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New Treatment for Depression Approved in Europe

INDIANAPOLIS, Indiana and INGELHEIM, Germany, January 5 /PRNewswire/ --

- Cymbalta®/Xeristar® Approved in European Union to Treat Major Depressive Episodes

Eli Lilly and Company and Boehringer Ingelheim announced today that Cymbalta®/Xeristar® (duloxetine hydrochloride)(+) has been granted marketing authorization by the European Commission for the treatment of major depressive episodes.

Cymbalta/Xeristar, a balanced dual-reuptake inhibitor of serotonin and noradrenaline (norepinephrine), has been studied in more than 6,000 adults with major depression worldwide. Safety and efficacy have been demonstrated in four positive acute placebo-controlled clinical trials and a relapse prevention study.

"This is a significant breakthrough as clinical trials show Cymbalta to be a very effective antidepressant," said Robert Peveler, MA, DPhil, FRCPsych, Professor of Psychiatry at the University of Southampton, United Kingdom. "And, unfortunately, there are still a significant number of people suffering from depression in Europe despite the advances in modern medicine."

Researchers believe Cymbalta/Xeristar is effective in treating the emotional and somatic symptoms of depression due to its dual action on two key neurotransmitters, serotonin and noradrenaline. These neurotransmitters are believed to help regulate emotions and sensitivity to pain. Scientists believe that if these neurotransmitters are out of balance, a person may become depressed and be more likely to feel emotional and somatic symptoms. The combination of emotional and somatic symptoms of depression can have a tremendous negative impact on a person's quality of life.

Emotional symptoms include sadness, anxiety, low mood and hopelessness. Somatic symptoms can include fatigue, vague aches and pains, and shoulder, neck and back pain.

"The approval of Cymbalta/Xeristar in the European Union is a major step forward in giving healthcare professionals and patients in all major European countries a long-awaited efficient and well-tolerated new option for treating the full spectrum of symptoms of depression," said Dr. Andreas Barner, member of the Board of Managing Directors and Head of Research, Development and Medicine at Boehringer Ingelheim.

"This is a breakthrough, born out of decades of investment and experience in neuroscience," added Rich Pilnik, President of European Operations at Eli Lilly and Company. "We are pleased to soon make Cymbalta available to patients in Europe because it brings to life our commitment to make a positive impact in the lives of patients."

In Europe alone, an estimated 60 million people suffer from depression.(1) More than 40 per cent of those fail to receive any treatment(2) and only 25-35 per cent of patients treated for depression in clinical studies experience remission or relief from all of their disease symptoms.(3) Experts agree that failure to achieve remission can lead to a greater risk of relapse, continued impairment at work and in social functioning, increased utilization of medical services, and sustained elevation of suicide and substance abuse risks.(4,5)

Eli Lilly and Company and Boehringer Ingelheim

In November 2002, Eli Lilly and Company and Boehringer Ingelheim signed a long-term agreement to jointly develop and commercialize duloxetine hydrochloride. Duloxetine is currently being developed for the treatment of depression, stress urinary incontinence and diabetic peripheral neuropathic pain. This partnership covers most countries worldwide with few exceptions. In the USA, the collaboration excludes neuroscience indications.

About Eli Lilly and Company

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

About Boehringer Ingelheim

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 152 affiliates in 45 countries and more than 34,000 employees. Since it was founded in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel products of high therapeutic value for human and veterinary medicine. In 2003, Boehringer Ingelheim posted net sales of 7.4 billion euro while spending more than one fifth of net sales in its largest business segment, Prescription Medicines, on research and development. For more information please visit www.boehringer-ingelheim.com.

(+) Note to Editors:

Duloxetine for major depressive episodes will be marketed by Lilly and Boehringer Ingelheim in all countries included in the partnership under the brand name Cymbalta[®], except for Greece, Italy and Spain. In Greece, Italy and Spain Lilly will market the product as Cymbalta and Boehringer Ingelheim will market the product as Xeristar[®]. In the USA the collaboration does not include Cymbalta.

Duloxetine for stress urinary incontinence will be marketed by Lilly and Boehringer Ingelheim in all countries included in the partnership under the brand name Yentreve, except for Greece, Italy and Spain. In Greece, Italy and Spain Lilly will market the product as Yentreve and Boehringer Ingelheim will market the product as AriClaim[®].

References

(1) Ayuso-Mateos JL, et al. Brit J Psychiatry. 2001; 179:308-316.

(2) Wittchen HU, et al. J Clin Psych. 2001; 62 (suppl. 26).

(3) Tran PV, Bymaster FP, McNamara RK, et al. Dual Monoamine Modulation for Improved Treatment of Major Depressive Disorder, J Clin Psychopharmacology, 2003; 23: 78-86.

(4) Thase ME. J Clin Psychiatry. 1999; 60 (suppl 22):35-36.

(5) Hirschfeld RM, et al. JAMA. 1997; 277: 333-340.

This press release contains forward-looking statements about the potential of duloxetine for the treatment of depression and reflects Lilly's and Boehringer Ingelheim's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of commercialization. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly and Boehringer Ingelheim undertake no duty to update forward-looking statements.

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