



Lilly Withdraws Application for Additional U.S. Indication for Cymbalta(R) for Chronic Pain

Resubmission to FDA Planned for First Half of 2009 with Additional Data

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Eli Lilly and Company (NYSE: LLY) has withdrawn its supplemental New Drug Application (sNDA) from the U.S. Food and Drug Administration (FDA) for Cymbalta(R) (duloxetine HCl) for the management of chronic pain. Lilly plans to resubmit the application in the first half of 2009, adding data from a recently completed positive study in chronic osteoarthritis pain of the knee.

The decision does not affect duloxetine's FDA-approved indications for major depressive disorder, generalized anxiety disorder, management of diabetic peripheral neuropathic pain and management of fibromyalgia.

Lilly submitted the chronic pain application in the second quarter of 2008 based primarily on outcomes of three clinical trials: one positive study in chronic osteoarthritis pain of the knee(i) and two studies(ii,iii), -- one positive and one that is supportive but didn't meet its primary endpoint -- in chronic low back pain. In discussions between Lilly and the FDA, agency reviewers raised questions about efficacy and dosing that revolved primarily around statistical methodology and study design.

"This was a difficult decision, but we believe the updated data package will give the FDA a broader basis for reviewing our application," said John Hayes, M.D., a Lilly Research Laboratories vice president at Lilly.

Chronic pain affects more than 50 million Americans(iv) and pain is a major cause of work absenteeism, underemployment and unemployment.(v,vi,vii,viii)

About Duloxetine

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, Duloxetine 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 exact mechanism of action of Duloxetine is unknown, 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.

Duloxetine 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 and fibromyalgia in adults age 18 years and older. Duloxetine is not approved for use in pediatric patients.

Important Safety Information

Duloxetine 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. Duloxetine is approved only for adults 18 and over.

Duloxetine is not for everyone. Patients should not take Duloxetine 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. Taking Duloxetine with NSAID pain relievers, aspirin, or blood thinners may increase bleeding risk. Patients should consult with their doctor before stopping Duloxetine or changing the dose and if they are pregnant or nursing.

Patients taking Duloxetine may experience dizziness or fainting upon standing. The most common side effects of Duloxetine 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 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 Duloxetine 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 resubmission will occur as currently planned, 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) Chappell, A. et al. Duloxetine 60 to 120 mg versus Placebo in the Treatment of Patients with Osteoarthritis Knee Pain. Poster presented at the European League Against Rheumatism. 13 June 2008.
- (ii) Skljarevski, V. et al. Efficacy of Duloxetine in Chronic Low Back Pain. Poster presented at the European Federation of Neurological Societies Annual Congress. 25 August 2008.
- (iii) Skljarevski, V. et al. Duloxetine versus Placebo in the Treatment of Chronic Low Back Pain. Poster presented at the 12th World Congress of Pain. 21 August 2008.
- (iv) APF 2008.
- (v) NIH 1998.
- (vi) Fox et al. 2000.
- (vii) Stewart et al. 2003.
- (viii) White et al. 2005.

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