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New Data Presented on the Effect of Cymbalta(R) on Sexual Function in Depressed Patients

Cymbalta and Lexapro(R) Compared in New Study, Presented at Major Medical Meeting

INDIANAPOLIS, May 22, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Data suggests that male patients with major depressive disorder (MDD) treated with Cymbalta(R) (duloxetine HCl) had significantly better sexual functioning when compared to those taking Lexapro(R) (escitalopram) within the first eight weeks of treatment, according to a head-to-head study of more than 680 patients. These results were presented today at a major medical meeting of psychiatrists.

The sexual functioning assessment was part of a larger trial, the primary end point of which was to compare the onset of efficacy between Cymbalta, an SNRI, and Lexapro, an SSRI. In this study, 42 percent of Cymbalta-treated patients met the definition of onset of efficacy compared to 35 percent of Lexapro-treated patients. Onset of efficacy was defined as at least a 20 percent decrease in Maier Subscale of the Hamilton Depression Rating Scale (HAM-D17) at week two and sustained throughout eight weeks of acute treatment. While not indicative of faster onset of efficacy than Lexapro in patients with MDD, this study showed the onset of Cymbalta to be at least as fast as that of Lexapro. (i)

At the end of the acute period of the sexual functioning assessment (eight weeks), 37 percent of male patients treated with Cymbalta reported a worsening in sexual functioning, 59 percent treated with Lexapro reported worsening and 49 percent taking a sugar pill experienced worsening, as measured by the Changes in Sexual Functioning Questionnaire (CSFQ). Whereas, 36 percent of female patients treated with Cymbalta reported a worsening of sexual functioning, 38 percent taking Lexapro reported worsening and 26 percent taking a sugar pill experienced worsening, as measured by the CSFQ.

"Sexual dysfunction is common among patients with depression, affecting up to 64 percent of people with the illness (ii)," said Dr. Madelaine Wohlreich, a study co-author and medical advisor at Eli Lilly and Company. "Antidepressant treatment can also impact sexual functioning, so differences in the likelihood of sexual side effects are an important consideration for patients taking antidepressants."

Sexual dysfunction can be marked by a loss of sexual drive, interest, and/or performance. Loss of sexual functioning is a common side effect of antidepressant treatments, causing up to 70 percent of those who experience it to stop taking medication. (iii)

"When sexual dysfunction due to medication occurs, a person may be inclined to stop treatment, which can have a devastating impact on his or her illness," said Dr. Wohlreich. "In the case of depression, noncompliance with antidepressants can lead to a relapse."

Among the up to 19 million Americans who suffer from depressive disorders, including major depression, annually, an estimated 50 percent will suffer a relapse within two years. (iv)

Additional Study Highlights

* At four weeks and eight weeks, there was statistically significant worsening of sexual functioning for Lexapro compared to patients treated with a sugar pill, while Cymbalta was not statistically different from sugar pill at any time.

* At eight weeks, categorical changes in sexual functioning on the CSFQ differed significantly for men treated with Cymbalta compared to men treated with Lexapro. There were no significant differences between Cymbalta and Lexapro in women.

* Anorgasmia was the only treatment-emergent sexual adverse event reported statistically more frequently for Cymbalta or Lexapro compared to sugar pill during the course of the study.

* At the end of the study, there were no significant differences in discontinuation rates due to sexual side effects for those treated with Cymbalta (n=2) compared to those treated with Lexapro (n=7).

- Adverse events causing discontinuation included erectile dysfunction, decreased libido, and orgasmic dysfunction including anorgasmia and ejaculation delay.

Methods

In this double-blind, placebo-controlled study of adult patients with MDD, 273 patients treated with Cymbalta 60 mg once-daily, 274 patients treated with Lexapro 10 mg once per day and 137 treated with a sugar pill, participated in an eight-week acute phase, fixed-dose comparison. Following the acute phase, patients participated in a six-month, flexible dose extension phase where they received Cymbalta 60, 90, or 120 mg once-daily; Lexapro 10 or 20 mg once per day or sugar pill. Dose escalations and switching from sugar pill to active drug were based on predefined blinded criteria, but the number of patients taking sugar pill decreased significantly after eight weeks.

Onset of action, the primary endpoint of this study, was defined as at least a 20 percent decrease in the Maier Subscale of the HAM-D17 Rating Scale at week two, maintained at each visit throughout eight weeks of acute treatment. Sexual dysfunction was measured in this study by the 14-item, self-reported CSFQ and the Quality of Life Enjoyment and Satisfaction Questionnaire-short form (Q-LES-Q-SF), as well as spontaneously reported sexual side effects and discontinuation due to sexual side effects.

This study compared Cymbalta at its highest approved dose of 60 mg per day to the lowest approved dose of Lexapro, 10 mg per day. However, those doses represent the recommended therapeutic doses of each medication and are widely used.

After eight weeks, the power to detect a difference between the active treatments and sugar pill was significantly decreased due to attrition and switching to placebo, and by the study endpoint very few patients (n=15) remained on sugar pill compared with Cymbalta (n=105) or Lexapro (n=124).

In four pooled studies of Cymbalta 40 to 120 mg/day for registration, sexual functioning was proactively measured by the Arizona Sexual Experience Scale (ASEX). Sexual dysfunction occurred more often in patients treated with Cymbalta compared to those receiving sugar pill. For males, only the ease of orgasm individual ASEX score was significantly different compared to sugar pill. For females, no ASEX scores were significantly different versus sugar pill.

About Depression

Up to 19 million Americans suffer from depressive disorders, including major depression. (v) It can happen to anyone of any age, race or ethnic group, however women are nearly twice as likely to experience depression as men. (vi) Although it is one of the most frequently seen psychiatric disorders in the primary care setting, it often goes undiagnosed or is under- treated. (vii) This may be because depressed patients often present physical symptoms rather than emotional complaints. In fact, in one study about seven out of 10 patients diagnosed with MDD presented with only physical symptoms as their chief complaint. Pain is present in approximately 45 to 75 percent of patients with MDD, (viii, ix, x) and can include headache, back, shoulder and abdominal pain. (xi, xii, xiii)

The goal of treatment is to help people with depression feel more like themselves, so they can move forward with their lives. Depression symptoms that don't go away completely can prevent people with depression from getting fully well, and may increase the risk of symptoms coming back. (xiv) Nobody should settle for feeling only slightly better. With the right treatment and support, recovering from depression is possible.

About Cymbalta

Cymbalta is believed to modulate both serotonin and norepinephrine in the brain and the spinal cord. Based on pre-clinical studies, Cymbalta is a balanced and potent reuptake inhibitor of serotonin and norepinephrine. While the mechanism of action of Cymbalta in humans is not fully known, scientists believe its effect on mood 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 MDD 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

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 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.

(i) Study presented as a poster at the annual meeting of the American College of Neuropsychopharmacology, December 13, 2005.

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(v) 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.

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

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