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FDA Approves Cymbalta® for Treatment of Generalized Anxiety Disorder

INDIANAPOLIS, Feb 26, 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 the antidepressant Cymbalta(R) (duloxetine HCl) for the treatment of generalized anxiety disorder (GAD), a condition that affects more than 6.5 million American adults in a given year.(1) Because GAD presents with a variety of symptoms, it can be difficult to diagnose(2) and may have a negative impact on a person's ability to function properly in work, family and social situations.(3)

The safety and efficacy of Cymbalta in the treatment of GAD was established in three randomized, double-blind, placebo-controlled studies in more than 800 non-depressed adults with GAD. In all studies, Cymbalta significantly improved core anxiety symptoms as measured by the Hamilton Anxiety Scale (HAMA), compared with placebo. In addition, Cymbalta patients reported greater improvement in functional impairment associated with the illness, including improved ability to perform everyday activities at work, home, and in social situations.

"If left untreated, symptoms of generalized anxiety disorder may worsen, potentially impacting many aspects of a person's life, including their job and social relationships," said Susan Kornstein, M.D., professor of psychiatry at Virginia Commonwealth University. "With this approval, physicians and patients will be happy to know that there is another medication now available to treat this debilitating condition."

Cymbalta, a member of a class of drugs commonly referred to as serotonin and norepinephrine reuptake inhibitor (SNRI),(4) has been studied in more than 25,000 patients worldwide and is already approved for the treatment of major depressive disorder and management of diabetic peripheral neuropathic pain, both in adults.

"More than 4.5 million adults in the United States have been prescribed Cymbalta for major depressive disorder or diabetic peripheral neuropathic pain," said Mike Detke, M.D., Ph.D, Cymbalta medical director for Eli Lilly and Company. "We are excited to offer a new, approved treatment option for generalized anxiety disorder patients and are eager to continue our research with this medication."

In clinical trials, on average, patients treated with Cymbalta for generalized anxiety disorder experienced a 46 percent improvement in anxiety symptoms compared to 32 percent for those who took placebo, as measured by the Hamilton Anxiety Scale. In addition, patients in these studies experienced a 46 percent improvement in function compared to 26 percent for those who took placebo as measured by the Sheehan Disability Scale. The most common side effects in these studies included nausea, fatigue, dry mouth, drowsiness, constipation, insomnia, decreased appetite, hyperhidrosis, decreased libido, vomiting, ejaculation delay and erectile dysfunction. In clinical trials, Cymbalta was studied in a dose range of 60-120 mg per day. While a 120mg/day dose was shown to be effective, there is no evidence that doses greater than 60mg/day confer additional benefit. Cymbalta comes in a capsule, and the target daily dose is 60 mg.

About Generalized Anxiety Disorder

Approximately 6.5 million Americans are diagnosed with generalized anxiety disorder each year.(5) Symptoms persist for at least six months and can include exaggerated worry or chronic anxiety, irritability, poor concentration, sleep disturbance and fatigue.(6,7) Generalized anxiety disorder may be brought on, or worsened by, stressful life events. The illness also tends to be chronic with periods of exacerbation and remission.(8)

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, 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.

Cymbalta is approved in the United States for the treatment of major depressive disorder, the management of diabetic peripheral neuropathic pain and now the treatment of generalized anxiety disorder, all in adults. Cymbalta is not approved for

use in pediatric patients.

Important Safety Information

Cymbalta is approved to treat major depressive disorder, diabetic peripheral neuropathic pain and generalized anxiety disorder. In children and teens, antidepressants can increase the risk of suicidal thoughts or actions. Patients should call their doctor right away if they experience worsening depression symptoms, unusual changes in behavior or thoughts of suicide, especially at the beginning 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 all medicines they are taking, including those for migraine to avoid a potentially life- threatening condition. Patients should tell their doctor about their alcohol consumption, if they have liver disease, and about all of their medical conditions.

Patients taking Cymbalta may experience dizziness or fainting upon standing. The most common side effects of Cymbalta include:

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--  For MDD: nausea, dry mouth and constipation
--  For DPNP: nausea, sleepiness and dizziness
--  For GAD: nausea, fatigue and dry mouth
This is not a complete list of side effects.

For full Patient Information, visit www.cymbalta.com.
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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 treatment of generalized anxiety 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.

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(2) Gliatto, Michael, F. "Generalized Anxiety Disorder." American Family Physicians, Vol. 62/No. 7, October 1, 2000.

(3) Leon, Andrew et al. "Assessing Psychiatric Impairment in Primary Care with the Sheehan Disability Scale." Int'l J. Psychiatry in Medicine. Vol. 27 (2), 1997, pp. 93-105

(4) Bymaster, FP et al. "The Dual Transporter Inhibitor Duloxetine: A Review of its Preclinical Pharmacology, Pharmacokinetic Profile, and Clinical Results in Depression." Current Pharmaceutical Design. 2005; 11: 1475-1493.

(5) Mental Health America. "Generalized Anxiety Disorder." Available at: http://www1.nmha.org/camh/anxiety/gad.cfm. Accessed on January 17, 2007.

(6) National Institute of Mental Health (NIMH). "Anxiety Disorders." Available at: http://www.nimh.nih.gov/publicat/anxiety.cfm#anx7. December 2006.

(7) APA. "Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition." 1994, pp 472-476.

(8) APA. "Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition." 1994, pp 472-476.

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