



New Data Suggest Cymbalta(R) Reduced Pain in Fibromyalgia Patients With and Without Depression

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New data suggest that patients with fibromyalgia treated with 60mg or 120mg of Cymbalta(R) (duloxetine HCl) experienced greater reduction in pain severity beginning one week after starting duloxetine than those taking placebo (sugar pill), as measured by the Brief Pain Inventory Average Pain Score (BPI). The study, which included patients with and without depression, also showed greater improvements in patients taking duloxetine than in those taking placebo in scores on the Patient's Global Impression of Improvement questionnaire (PGI- I), which measures how the patient has felt overall since beginning to take the medication. The data were presented today at the 2007 Congress of the International MYOPAIN Society in Washington, D.C.

At three months, patients treated with 60mg per day or 120mg per day of duloxetine showed significantly greater reduction in pain and improvement in PGI-I scores compared with patients taking placebo. At three months, more patients treated with either 60mg or 120mg of duloxetine showed significantly greater reduction in pain as measured by a 30 percent improvement in baseline BPI scores (50.7 percent and 52.1 percent, respectively) compared with patients taking placebo (36 percent).

"Fibromyalgia is a chronic illness, characterized by widespread pain, tenderness and fatigue. It can also affect the patient's overall emotional health and well-being," said I. Jon Russell, M.D., Ph.D., associate professor of medicine at the University of Texas Health Science Center in San Antonio. "Between 34 percent(1) and 62 percent(2) of those living with fibromyalgia will experience depression at some point in their lives. In this study, which included patients with and without depression, duloxetine reduced the pain associated with fibromyalgia."

Fibromyalgia is estimated to affect 2 percent to 4 percent of the U.S. population(3), the majority being women. In addition to chronic pain, fibromyalgia patients often have complaints about cloudy thinking, morning stiffness and overall inability to function in their everyday lives.

Additional Study Highlights

- At six months, patients taking duloxetine 60mg or 120mg maintained reduced BPI scores and patients taking 120mg had improved PGI-I scores compared with those taking placebo.
- At the end of the six-month trial, more patients treated with both 60mg or 120mg of duloxetine showed a response to treatment, defined as a 50 percent reduction of baseline BPI scores (32.6 percent and 35.9 percent of patients, respectively), compared with patients taking placebo (21.6 percent).
- Discontinuation rates over six months were similar among the groups (45.3 percent and 46.3 percent for duloxetine 60mg and 120mg patients, compared with 50 percent for placebo).
 - * Adverse event-related discontinuation was significantly higher in patients taking 120mg (26.5 percent) but not in the 60mg (15.3 percent) group as compared with placebo (13.2 percent). Discontinuations due to lack of efficacy were not statistically different among treatment groups.
 - * Adverse events were similar to those seen in prior duloxetine studies. 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) included nausea, dry mouth, constipation, somnolence (sleepiness), fatigue, insomnia, decreased appetite, hyperhidrosis, cough, tremor, rash and weight increase.

Eli Lilly and Company (NYSE: LLY) also announced today that it recently submitted a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) for Cymbalta for the management of fibromyalgia. The sNDA submission is based on data from approximately 1,400 patients in five clinical trials.

"Lack of awareness of fibromyalgia can lead to frustration as patients often see multiple physicians over a number of years before receiving a formal diagnosis," said Alan Breier, M.D., vice president for medical and chief medical officer, Eli Lilly and Company. "This research may help increase recognition of fibromyalgia and offer hope to those living with this debilitating condition."

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 (MDD), the management of diabetic peripheral neuropathic pain (DPNP) and the treatment of generalized anxiety disorder (GAD), all in adults (age 18+). Cymbalta is not approved for use in pediatric patients.

Important Safety Information

Cymbalta is approved to treat major depressive disorder and generalized anxiety disorder and manage diabetic peripheral neuropathic pain. Antidepressants can increase suicidal thoughts and behaviors in children, adolescents and young adults. Patients should call their doctor right away if they experience worsening depression symptoms, unusual changes in behavior or thoughts of suicide. Be especially observant within the first few months 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, somnolence (sleepiness), dizziness and constipation
- For GAD: Nausea, fatigue, dry mouth, somnolence (sleepiness) and constipation

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 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 fibromyalgia, 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.

- (1) Ahles TA, et al. "Psychiatric status of patients with primary fibromyalgia, patients with rheumatoid arthritis, and subjects without pain: a blind comparison of DSM-III diagnoses." American Journal of Psychiatry 1991; 148:1721-1726.
- (2) Arnold LM, et al. "Comorbidity of fibromyalgia and psychiatric disorders." Journal of Clinical Psychiatry 2006; 67:1219-1225.
- (3) American College of Rheumatology Web site - http://www.rheumatology.org/public/factsheets/fibromya_new.asp; visited Aug. 3, 2007.

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SOURCE Eli Lilly and Company

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