



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

INDIANAPOLIS, June 3, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- As projected, [Eli Lilly and Company](#) (NYSE: LLY) has resubmitted its supplemental New Drug Application (sNDA) for Cymbalta(R) (duloxetine HCl) for the management of chronic pain to the U.S. Food and Drug Administration (FDA). Lilly's resubmission is based on a recently completed study in chronic pain due to osteoarthritis, the extension phase of a chronic low back pain study and previously completed studies in pain due to osteoarthritis and chronic low back pain. The application is supported by studies in diabetic peripheral neuropathic pain (DPNP) and fibromyalgia.

Lilly originally submitted the sNDA in the second quarter of 2008 but withdrew the application in November 2008 following discussions with the FDA primarily about statistical methodology and study design. At that time, Lilly said it expected to resubmit the application in the first half of 2009.

"The additional chronic osteoarthritis pain and chronic low back pain data were not available at the time of the initial submission," said John Hayes, M.D., a Lilly Research Laboratories vice president. "We believe including these new data in the updated sNDA package will provide a broader clinical basis for the FDA to review the application."

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) Chronic pain disorders affect millions of Americans and can be a major cause of work absenteeism, underemployment and unemployment.

About Cymbalta

Based on preclinical studies, Cymbalta is a potent reuptake inhibitor of serotonin and norepinephrine. Although the exact way that Cymbalta works in people is unknown, it is believed to be related to an increase in the activity of serotonin and norepinephrine, which are two naturally occurring substances in the brain and spinal cord.

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.

Important Safety Information

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

If patients have any questions, they should talk to their doctor before taking Cymbalta.

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 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.

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(Logo: <http://www.newscom.com/cgi-bin/prnh/20031219/LLYLOGO>)

(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 5/8/09.

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

SOURCE Eli Lilly and Company

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