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New Data Show Cymbalta Improved Physical, Social and Emotional Functioning and Overall Health of Patients With Painful Diabetic Neuropathy

SAN DIEGO, June 11, 2005 /PRNewswire-FirstCall via COMTEX/ -- Cymbalta(R) (duloxetine hydrochloride) significantly improved physical, social and emotional functioning, in addition to overall health, in patients with pain associated with diabetic peripheral neuropathy (DPNP), compared with those treated with a sugar pill, according to a pooled analysis of three studies presented today at the annual meeting of the American Diabetes Association.

In the pooled analysis of more than 1,000 DPNP patients, those treated with 60 or 120 mg of Cymbalta (given as 60 mg either once or twice daily), reported significant improvements in all functional components defined in three commonly used scales -- the interference portion of the Brief Pain Inventory (BPI), the Short Form 36 (SF-36) and the European Quality of Life Instrument 5D version (EQ-5D).

That means Cymbalta patients reported significantly less interference from pain on key measures of physical functioning, including their ability to walk, work and sleep. On a social level, patients taking Cymbalta reported significantly less interference from pain on their relationships with other people and their enjoyment of life. Additionally, Cymbalta patients reported significantly less interference from pain on mental health and mood.

"The pain that patients with diabetic neuropathy experience is severely limiting, making everyday activities, like putting on socks or walking around, extremely painful," said Dr. Amy Chappell, Eli Lilly and Company. "In these studies, patients taking Cymbalta are feeling relief from pain, but more importantly, they are actually able to get their lives back and do the things they love."

Nearly 5 million Americans(i) experience the persistent tingling, burning or stabbing pain caused by uncontrolled diabetes,(ii) which can have a tremendous impact on a patient's quality of life. Painful diabetic neuropathy can cause patients to feel isolated and worthless, as the condition limits the ability to participate in life. Many DPNP patients have trouble enjoying family activities, and may even need to change jobs as a result of the pain.(iii)

The U.S. Food and Drug Administration (FDA) approved Cymbalta in September 2004 as the first prescription drug proven to reduce DPNP in adults. It is the only FDA-approved prescription treatment for DPNP available in the United States. Cymbalta is also approved to treat major depressive disorder in adults.

Additional Study Highlights

* Compared with patients in the study who received placebo, or sugar pill, those treated with 60 or 120 mg of Cymbalta per day reported significant improvements in

- functioning, according to the average of the seven questions on the interference portion of the BPI.
- bodily pain, general health, mental health, physical function, role in physical activity, emotional role, social function and vitality, according to the SF-36.
- general health (mean change of 0.10, compared with 0.15 and 0.16), according to the EQ-5D.
- pain, including 24-Hour Average Pain Severity, 24-Hour Worst Pain Score, Night Pain Score, McGill Pain Total Score, CGI-Severity, PGI Improvement and BPI Severity.

Methods

The data were pooled from three 12-week multicenter, double-blind studies. In one study (N=457) patients diagnosed with DPNP were randomly assigned to receive 20 mg of Cymbalta once daily, 60 mg of Cymbalta once daily, 60 mg of Cymbalta twice daily or a sugar pill. In the other two studies (N=334, N=348) patients diagnosed with DPNP were randomly assigned to receive 60 mg of Cymbalta once daily, 60 mg of Cymbalta twice daily or a sugar pill.

Functional outcomes were measured based on patients' answers on the interference portion of the Brief Pain Inventory, the Short Form 36 and the European Quality of Life Instrument 5D version. The Interference Portion of the BPI is commonly used in pain trials to measure the degree to which pain interferes with daily life (i.e. general activity, walking, working, sleep, mood, relationships and enjoyment of life). The SF-36 consists of 36 items that evaluate eight health domains related to quality of life: bodily pain, general health, mental health, physical function, role-physical, role-emotional, social function and vitality. The European Quality of Life Instrument 5D measures mobility, usual activities, self care, pain and discomfort, and anxiety and depression.

Only those who completed one of the three studies were included in the analyses. Patients treated with Cymbalta 20 mg once daily were excluded from the analyses.

About Cymbalta

Scientists believe Cymbalta reduces diabetic peripheral neuropathic pain by blocking the re-absorption of serotonin and norepinephrine, neurotransmitters involved in regulating a person's sensitivity to pain. These chemical messengers are part of the body's own internal pain-relief system and, in the spinal cord, exert an analgesic effect in descending pain pathways. Cymbalta is also indicated to treat major depressive disorder in adults. Cymbalta has not been studied in children, and therefore Lilly discourages its use in those under 18.

Cymbalta should not be confused with Symbyax(TM) (pronounced SIMM-bee-ax), a medicine for bipolar depression also marketed by Lilly. Cymbalta is available in 20 mg, 30 mg and 60 mg capsules. Symbyax is a combination of olanzapine, the active ingredient in Zyprexa(R), and fluoxetine, the active ingredient in Prozac(R). Symbyax is available in capsules of 6 mg/25 mg (olanzapine/fluoxetine), 12 mg/25 mg, 6 mg/50 mg and 12 mg/50 mg.

About Diabetic Peripheral Neuropathy

According to the National Institute of Diabetes & Digestive & Kidney Diseases, approximately half of those with diabetes have some form of nerve damage, or neuropathy, but not all will develop symptoms. While nerve problems can occur at any time, the highest rates are among those who have had diabetes for at least 25 years. People who have had problems controlling their blood sugar levels, have high blood pressure, are overweight, have high levels of blood fat, or are over the age of 40, may also have a greater risk of developing diabetic peripheral neuropathy.

Symptoms can include numbness, tingling or pain and weakness in the toes, feet, legs, hands, arms and fingers. These symptoms are often worse at night.(iv)

Important Safety Information

In clinical studies, antidepressants increased the risk of suicidal thinking and behavior in children and adolescents with depression and other psychiatric disorders. Anyone considering the use of Cymbalta or any other antidepressant in a child or adolescent must balance the risk with the clinical need. Patients who are starting therapy should be observed closely. Families and caregivers should discuss with the doctor any observations of worsening depression symptoms, suicidal thinking and behavior, or unusual changes in behavior. Cymbalta is not approved for use in patients under the age of 18.

Patients on antidepressants and their families or caregivers should watch for worsening depression symptoms, unusual changes in behavior and thoughts of suicide, as well as for anxiety, agitation, panic attacks, difficulty sleeping, irritability, hostility, aggressiveness, impulsivity, restlessness, or extreme hyperactivity. Call the doctor if you have thoughts of suicide, or if any of these symptoms are severe or occur suddenly. Be especially observant at the beginning of treatment or whenever there is a change in dose.

Prescription Cymbalta is not for everyone. People who are allergic to Cymbalta or the other ingredients in Cymbalta should not take it. If you have recently taken a type of antidepressant called a monoamine oxidase inhibitor (MAOI), are taking thioridazine or have uncontrolled narrow-angle glaucoma, you should not take duloxetine. Talk with your doctor before taking duloxetine if you have liver or kidney problems, glaucoma or consume large quantities of alcohol. Women who are pregnant should talk with their doctor before taking duloxetine. Nursing while taking duloxetine is not recommended.

In clinical studies of duloxetine for the management of neuropathic pain associated with diabetic peripheral neuropathy, the most common side effects were nausea, sleepiness, dizziness, constipation, dry mouth, increased sweating, decreased appetite, and loss of strength or energy. In clinical studies of duloxetine for depression, the most common side effects were nausea, dry mouth, constipation, decreased appetite, fatigue, sleepiness, and increased sweating. In all clinical trials, most people were not bothered enough by side effects to stop taking Cymbalta. Your doctor may periodically check your blood pressure. Don't stop taking Cymbalta without talking to your doctor.

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

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This press release contains forward-looking statements about the potential of Cymbalta for the treatment of diabetic peripheral neuropathic 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 prove 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.

(i) D Ziegler, FA Gries, M Spuler and F Lessman. The epidemiology of diabetic neuropathy. J Diabetic complications. (1992) 49-57.

(ii) National Institute of Diabetes and Digestive and Kidney Diseases. Diabetic Neuropathies: The Nerve Damage of Diabetes. <http://diabetes.niddk.nih.gov/dm/pubs/neuropathies/>. Accessed 5/16/05.

(iii) Data on file.

(iv) National Diabetes Information Clearinghouse. Diabetic Neuropathies: The Nerve Damage of Diabetes. National Institute of Diabetes and Digestive and Kidney Diseases. <http://www.diabetes.niddk.nih.gov/dm/pubs/neuropathies/>, August 2004.

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