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Study Suggests Cymbalta(R) Significantly Reduces Core Anxiety Symptoms of Generalized Anxiety Disorder

Patients Taking Cymbalta Also Reported Reduced Painful Physical Symptoms and Improved Functioning

MIAMI, March 24, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- A new study of approximately 500 patients evaluated the safety and efficacy of the antidepressant Cymbalta(R) (duloxetine HCl) on the core anxiety symptoms in patients with generalized anxiety disorder. Cymbalta significantly reduced core anxiety symptoms and associated painful physical symptoms and improved functional impairment associated with the illness. Results will be announced on Saturday, March 25, in two separate presentations(i,ii) at the Anxiety Disorders Association of America (ADAA) Annual Conference.

In this nine-week study, Cymbalta significantly improved core anxiety symptoms such as anxious mood, fears and tension by 51 percent in patients taking 60mg/day and by 50 percent in patients taking 120mg/day compared to an improvement of 32 percent in patients taking sugar pill. Patients taking both 60mg/day and 120mg/day had significantly greater response and remission rates compared to patients taking sugar pill. In addition, Cymbalta significantly reduced overall pain by 41 percent and 37 percent respectively, compared to 16 percent in patients taking sugar pill. Cymbalta patients also reported greater improvement in quality of life as measured by the Sheehan Disability Scale, Quality of Life Enjoyment and Satisfaction Questionnaire and European Quality of Life 5 Dimensions, including improved ability to perform everyday activities at work, home, and in social situations compared to sugar pill.

"While it is important to evaluate anxiety symptoms such as excessive worry and irritability, it is also important to evaluate associated painful physical symptoms and functioning because many patients also report these symptoms," said Christer Allgulander, MD, associate professor, senior lecturer, Karolinska Institutet, and lead author on the study. "These data suggest that not only was Cymbalta able to significantly improve the core anxiety symptoms, but it also reduced painful physical symptoms associated with the disorder and improved functioning resulting in improved quality of life."

"We are encouraged by these results that suggest Cymbalta may address a broad range of core anxiety symptoms and the associated physical symptoms that are often reported in patients with generalized anxiety disorder," said James Russell, MD, medical advisor, Eli Lilly and Company.

Study Highlights

* Compared to sugar pill, patients receiving Cymbalta 60mg/day and 120mg/day experienced significant improvement in symptom severity and disability associated with generalized anxiety disorder, including:
  - Significantly greater improvement in the severity of anxiety symptoms, such as anxious mood, fears and tension, as measured by the Hamilton Anxiety Scale. (average improvement 60mg = 51%, 120mg = 50%, sugar pill = 32%)
  - Greater response rates (58%, 56%, 31%, respectively)
  - Greater sustained improvement rates (64%, 67%, 43%, respectively)
* Patients receiving Cymbalta 60mg/day and 120mg/day experienced greater remission rates compared to those receiving sugar pill (31%, 38% and 19%, respectively).
* Compared to sugar pill, patients receiving Cymbalta 60mg/day and 120mg/day reported significant improvement in ratings on the Visual Analogue Scale for Pain for each of the following pain items:
  - Overall pain (average improvement 60mg = 41%, 120mg = 37%, sugar pill = 16%)
  - Headaches (34%, 38%, 13%, respectively)
  - Back pain (44%, 46%, 14%, respectively)
  - Shoulder pain (47%, 43%, 19%, respectively)
  - Interference due to pain (39%, 41%, 10%, respectively)
  - Pain during waking hours (42%, 43%, 12%, respectively)
* In this study, the most common adverse events (occurred at a rate of

greater than or equal to 5 percent and at least twice the rate of placebo) were nausea, dizziness, dry mouth, fatigue, hyperhidrosis, insomnia, constipation, diarrhea, decreased libido, anorexia, somnolence, vomiting and sedation.

Methods

In this study of patients with generalized anxiety disorder, 168 patients were randomly assigned to receive 60mg of Cymbalta a day, 170 patients received 120mg of Cymbalta a day and 175 patients received a sugar pill. Patients with a recent diagnosis (within six months) of major depression were excluded from this study. The primary endpoint of the study was effect on anxiety symptoms as measured by the Hamilton Anxiety Scale (HAMA). Changes from baseline to endpoint were analyzed using ANCOVA. Secondary measures included effects on associated pain and functioning. Pain was assessed using a Visual Analogue Scale. Functional outcomes, such as the ability to complete everyday activities at work, home, and in social situations, were measured using the Sheehan Disability Scale (SDS), the Quality of Life Enjoyment and Satisfaction Questionnaire short form (Q-LES-Q-SF) and the European Quality of Life 5 Dimensions (EQ-5D).

About Generalized Anxiety Disorder

Approximately four million Americans are diagnosed with generalized anxiety disorder each year.(iii) Symptoms persist for at least six months and can include exaggerated worry or chronic anxiety and irritability, which can lead to poor concentration, and procrastination, as well as physical symptoms like muscle tension, fatigue and nausea.(iv) 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.(v)

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. It is common for anxiety disorders to be associated with other disorders, such as depression. (vi)

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.

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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.

(i) Duloxetine as an Effective Treatment for Improving Painful Physical Symptoms and Functioning Associated with Generalized Anxiety Disorder; C Allgulander, H Koponen, J Erickson, Y Pritchett, M Detke, S Ball, J Russell

(ii) A Fixed Dose Study of the Efficacy and Safety of Duloxetine for the Treatment of Generalized Anxiety Disorder; H Koponen, C Allgulander, Y Pritchett, J Erickson, M Detke, S Ball, J Russell

(iii) National Institute of Mental Health. "Facts About Generalized Anxiety Disorder." Available at: http://www.nimh.nih.gov/publicat/gadfacts.cfm. Accessed on: February 6, 2006

(iv) National Mental Health Association. "Anxiety Disorders." Available at: http://www.nmha.org/pbedu/anxiety/anxdis.cfm. Accessed on: February 7, 2006

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

(vi) Anxiety Disorders Association of America "Medications for Anxiety Disorders" Available at: http://www.adaa.org/GettingHelp/AnxietyDisorders/chart.htm. Accessed on March 13, 2006.

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