



Lilly Submits Cymbalta(R) Supplemental New Drug Application for Chronic Pain to U.S. Food and Drug Administration

INDIANAPOLIS, May 29, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) has submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking approval for a new indication for Cymbalta(R) (duloxetine HCl) for the management of chronic pain, the company announced today. The submission is based on outcomes of clinical trials in chronic osteoarthritis pain of the knee and chronic low back pain, in addition to data from previously completed pain studies in diabetic peripheral neuropathic pain (DPNP) and fibromyalgia. Cymbalta was studied in chronic pain of at least moderate severity in adults who required daily treatment for an extended period of time.

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.(i) Chronic pain persists beyond acute pain or beyond the expected time for an injury to heal.(ii)

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 pre-clinical 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 fully 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 acute and maintenance treatment of major depressive disorder, the acute treatment of generalized anxiety disorder and the management of diabetic peripheral neuropathic pain, all in adults (18+). Cymbalta is not approved for use in pediatric patients.

Important Safety Information

Cymbalta is approved to treat major depressive disorder and generalized anxiety disorder and manage diabetic peripheral neuropathic pain. Antidepressants can increase suicidal thoughts and behaviors in children, adolescents and young adults. 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. Patients should speak with their doctor about any medical conditions they may have, including liver or kidney problems, glaucoma, or diabetes. Patients should tell their doctor about all their medicines, including those for migraine, to avoid a potentially life-threatening condition. Taking Cymbalta with NSAID pain relievers, aspirin, or blood thinners may increase bleeding risk. They also should talk to their doctor about their alcohol consumption. Patients should consult with their doctor before stopping Cymbalta or changing the dose and if they are pregnant or nursing.

Patients taking Cymbalta may experience dizziness or fainting upon standing. The most common side effects of Cymbalta include nausea, dry mouth, sleepiness and constipation.

This is not a complete list of side effects.

For full Patient Information, visit 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 first-in-class and best-in-class 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.

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This press release contains forward-looking statements about the potential of Cymbalta for the management of chronic 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 receive regulatory approval for chronic pain, or that it 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.

(i) 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 5/27/08.

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

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