension phase." The phrase "13 in the placebo-treated group and five in the duloxetine-treated group" at the end of that sentence should be disregarded. The complete, corrected release follows:

New Data Show Patients With Chronic Low Back Pain Maintained Pain Reduction on Cymbalta(R)

New data show patients with chronic low back pain on Cymbalta(R) (duloxetine HCl) maintained reductions in pain for 41 weeks.(1) In patients who initially responded to duloxetine, this maintenance of pain reduction was accompanied by further reduction in pain that was statistically significant as measured by the Brief Pain Inventory (BPI) average pain rating.(1) The data will be presented today at the sixth triennial congress of the European Federation of Chapters of the International Association for the Study of Pain (EFIC(R)).

A total of 181 patients enrolled in the open-label 41-week extension phase of the study, designed to evaluate long-term maintenance of effect in patients with chronic low back pain taking duloxetine 60 mg or 120 mg once daily. Maintenance of effect was assessed in the responders - 58 duloxetine patients who had experienced at least 30 percent pain reduction from baseline during the 13-week, placebo-controlled acute phase of the study.

The most common adverse events in the study (those occurring in more than 5 percent of study participants) included headache, nausea, upper abdominal pain, excessive sweating (hyperhidrosis), back pain, diarrhea and fatigue. Adverse events were similar to those seen in previous duloxetine studies.(1) A total of 18 patients in the study discontinued due to adverse events during the extension phase.

"Chronic low back pain is a painful and debilitating condition and this study is an important step in the fight against it," said Vladimir Skljarevski, M.D., lead study author and a neurologist and medical fellow at Lilly Research Laboratories.

Experts estimate chronic low back pain affects between 4 percent and 33 percent of the world's population at any one time.(2) According to the International Association for the Study of Pain (IASP), the pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.(3) Chronic pain is defined as pain that persists beyond acute pain or beyond the expected time for an injury to heal.(4) Men and women are equally affected by chronic low back pain, and it occurs most often between the ages of 30 and 50.(5)

Study Methods

Patients (N=181) with chronic low back pain (defined as low back pain present on most days for the preceding six months or longer) entered the study's 41-week extension phase and received duloxetine 60 mg or 120 mg once daily after completing a 13-week, placebo-controlled acute phase. Patients completing the acute phase on duloxetine remained on the same dose while those on placebo were switched to duloxetine. Maintenance of effect was assessed in 58 duloxetine patients who were responders [greater than or equal to 30 percent reduction in Brief Pain Inventory (BPI) average pain] at the end of the acute phase. If the upper bound of the 97.5 percent Confidence Interval (CI) of the mean change from the end of the acute phase for the BPI average pain was less than the pre-specified margin of 1.5, then maintenance of effect was established.

About Cymbalta

Serotonin and norepinephrine in the brain and spinal cord are believed to both mediate core mood symptoms and help regulate the perception of pain. Based on preclinical studies, Cymbalta is a balanced and potent reuptake inhibitor of serotonin and norepinephrine that is believed to potentiate the activity of these chemicals in the central nervous system (brain and spinal cord). While the mechanism of action of Cymbalta is not known in humans, scientists believe its effects on depression and anxiety symptoms, as well as its effect on pain perception, may be due to increasing the activity of serotonin and norepinephrine in the central nervous system.

Cymbalta is approved in the United States for the acute and maintenance treatment of major depressive disorder, the acute treatment of generalized anxiety disorder, the management of diabetic peripheral neuropathic pain and the management of

fibromyalgia, all in adults (18+). Cymbalta is not approved for use in pediatric patients.

Indications and Important Safety Information for Cymbalta

Indications

Cymbalta is approved to treat major depressive disorder and generalized anxiety disorder, and to manage diabetic peripheral neuropathic pain and fibromyalgia.

Important Safety Information

Antidepressants can increase suicidal thoughts and behaviors in children, adolescents, and young adults. Suicide is a known risk of depression and some other psychiatric disorders. Patients should call their doctor right away if they experience new or worsening depression symptoms, unusual changes in behavior, or thoughts of suicide. Be especially observant within the first few months of treatment or after a change in dose. Cymbalta is approved only for adults 18 and over.

Cymbalta is not for everyone. Patients should not take Cymbalta if they have recently taken a type of antidepressant called a monoamine oxidase inhibitor (MAOI), are taking Mellaril(R) (thioridazine), or have uncontrolled glaucoma (increased eye pressure). Patients should speak with their doctor about all their medical conditions including kidney or liver problems, glaucoma, diabetes, seizures, or if they have bipolar disorder. Cymbalta may worsen a type of glaucoma or diabetes. Patients should talk to their doctor if they have itching, right upper belly pain, dark urine, yellow skin or eyes, or unexplained flu-like symptoms, which may be signs of liver problems. Severe liver problems, sometimes fatal, have been reported. They should also talk to their doctor about alcohol consumption. Patients should tell their doctor about all their medicines, including those for migraine, to avoid a potentially life-threatening condition. Symptoms may include high fever, confusion, and stiff muscles. Taking Cymbalta with NSAID pain relievers, aspirin, or blood thinners may increase bleeding risk. Patients should consult with their doctor before stopping Cymbalta or changing the dose. If after starting Cymbalta, patients experience dizziness or fainting upon standing, they should contact their doctor. Cymbalta can increase blood pressure. Healthcare providers should check patients' blood pressure prior to and while taking Cymbalta. Patients should tell their doctor if they experience headache, weakness, confusion, problems concentrating, memory problems, or feel unsteady while taking Cymbalta as this may be signs of low sodium levels. Patients should consult their doctor if they develop problems with urine flow while taking Cymbalta or if they are pregnant or nursing.

The most common side effects of Cymbalta include nausea, dry mouth, sleepiness, and constipation. This is not a complete list of side effects. Cymbalta may cause sleepiness and dizziness. Until patients know how Cymbalta affects them, they should not drive a car or operate hazardous machinery.

For full Patient Information, visit http://www.cymbalta.com.

For full Prescribing Information, including Boxed Warning and medication guide, visit http://www.cymbalta.com.

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 the potential of Cymbalta for chronic pain including the management of chronic low back pain 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 the product will continue to 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.

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(1) Skljarevski V. et al. "Maintenance of Effect of Duloxetine in Patients with Chronic Low Back Pain." Poster presented at European Federation of Chapters of the International Association for the Study of Pain, September 2009.

(2) World Health Organization. Chronic rheumatic conditions. Available at: http://www.who.int/chp/topics/rheumatic/en. Accessed on 26 May 2009.

(3) International Association for the Study of Pain. "IASP Pain Terminology" Available at: http://www.iasp-pain.org/AM/Template.cfm?Section=General_Resource_Links&Template=/CM/HTMLDisplay.cfm&ContentID=3058#Pain. Accessed on 26 May 2009.

(4) American Pain Society. "Pain Control in the Primary Care Setting." 2006:15.

(5) National Institute of Neurological Disorders and Stroke. "Low Back Pain Fact Sheet." Available at: http://www.ninds.nih.gov/disorders/backpain/detail_backpain.htm. Accessed on 26 May 2009.

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