FDA Approves Cymbalta(R) for Maintenance Treatment of Major Depressive Disorder

INDIANAPOLIS, Nov 30, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) announced today that the U.S. Food and Drug Administration (FDA) has approved Cymbalta(R) (duloxetine HCl) for the maintenance treatment of major depressive disorder (MDD) in adults.

"Relapse, the re-emergence of depressive symptoms after a successful treatment of depression, is a significant clinical concern," says Doug Williamson, M.D., Cymbalta associate medical director for Eli Lilly and Company. "This approval from the FDA is important because data from our Cymbalta clinical trial demonstrate that continuing to treat the patient delays the time to possible relapse."

Treating the broad range of depression symptoms may minimize the presence of residual symptoms (e.g., anxiety, guilt and low self-esteem) and can help delay the time to relapse(1). Common symptoms of depression can include sadness, loss of interest, fatigue, changes in appetite or weight, or bodily aches and pains.

"Once an episode of depression has been successfully treated, it is imperative that the symptoms do not return," said Lauren Marangell, M.D., an internationally recognized expert on depression and other mood disorders and a distinguished scholar at Lilly. "The American Psychiatric Association has recommended maintenance of antidepressant treatment to help decrease the chance of relapse."

The efficacy and safety of Cymbalta for maintenance treatment of major depression was established in a double-blind, placebo-controlled clinical trial. Patients with major depression in the trial (533 patients) received Cymbalta 60 mg once daily. After 12 weeks, 278 patients met the criteria for entering the continuation phase and were randomly assigned to either Cymbalta at the same dose or to a sugar pill for 6 months. Patients on Cymbalta experienced a statistically longer time to relapse of depression than did patients on placebo. Relapse was defined as an increase of two or more points on the Clinical Global Impression - Severity scale (CGI-S) compared with that obtained at week 12, and also meeting the criteria for major depressive disorder for two consecutive visits.

In this study, nausea was the most frequently reported side effect (also referred to as a treatment-emergent adverse event) during the acute phase and was reported as a reason for discontinuation for 2.1 percent of patients. In the continuation phase, there were no significant differences in reported side effects between patients taking Cymbalta compared with those taking sugar pills. Among patients who completed the first 12 weeks of the trial and entered the continuation phase, 3.6 percent reported side effects as reasons for discontinuation over the next 26 weeks (continuation phase) of the study.(2)

Cymbalta, a member of a class of drugs commonly referred to as serotonin and norepinephrine reuptake inhibitors (SNRI), has been studied in more than 27,000 patients worldwide. Cymbalta is already approved for the acute treatment of major depressive disorder, the management of diabetic peripheral neuropathic pain, and for the treatment of generalized anxiety disorder, all in adults. More than 9 million adults in the United States have been prescribed Cymbalta since approval.

About Cymbalta

Serotonin and norepinephrine in the brain and spinal cord are believed to both mediate mood symptoms of depression and help regulate the perception of pain. Based on pre-clinical 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 mechanism of action of duloxetine 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.

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 or glaucoma. Patients should tell their doctor about all of their medicines, including those for migraine to avoid a potentially life-threatening condition, and NSAIDs, aspirin or blood thinners due to an increased risk of bleeding. 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, 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 maintenance treatment of major depressive disorder, 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.

(1) Nierenberg, A. Long-Term Management of Chronic Depression. J Clin Psychiatry 2001; 62 (Suppl 6):17-20.
(2) Perahia DG, et al. 2006. Duloxetine in the prevention of relapse of major depressive disorder: double-blind placebo-controlled study. Br J Psychiatry 188:346-353.

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