December 9, 2005

Lilly Plans to Submit Cymbalta(R) (duloxetine hydrochloride) New Drug Application for Generalized Anxiety Disorder

Four Million Americans Are Diagnosed Annually With Generalized Anxiety Disorder

INDIANAPOLIS, Dec 09, 2005 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) plans to submit a supplemental New Drug Application (sNDA) in 2006 to the Food and Drug Administration for Cymbalta(R) (duloxetine hydrochloride) for the treatment of generalized anxiety disorder (GAD). Lilly has completed two clinical trials, which the company believes will support this submission.

"People with generalized anxiety disorder experience a wide array of symptoms from excessive worry to difficulty concentrating. In addition, it is also common for patients to experience physical symptoms like muscle tension, restlessness or fatigue," explains Michael Detke, M.D., Ph.D., Cymbalta medical director, Eli Lilly and Company.

Every year four million Americans are diagnosed with generalized anxiety disorder, the majority of them women.(i) Unfortunately, it is common for people with generalized anxiety disorder to also experience other physical and mental disorders, including depression, eating disorders or substance abuse.(ii) Because generalized anxiety disorder presents with a variety of symptoms and is often a comorbid illness, it can be difficult to diagnose.(iii) When left untreated, symptoms may get progressively worse, significantly diminishing a patient's quality of life.(iv,v)

Patients with generalized anxiety disorder experience symptoms like exaggerated worry or chronic anxiety and irritability, which can lead to poor concentration, and procrastination.(vii) Generalized anxiety disorder may also include physical symptoms like muscle tension, restlessness and insomnia. Symptoms usually occur gradually and persist for at least six months, although episodes of 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.(vi,vii)

Cymbalta was approved for the treatment of major depression in August 2004, followed by another approval for the management of diabetic peripheral neuropathic pain, also known as diabetic nerve pain, in September 2004.

About Cymbalta

Serotonin and norepinephrine in the brain and spinal cord are believed to both mediate core depression symptoms and help regulate the perception of pain. Disturbances of serotonin and/or norepinephrine may explain the presence of both the emotional and physical symptoms of depression. Based on pre- clinical studies, duloxetine is a balanced and potent reuptake inhibitor of serotonin and norepinephrine. While the mechanism of action of duloxetine is not fully known, scientists believe its effect on both emotional symptoms and pain perception is 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 and the management of diabetic peripheral neuropathic pain, both in adults. Cymbalta is not approved for use in pediatric patients.

Important Safety Information

In clinical studies, antidepressants increased the risk of suicidal thinking and behavior in children and adolescents with depression and other psychiatric disorders. Anyone considering the use of Cymbalta or any other antidepressant in a child or adolescent must balance the risk with the clinical need. Patients who are starting therapy should be observed closely for worsening depression symptoms, suicidal thoughts or behavior, or unusual changes in behavior. Cymbalta is not approved for use in patients under the age of 18.

Patients on antidepressants and their families or caregivers should watch for worsening depression symptoms, unusual changes in behavior and thoughts of suicide, as well as for anxiety, agitation, panic attacks, difficulty sleeping, irritability, hostility, aggressiveness, impulsivity, restlessness, or extreme hyperactivity. Call the doctor if you have thoughts of suicide or if any of these symptoms are severe or occur suddenly. Be especially observant at the beginning of antidepressive treatment or whenever there is a change in dose.

Prescription Cymbalta is not for everyone. People who are allergic to Cymbalta or the other ingredients in Cymbalta should not take it. If you have recently taken a type of antidepressant called a monoamine oxidase inhibitor (MAOI), are taking Mellaril(R) (thioridazine) or have uncontrolled narrow- angle glaucoma, you should not take Cymbalta. Talk with your doctor before taking Cymbalta if you have liver or kidney problems, glaucoma or consume large quantities of alcohol. Women who are pregnant should talk with their doctor before taking Cymbalta. Nursing while taking Cymbalta is not recommended. Tell your doctor if you are taking other prescription or nonprescription medications.

In clinical studies of Cymbalta for depression, the most common side effects were nausea, dry mouth, constipation, decreased appetite, fatigue, sleepiness, and increased sweating. Nausea was the most common side effect. For most people, the nausea was mild to moderate, and usually subsided within one-to-two weeks. Cymbalta is also approved for the management of neuropathic pain associated with diabetic peripheral neuropathy. In clinical studies of Cymbalta in these patients, the most common side effects were nausea, sleepiness, dizziness, constipation, dry mouth, increased sweating, decreased appetite, and loss of strength or energy. In all clinical trials, most people were not bothered enough by side effects to stop taking Cymbalta. Your doctor may periodically check your blood pressure. Don't stop taking Cymbalta without talking to your doctor.

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.

P-LLY

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.

(i) National Institute of Mental Health, "Anxiety Disorders." Available at http://www.nimh.nih.gov/publicat/anxiety.cfm. Accessed on December 5, 2005.

(ii) National Mental Health Association. "Anxiety Disorders." Available at: http://www.nmha.org/pbedu/anxiety/anxdis.cfm. Accessed on: November 28, 2005.

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

(iv) National Mental Health Association. "Anxiety Disorders." Available at: http://www.nmha.org/pbedu/anxiety/anxdis.cfm. Accessed on: November 28, 2005.

(v) National Institute of Mental Health. "Anxiety Disorders." Available at: http://www.nimh.nih.gov/publicat/anxiety.cfm. Accessed on: November 28, 2005.

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

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

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

SOURCE Eli Lilly and Company

Tamara Hull (US), +1-317-651-9116, pager: +1-888-232-0785, or David Shaffer (OUS), +1-317-651-3710, pager: +1-877-656-9084, both of Eli Lilly and Company

http://www.prnewswire.com