



Release No 312

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Forest Laboratories and Lundbeck announces positive results of Lexapro® phase III study in adolescents with major depression

Forest Laboratories, Inc. and H. Lundbeck A/S today announced preliminary top-line results from a phase III study of Lexapro® (escitalopram oxalate) in the treatment of adolescents, aged 12-17, with Major Depressive Disorder (MDD). These results indicate that patients treated with Lexapro® experienced statistically significant improvement in symptoms of depression, as measured by the study's primary endpoint, the Children's Depression Rating Scale-Revised (CDRS-R), compared to placebo. The CDRS-R is a commonly used clinician-rated instrument that covers 17 symptom areas of depression relevant to adolescents, including impaired schoolwork, difficulty having fun, social withdrawal, physical complaints, and low self-esteem. Additional data from this study are expected to be presented in 2008.

Researchers estimate that up to eight percent of adolescents are affected by depression. However, FDA-approved treatment options for this population are limited. Lexapro® is not currently approved by the FDA for use in pediatric patients.

Subject to ongoing communication with the FDA and review of the full study results for the just completed trial, Forest Laboratories, Inc. intend to file in 2008 for an adolescent depression indication for Lexapro®.

About the Study

A double-blind, parallel-group, placebo-controlled phase III study to evaluate the safety and efficacy of Lexapro® in the treatment of depressed adolescents, aged 12-17, was conducted in multiple centers across the U.S. During the eight week study, 316 patients were randomized to receive either Lexapro® 10-20 mg (n=158) or placebo (n=158). The primary endpoint was change from baseline to week 8 on the Children's Depression Rating Scale - Revised (CDRS-R) using last observation carried forward (LOCF) approach. The study showed statistically significant improvement in patients treated with Lexapro® relative to placebo (p=0.022).

The trial also showed that Lexapro® was generally well-tolerated. Overall premature discontinuation rates (all causes including adverse events)



were 19% for patients receiving Lexapro[®] and 15% for patients receiving placebo.

Depression and Adolescents

Adolescent depression is characterized by persistent sadness and loss of interest in usual activities.

Despite advances and progress in identifying and treating mental disorders in adolescents, epidemiologic studies indicate that only 20-35 percent of depressed patients in this age group currently receive treatment. Depression is a chronic disease that requires medical attention and treatment, and if left untreated, may have serious consequences.

For adolescents who suffer from depression, psychotherapy, cognitive-behavior therapy, interpersonal therapy and medication play an important role in the management of their illness. Patients on antidepressant treatment should also be closely monitored by healthcare providers, family members and other caregivers.

The content of this release will have no influence on the Lundbeck Group's financial result for 2007.

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About Lundbeck

H. Lundbeck A/S is an international pharmaceutical company engaged in the research and development, production, marketing and sale of drugs for the treatment of psychiatric and neurological disorders. In 2006, the company's revenue was DKK 9.2 billion (approximately EUR 1.2 billion or USD 1.6 billion). The number of employees is approximately 5,300 globally. For further information, please visit www.lundbeck.com