FDA Approves Cymbalta® for the Management of Chronic Musculoskeletal Pain

INDIANAPOLIS, Nov. 4, 2010 /PRNewswire-FirstCall/ -- Eli Lilly and Company (NYSE: LLY) announced that the U.S. Food and Drug Administration (FDA) has approved Cymbalta® (duloxetine HCl) for the management of chronic musculoskeletal pain. This has been established in studies in patients with chronic low back pain and chronic pain due to osteoarthritis. This is the fifth indication the FDA has approved for Cymbalta.

Cymbalta, which has been shown to significantly reduce chronic low back pain and chronic pain due to osteoarthritis, is a non-narcotic pain reliever that is meant to be taken once a day, every day by people with these pain conditions.

"People with chronic musculoskeletal pain often struggle to find a medication that works for them. The approval of Cymbalta for chronic musculoskeletal pain by the FDA gives doctors another option to help an underserved and suffering group of patients," said Michael Clark, M.D., MPH, director, Chronic Pain Treatment Program, Department of Psychiatry and Behavioral Sciences, The Johns Hopkins Medical Institutions.

Although the exact way that Cymbalta works to reduce chronic musculoskeletal pain is unknown, it is believed that Cymbalta helps lessen pain by enhancing the body's natural pain suppressing system by increasing the activity of serotonin and norepinephrine in the brain and spinal cord.

In chronic musculoskeletal pain clinical studies, the most commonly observed adverse events (those occurring in at least 5 percent of study participants taking Cymbalta and at least twice the rate of placebo) in Cymbalta-treated patients with chronic low back pain were nausea, dry mouth, insomnia, sleepiness, constipation, dizziness and fatigue. The most commonly observed adverse events in Cymbalta-treated patients with chronic pain due to osteoarthritis were nausea, fatigue and constipation.

"It's important that people with chronic musculoskeletal pain have different treatments available to them because responses to medications can be highly individualized," said Robert Baker, M.D., global development leader for psychiatry and pain disorders at Lilly. "This is why we are happy to be able to provide doctors and patients with a new option."

Osteoarthritis affects an estimated 27 million adults in the U.S.(i) An estimated 70 to 85 percent of adults experience low back pain at some time,(ii) with some reports estimating that 2 to 10 percent of these people go on to experience chronic low back pain.(iii) (iv) (v) (vi)

"Having a medication that is approved specifically for people with chronic musculoskeletal pain is a great step in helping these individuals live with less chronic low back pain or chronic pain due to osteoarthritis. Good medical care from a health care professional and involvement by the person with the condition is important," said Penney Cowan, executive director, American Chronic Pain Association.

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. Although the exact way that Cymbalta works in people is unknown, it is believed to be related to an increase in the activity of serotonin and norepinephrine, two naturally occurring substances in the brain and spinal cord.

Cymbalta is approved in the United States for the treatment of major depressive disorder, the treatment of generalized anxiety disorder, the management of diabetic peripheral neuropathic pain, fibromyalgia and chronic musculoskeletal pain, which has been established in studies in patients with chronic low back pain and chronic pain due to osteoarthritis, all in adults (18+). Cymbalta is not approved for use in pediatric patients.

Indications and Important Safety Information About Cymbalta

Indications

Cymbalta is approved to treat major depressive disorder and generalized anxiety disorder, and to manage diabetic peripheral neuropathic pain and fibromyalgia. Cymbalta is also approved for the management of chronic musculoskeletal pain including chronic osteoarthritis pain and chronic low back pain.

Important Safety Information About Cymbalta

Antidepressants can increase suicidal thoughts and behaviors in children, adolescents, and young adults. Suicide is a known risk of depression and some other psychiatric disorders. Patients should call their doctor right away if they experience new or 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® (thioridazine), or have uncontrolled narrow-angle glaucoma (increased eye pressure).

Patients should speak with their doctor about all their medical conditions including kidney or liver problems, glaucoma, diabetes, seizures, or if they have bipolar disorder. Cymbalta may worsen a type of glaucoma or diabetes. Patients should talk to their doctor if they have itching, right upper belly pain, dark urine, yellow skin or eyes, or unexplained flu-like symptoms, which may be signs of liver problems. Severe liver problems, sometimes fatal, have been reported. They should also talk to their doctor about alcohol consumption. Patients should tell their doctor about all their medicines, including those for migraine, to avoid a potentially life-threatening condition. Symptoms may include high fever, confusion, and stiff muscles. Taking Cymbalta with NSAID pain relievers, aspirin, or blood thinners may increase bleeding risk. Patients should consult with their doctor before stopping Cymbalta or changing the dose. If patients experience dizziness or fainting upon standing while taking Cymbalta, they should contact their doctor. This is likely to occur in the first week or when increasing the dose, but may occur at any time during treatment. Cymbalta can increase blood pressure. Healthcare providers should check patients' blood pressure prior to and while taking Cymbalta. Patients should tell their doctor if they experience headache, weakness, confusion, problems concentrating, memory problems, or feel unsteady while taking Cymbalta as this may be signs of low sodium levels. Patients should consult their doctor if they develop problems with urine flow while taking Cymbalta. Female patients should tell their doctor if they are pregnant or plan to become pregnant during therapy or are breastfeeding.

The most common side effects of Cymbalta include nausea, dry mouth, sleepiness, fatigue, constipation, dizziness, decreased appetite, and increased sweating. This is not a complete list of side effects. Cymbalta may cause sleepiness and dizziness. Until patients know how Cymbalta affects them, they should not drive a car or operate hazardous machinery.

Take Cymbalta exactly as directed by your healthcare provider. Cymbalta should be taken by mouth. Do not open, break or chew capsule, it must be swallowed whole. Cymbalta can be taken with or without food.

For full Prescribing Information, including Boxed Warning, visit: http://pi.lilly.com/us/cymbalta-pi.pdf

For Medication Guide, visit: http://pi.lilly.com/us/Cymbalta-Medguide.pdf

For additional information, visit: http://www.cymbalta.com.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of 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.

This press release contains forward-looking statements about the potential of Cymbalta for the management of chronic musculoskeletal pain, 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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(i) Lawrence RC, et al. Arthr Rheum. 2008.58(1):26-35.

(ii) Andersson GBJ. *Lancet*. 1999;354:581-585.

(iii) Burton AK et al. European Guidelines for Prevention of Low Back Pain. www.backpaineurope.org. 2004:1-53.

(iv) Freburger JK, et al. *Arch Int Med.* 2009; 169(3):251-258.

(v) Klenerman L, et al. *Spine*. 1995; 20(4):478-484.

(vi) Van Den Hoogen HJM, et al. *Ann Rheum Dis*. 1998; 57:13-19.

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