



September 17, 2004

EU Scientific Committee Recommends Approval of Cymbalta

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Eli Lilly and Company and Boehringer Ingelheim today announced that the Committee for Medicinal Products in Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending approval of duloxetine for the treatment of major depressive episodes. The CHMP has recommended that the European Commission authorize the drug to be marketed. If approved, this pharmaceutical treatment for depression will be marketed throughout the European Union by Lilly under the brand name Cymbalta® and by Boehringer Ingelheim under the brand names Cymbalta and in Greece, Italy and Spain, as Xeristar®.

The European Commission is expected to grant marketing authorization within the next few months. Duloxetine was recently approved by the U.S. Food and Drug Administration and launched in the United States.

The CHMP, comprised of regulators from the European Union countries, based its positive opinion on its review of a comprehensive data package of duloxetine in the treatment of major depressive episodes. The submission package to support the efficacy and safety of duloxetine consisted of data collected from studies that enrolled nearly 3,000 patients with depression.

The European Medicines Agency issued a press release communicating the following: "The benefits with Cymbalta are its demonstrated statistical superiority over placebo as measured by improvement in the 17-item Hamilton Depression Rating Scale (HAM-D) total score (including both the emotional and somatic symptoms of depression). ...The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Cymbalta and therefore recommends the granting of the marketing authorisation."

Duloxetine is also being studied for the treatment of stress urinary incontinence and diabetic neuropathic pain, conditions believed to respond to treatment with medicines that affect the neurotransmitters serotonin and norepinephrine. On August 11, 2004 the European Commission granted marketing authorization throughout the European Union for duloxetine, to be marketed under the brand names, Yentreve®.

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 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, 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.

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.

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 undertakes no duty to update forward-looking statements.