



Data Suggest Cymbalta(R) Improved Functioning in Patients With Generalized Anxiety Disorder

Relationship Between Ability to Function and Treatment of Anxious and Painful Physical Symptoms Studied

INDIANAPOLIS, IN, May 21, 2007 (MARKET WIRE via COMTEX News Network) -- Data suggest that patients with generalized anxiety disorder (GAD) treated with Cymbalta(R) (duloxetine HCl) experienced improved ability to perform everyday activities at home, work and in social situations compared to sugar pill. These improvements in global functioning were the result of improvements in anxious symptoms, as well as through an improvement in the painful physical symptoms that can be associated with the condition. The results of these data from two GAD registration studies of more than 840 patients were presented today at a major medical meeting of psychiatrists.

These analyses focused on the relationship between global functional impairment and the treatment of anxious and painful physical symptoms in patients with GAD. Improvement in global functioning was measured by the Sheehan Disability Scale (SDS), which assesses the extent emotional symptoms disrupt ability to perform everyday activities at work, home and in social situations.

In one of the two studies, patients treated with 60 mg and 120 mg once daily of Cymbalta experienced statistically significant improvements compared to those treated with a sugar pill (defined by mean change on SDS, 7.76 and 7.04 vs. 3.83). In the second study, patients treated with 60-120 mg once daily of Cymbalta experienced statistically significant improvements compared to those treated with a sugar pill (defined by mean change on SDS 5.78 vs. 3.11). In the pooled analysis, among Cymbalta-treated patients, 48 percent of improvement in global functioning was from improvements in psychic anxiety, while 9 percent was from improvements in painful physical symptoms and 7 percent was from improvements in somatic anxiety associated with GAD.

Since GAD presents with a variety of symptoms, it can be difficult to diagnose⁽¹⁾ and may have a negative impact on a person's ability to function properly in work, family and social situations.⁽²⁾

"This study underscores the importance of treating all of the many symptoms of GAD and reducing the global functional impairment associated with the disorder," says Dr. David Sheehan, lead study author and professor of psychiatry at the University of South Florida College of Medicine in Tampa. "This information may be important for physicians to consider when choosing a treatment for their patients with GAD since different medications may affect symptoms differently."

Additional Study Highlights

- Thirty-six percent of the improvement in global functioning was due to an undefined effect of Cymbalta, which was not measured on any of the three scales used in the study.
- In improvement in work functioning, 36 percent was due to treatment of psychic anxiety, eight percent was due to treatment of painful physical symptoms and 4 percent was due to treatment of somatic anxiety, while 51 percent was due to an undefined effect of Cymbalta.
- In improvement in social functioning, 46 percent of the improvement was due to treatment of psychic anxiety, 9 percent was due to treatment of painful physical symptoms and 6 percent was due to treatment of somatic anxiety, while 39 percent was due to an unexplained effect of Cymbalta.
- In improvement in family life functioning, 51 percent of the improvement was due to treatment of psychic anxiety, 10 percent was due to treatment of painful physical symptoms and 10 percent was due to treatment of somatic anxiety, while 30 percent was due to an undefined effect of

Cymbalta.

- In the pooled analyses of all the GAD registration studies, the most commonly observed adverse events (incidence of 5 percent or greater and at least twice the incidence of sugar pill) were: nausea; fatigue; dry mouth; somnolence; constipation; insomnia; appetite decreased; hyperhidrosis; libido decreased; vomiting; ejaculation delayed; and erectile dysfunction. Approximately 16 percent of patients taking Cymbalta discontinued treatment due to an adverse event compared to 4 percent of patients receiving sugar pill. The most common adverse events reported as reasons for discontinuation (occurring at a rate of greater than or equal to 1.2 percent and at a significantly higher rate compared to sugar pill) were nausea, vomiting and dizziness.(3)

Methods

Data from two double-blind, placebo-controlled trials in adults with generalized anxiety disorder were pooled. In the first trial, patients received 60 mg of Cymbalta once daily, 120 mg once daily or sugar pill for nine weeks. In the second trial, patients were started at a dose of 60 mg of Cymbalta but dose could be increased to 120 mg once daily, or they were given sugar pill for 10 weeks.

In both trials, the Hamilton Anxiety Scale (HAMA) was used to measure anxious symptoms, the SDS was used to assess global functional impairment and the Visual Analog Scale for Overall Pain (VAS) was used to measure severity of painful physical symptoms. Pearson partial correlations were used to assess the magnitude and significance of the associations between global functional impairment and psychic anxiety or painful physical symptoms. Path analysis was used to assess the relative contributions of changes in psychic and somatic anxiety and painful physical symptoms on improved functional outcomes.

The large unexplained effect of Cymbalta implies that Cymbalta improves global functioning through the treatment of additional symptoms that the scales in our clinical trials do not measure. These symptoms could be related to other anxious symptoms, painful physical symptoms, or entirely separate symptom domains not mentioned in this analysis.

About Generalized Anxiety Disorder

Approximately 6.5 million Americans are diagnosed with generalized anxiety disorder each year.(4) Symptoms persist for at least six months and can include exaggerated worry or chronic anxiety, irritability, poor concentration, sleep disturbance and fatigue.(5)(6) 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.(7)

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 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:

- 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.

For full Prescribing Information, including Boxed Warning, visit <http://www.cymbalta.com/>.

About Eli Lilly and Company (NYSE: LLY)

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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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