



## **Cymbalta(R) Significantly Reduced Chronic Low Back Pain in New Study**

INDIANAPOLIS, Feb 03, 2010 /PRNewswire via COMTEX News Network/ -- In a new study, 60 mg of Cymbalta(R) (duloxetine HCl) taken once daily significantly reduced chronic low back pain, as measured by the Brief Pain Inventory (BPI) average pain rating, compared with placebo.(1) The data were presented today at the annual meeting of the American Academy of Pain Medicine (AAPM) in San Antonio, Texas.

A total of 401 patients participated in the 12-week, double-blind, placebo-controlled study, designed to assess the efficacy of duloxetine 60 mg once daily on the reduction of pain severity in patients with chronic low back pain. In the study, duloxetine-treated patients experienced a statistically significantly greater improvement on BPI average pain scale compared with placebo in chronic low back pain ( $p < 0.005$ ).

The most common adverse events (those occurring in more than 5 percent of study participants) in duloxetine-treated patients were nausea, headache, dry mouth, constipation and dizziness. A total of 41 patients in the study discontinued due to adverse events - 30 in the duloxetine-treated group and 11 in the placebo-treated group. Adverse events were similar to those seen in previous duloxetine studies.

"Chronic low back pain affects a significant number of people. In fact, research suggests that the incidence of the condition may be as high as 48 percent,(2)" said Vladimir Skljarevski, M.D., lead study author and a neurologist and senior medical director at Lilly Research Laboratories.

According to the International Association for the Study of Pain (IASP), 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)

### Study Methods

Adults (N=401) with non-neuropathic chronic low back pain (defined as low back pain present on most days for the preceding six months or longer) and pain intensity of greater than or equal to 4 on the 11-point BPI average pain scale were treated with either duloxetine 60 mg once daily (N=198) or placebo (N=203) for 12 weeks in this randomized, double-blind trial. The primary measure was BPI average pain.

### **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, 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 treatment of major depressive disorder, the 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 (NYSE: LLY)**

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](http://www.lilly.com).

*This press release contains forward-looking statements about the potential of Cymbalta for 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, et al. "Effect of Duloxetine 60 mg Once-daily Versus Placebo in Patients With Chronic Low Back Pain: A 12-week, Randomized, Double-blind Trial." Presented at 2010 American Academy of Pain Medicine Annual Meeting, Feb. 3, 2010.

(2) Thomas E, et al. BMJ. 1999;318:1662-1667.

(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](http://www.iasp-pain.org/AM/Template.cfm?Section=General_Resource_Links&Template=/CM/HTMLDisplay.cfm&ContentID=3058#Pain). Accessed on Jan. 15, 2010.

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

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