December 13, 2005

New Study Suggests Cymbalta(R) Reduced Depression Symptoms At Least As Fast As a Leading Competitor

INDIANAPOLIS, Dec 13, 2005 /PRNewswire-FirstCall via COMTEX News Network/ -- Cymbalta(R) (duloxetine hydrochloride) reduced symptoms of depression at least as fast as Lexapro(R) (escitalopram) by the end of two weeks, according to results from the first head-to-head study comparing the two antidepressants. The results were released by Eli Lilly and Company at a meeting of a major scientific society.

In this eight-week study, Cymbalta, a serotonin and norepinephrine reuptake inhibitor, was effective in reducing depression symptoms (defined as onset of efficacy) by two weeks for 42 percent of patients. Within the same time period, 35 percent of patients taking Lexapro, a selective serotonin reuptake inhibitor, and 22 percent of patients who received a sugar pill had 20 percent reduction of symptoms. While not indicative of faster onset of action than Lexapro in patients with major depressive disorder, this study showed Cymbalta's onset to be at least as fast as that of Lexapro.

While Cymbalta was significantly better than sugar pill at reducing depression symptoms, Lexapro was not in this study. In other studies Lexapro has shown significant improvement versus sugar pill in reducing depression symptoms.

"Previous data has shown that Cymbalta may work as early as one week. In this study Cymbalta works at least as fast as Lexapro," says John Greist, M.D., clinical professor of psychiatry, University of Wisconsin Medical School.

"This study was the first to compare Cymbalta with Lexapro, and the first to measure onset of efficacy of Cymbalta as compared to an SSRI," says Madelaine Wohlreich, M.D., medical advisor for Eli Lilly and Company.

Additional study highlights

* The percentages of patients who responded to treatment with Cymbalta, Lexapro or sugar pill (48.7 percent, 45.3 percent and 36.9 percent, respectively) were statistically no different.
* Percentage of patients achieving remission on Cymbalta, Lexapro or sugar pill (40.1 percent, 33.0 percent and 27.7 percent, respectively) were statistically no different in this study.
* Cymbalta and Lexapro both had statistically significant changes in the Clinical Global Impression of Severity (CGI-S) scale and the self-reported Patient Global Impression of Improvement (PGI-I) scale, when compared with sugar pill.
* Patients taking Cymbalta experienced more side effects, including nausea and dry mouth, compared with those taking Lexapro and sugar pill, but the rates at which patients dropped out of the study because of side effects were statistically no different (7.3 percent for Cymbalta, 5.1 percent for Lexapro and 5.8 percent for sugar pill).

Methods

A total of 684 patients with major depressive disorder aged 18 years and older participated in the eight-week, multi-center, double-blind, placebo- controlled clinical trial, conducted entirely within the United States from November 2003 to May 2005. The patients were randomized to receive either 60 mg of Cymbalta once daily (n=273), 10 mg of Lexapro once daily (n=274), or a sugar pill once daily (n=137).

Onset of efficacy was defined as at least a 20 percent decrease from baseline in the Maier subscale of the Hamilton Depression Scale (HAM-D17) that was maintained at each visit. Secondary measures included the Hamilton Anxiety Ratings Scale (HAMA), CGI-S and PGI-I. Standard safety measures were also collected.

This is the only study that has compared Cymbalta and Lexapro. The study compared Cymbalta at its highest approved dose of 60 mg per day to Lexapro's lowest approved dose of 10 mg per day, however those doses represent the recommended therapeutic doses of each medication and are widely used.

About Depression

Up to 19 million Americans have depressive disorders, including major depression.(i) It can happen to anyone of any age, race or ethnic group, however women are nearly twice as likely to experience depression as men.(ii) Although it is one of the most frequently seen psychiatric disorders in the primary care setting, it often goes undiagnosed, or is under-treated.(iii) This may be because depressed patients often present physical symptoms rather than emotional complaints. In one study, nearly 70 percent of patients diagnosed with depression reported physical symptoms as their chief reason for seeking help.(iv)

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/.

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About Eli Lilly and Company

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This press release contains forward-looking statements about the potential of Cymbalta hydrochloride for the 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 prove 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. Depression Research at the National Institute of Mental Health: Fact Sheet. Available at http://www.nimh.nih.gov/publicat/depresfact.cfm. Accessed May 12, 2004.

(ii) American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 4th ed., Text Revision. Washington DC: American Psychiatric Association; 2000:345-428.

(iii) Kroenke K, et al. Am J Med. 1997; 103(5):339-347.
(iv) Simon GE, et al. N Engl J Med. 1999; 341(18):1329-1335.

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