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Lilly Obtains Six Months U.S. Pediatric Exclusivity for Cymbalta® (duloxetine HCl)

INDIANAPOLIS, July 6, 2012 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that it has met the United States Food and Drug Administration (FDA) requirements for pediatric exclusivity for Cymbalta® (duloxetine HCl). Based on this decision by the FDA, Lilly has gained an additional six months of U.S. market exclusivity for Cymbalta, which now will expire in December 2013.

The approval of pediatric exclusivity does not mean that Cymbalta is approved for use in pediatric patients. Cymbalta is FDA-approved only for use in adults aged 18 and older. Based on study results, Lilly will not be seeking a pediatric indication for Cymbalta.

About Cymbalta
Cymbalta is a serotonin and norepinephrine reuptake inhibitor (SNRI). Cymbalta is available in 20-mg, 30-mg, and 60-mg capsules.

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 in people with chronic osteoarthritis pain or 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).

Before taking Cymbalta, 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 tell their doctor about all their prescription and nonprescription medicines. A potentially life-threatening condition has been reported when Cymbalta was taken with certain drugs for migraine, mood, or psychotic disorders. Taking Cymbalta with NSAID pain relievers, aspirin, or blood thinners may increase bleeding risk. Patients should tell their doctor about alcohol consumption. Cymbalta can increase blood pressure. Healthcare providers should check patients' blood pressure prior to and while taking Cymbalta. Female patients should tell their doctor if they are pregnant or plan to become pregnant during therapy or are breastfeeding.

While taking Cymbalta, patients should talk to their doctor right away 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. Patients should call their doctor if they have high fever, confusion, and stiff muscles, which may be symptoms of a potentially life-threatening condition. Patients also should talk to their doctor if they have skin blisters, serious or peeling rash, hives, mouth sores or any other allergic reaction while taking Cymbalta. These may be serious, possibly life-threatening, skin reactions. If patients experience dizziness or fainting upon standing while taking Cymbalta, they should contact their doctor. This tends to occur in the first week or when increasing the dose, but may occur at any time during treatment. Patients should consult with their doctor before stopping Cymbalta or changing the dose. 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.

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. People age 65 and older who took Cymbalta reported more falls, some resulting in serious injuries.

Patients should take Cymbalta exactly as directed by their 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 more information about Cymbalta, please see the Prescribing Information, including Boxed Warning about antidepressants and risk of suicide, at http://pi.lilly.com/us/cymbalta-pi.pdf and Medication Guide at http://pi.lilly.com/us/Cymbalta-Medguide.pdf

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

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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 extended market exclusivity of Cymbalta, 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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