Statement from Eli Lilly and Company Regarding Approval Recommendation from FDA Advisory Committee for Expanding the Pain Indications for Cymbalta(R) to a Broader Pain Population

BETHESDA, Md., Aug 19, 2010 /PRNewswire via COMTEX News Network/ -- The U.S. Food and Drug Administration (FDA) Anesthetic and Life Support Drugs Advisory Committee voted today 8-6 in favor of expanding the pain indications for Eli Lilly and Company's (NYSE: LLY) Cymbalta(R) (duloxetine HCl) to a broader pain population that will be further defined by the FDA, if approved.

The committee reviewed efficacy and safety data from three new Cymbalta studies in chronic low back pain and two new studies in chronic pain due to osteoarthritis of the knee, along with overall safety data for the medication. The submission also was supported by currently approved indications in the management of diabetic peripheral neuropathic pain and fibromyalgia.

While the submission was not designed to support individual indications, the committee was also asked to vote on the adequacy of evidence for efficacy in chronic low back pain and chronic pain due to osteoarthritis individually. In split votes the advisory committee was supportive of chronic low back pain based on two positive studies, but not chronic pain due to osteoarthritis based on a single positive study. The committee also voted that there was insufficient evidence of significant additional efficacy of 120 mg compared with 60 mg in these conditions.

In addition, the committee voted positively regarding the overall safety profile of Cymbalta, including potential liver toxicity, with the majority agreeing that the benefit-risk profile warrants an expanded indication.

"Lilly is committed to helping people with unmet medical needs. For people living with chronic low back pain and chronic pain due to osteoarthritis, we believe it's important they have different treatment options available since responses to medications can be highly individualized," said Robert Baker, M.D., global development leader for psychiatry and pain disorders at Lilly. "We see today's vote as an important step in potentially making Cymbalta available to a broader pain population."

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 ways 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 and fibromyalgia, 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.

Important Safety Information About Cymbalta

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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.
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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 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, constipation, sleepiness, increased sweating, decreased appetite, dizziness, and weakness. 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.

For full Patient Information, visit http://www.cymbalta.com.

For full Prescribing Information, including Boxed Warning and Medication Guide, 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 statement contains forward-looking statements about the potential of Cymbalta for additional chronic pain indications, 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 be approved for additional chronic pain indications or 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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