



FDA Approves Cymbalta(R) for Maintenance Treatment of Generalized Anxiety Disorder

INDIANAPOLIS, Nov 30, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- The U.S. Food and Drug Administration (FDA) has approved Cymbalta(R) (duloxetine HCl) for the maintenance treatment of generalized anxiety disorder (GAD) in adults, Eli Lilly and Company (NYSE: LLY) announced today.

"Since generalized anxiety disorder can be a chronic illness, it is important that doctors and their patients find a treatment option that is effective in both the acute and maintenance phase of treatment," said James M. Martinez, MD, U.S. Medical Director for Cymbalta. "With this additional approval, Cymbalta offers a new option for the maintenance treatment of this often-debilitating condition."

The efficacy and safety of Cymbalta for the maintenance treatment of GAD were established in a double-blind, placebo-controlled trial. Patients with GAD who initially had responded to treatment with Cymbalta 60-120 mg/day during a 26-week open-label phase were randomly assigned to receive Cymbalta 60-120mg/day (216 patients) or placebo (213 patients). At the end of the trial, patients taking Cymbalta experienced a statistically significantly longer time to relapse of GAD than did patients taking placebo. The estimated probability of relapse at 26 weeks of maintenance treatment was 46.4 percent for placebo and 15 percent for Cymbalta. The most commonly reported treatment-emergent adverse events in patients taking Cymbalta in the open-label phase of the trial included nausea, headache, dry mouth, diarrhea, dizziness, constipation, fatigue and increased sweating.

"This FDA approval, which is the sixth approval for Cymbalta, continues to validate the safety and efficacy profile of the medication in its approved indications," added Martinez.

Cymbalta also is approved for the acute and maintenance treatment of major depressive disorder, the management of diabetic peripheral neuropathic pain and fibromyalgia, and for the acute treatment of generalized anxiety disorder, all in adults.

Generalized anxiety disorder affects nearly 7 million Americans at any given time.(i) While the symptoms of GAD can vary from person to person, they may include excessive worry or anxiety over a period of six months or longer, difficulties controlling worry, irritability, poor concentration, sleep disturbances, fatigue, restlessness and muscle tension.(ii) If left untreated, symptoms may get progressively worse.(iii) Additionally, GAD can have a negative impact on a person's ability to function well in work, family and social situations.(iv)

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.

Indications and Important Safety Information About 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 About Cymbalta

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

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.

P-LLY

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.

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

i Kessler RC, Chiu WT, Demler O, Walters EE. Prevalence, severity, and comorbidity of twelve-month DSM-IV disorders in the National Comorbidity Survey Replication (NCS-R). Archives of General Psychiatry, 2005 Jun;62(6):617-27.

ii Diagnostic and Statistical Manual of Mental Disorders. 4th ed. Washington DC. American Psychiatric Association; 2000, 431-432.

iii National Institute of Mental Health (NIMH). "Anxiety Disorders." Available at: <http://www.nimh.nih.gov/publicat/anxiety.cfm#anx7> . Accessed on May 08, 2009.

iv Mendlowicz, Maura V. and Stein, Murray B. "Quality of Life Individuals with Anxiety Disorders." American Journal of Psychiatry, Vol. 157/No.5, May 2000, pp 677-678

SOURCE Eli Lilly and Company

Copyright (C) 2009 PR Newswire. All rights reserved