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Forest Discusses Disclosure of Citalopram Clinical Trial Data in Children and Adolescents

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Forest Laboratories, Inc. (NYSE: FRX) wishes to provide additional information regarding the dissemination of the clinical trial results of two studies of its antidepressant Celexa(R) (citalopram HBr) in the treatment of children and adolescents. Citalopram is not approved for use in children or adolescents and has not been promoted by Forest for use in these populations.

There are two placebo-controlled studies of citalopram in the treatment of pediatric and/or adolescent depression. These studies include a European trial in both hospitalized and outpatient adolescents conducted by H. Lundbeck A/S (the Danish company that developed citalopram), which did not show efficacy versus placebo, and a U.S. trial in child and adolescent outpatients, conducted by Forest, the results of which showed efficacy versus placebo. The U.S. study was published in June 2004 in the American Journal of Psychiatry.

Although no published peer-reviewed reference of the European citalopram pediatric study is currently available, the results of this study were disclosed on several occasions to the scientific community in various formats prior to the June 2004 publication of the U.S. study(1). These disclosures included information from submissions by Forest or Lundbeck to the U.S. and United Kingdom (U.K.) regulatory authorities, both of which posted summary results on the Internet. H. Lundbeck A/S also has advised Forest that the principal investigator of the European study is preparing a report for publication.

Given the current increased interest in industry publication practices as well as outstanding questions about the role of antidepressants in the pediatric populations, questions about the availability of these results have been raised. It is crucial in this context to point out that results of the European study were not hidden but were disclosed and available. In addition, the results may not be comparable to the U.S. study because of contrasting trial designs and patient populations.

Modern depression trials typically utilize a study design and patient selection criteria that will most objectively define the effect of a medication. Greater accuracy is accomplished by studying patients under conditions in which many of the known social and medical factors that can affect patients' response can be prospectively identified and controlled for, so as to separate those factors from the determination of the actual drug effect. Carefully balancing the patient groups is important to obtain a proper interpretation of the results.

This approach is commonly used in today's antidepressant trials and was used in the U.S. citalopram trial. However, in the European trial, both hospitalized patients and outpatients were allowed to enroll, many of whom had a history of more complicated depressive disorders. The trial analysis could not be adjusted for such differences in the patients between the drug treated or placebo groups, which makes it more difficult to evaluate the drug's effect as well as to establish comparability of the results of this study to those of the U.S. trial.

With respect to safety, Forest believes that its overall analysis of the clinical trial data, including both the placebo-controlled pediatric citalopram studies, shows that there is no increased risk of suicidality or worsening of depression associated with citalopram therapy. In addition, there were no suicides in these studies. The FDA is actively reviewing the data it has for pediatric studies involving a number of different antidepressants and in the interim, and in accordance with the FDA's request of all anti-depressant manufacturers, Forest has included in its labeling for Celexa additional

information regarding suicidality(2).

Forest believes there was nothing unusual or incorrect about the disclosure of the results of the two studies. We recognize the complexity involved in determining the role of antidepressants in the treatment of pediatric depression especially given the difficulty of diagnosing and evaluating response in this group of patients. We are also aware of interest in augmenting the exchange of scientific information. Therefore, today, Forest has issued a press release with respect to a pediatric study just completed on the safety and efficacy of our antidepressant Lexapro(R) (escitalopram oxalate) based upon initial analyses of that study.

Forest will work with the government, the scientific community and the industry to evolve generally accepted standards and practices supporting the scientific exchange of information, particularly with regard to the treatment of children and adolescents suffering from depression.

About Forest Laboratories and Its Products

Forest Laboratories' growing line of products includes: Lexapro(R), an SSRI antidepressant indicated for the initial and maintenance treatment of major depressive disorder and for generalized anxiety disorder; Celexa(R), an antidepressant; Namenda(R), an N-methyl-D-aspartate (NMDA)-receptor antagonist indicated for the treatment of moderate to severe Alzheimer's disease; Tiazac(R), a once-daily diltiazem, indicated for the treatment of angina and hypertension; Benicar(R),* an angiotensin receptor blocker indicated for the treatment of hypertension; Benicar HCT(TM), an angiotensin receptor blocker and diuretic combination product indicated for the second-line treatment of hypertension; and Aerobid(R), an inhaled steroid indicated for the treatment of asthma.

*Benicar(R) is a registered trademark of Sankyo Pharma, Inc.

Except for the historical information contained herein, this release contains "forward-looking statements" within the meaning of the Private Securities Reform Act of 1995. These statements are subject to risks and uncertainties that affect our business, including risk factors listed from time to time in the Company's SEC reports, including the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2004. Actual results may differ materially from those projected.

(1) Following is a detailed account of the prior disclosure of the European pediatric results:

* October 16, 2003 -- Forest Laboratories discusses topline efficacy results and presents a detailed safety analysis of both the U.S. and European citalopram pediatric depression trials at the annual meeting of the American Academy of Child and Adolescent Psychiatry.

* October 30, 2003 -- Medical textbook in Danish titled, "Children and Adolescents with Depression" that referenced the efficacy results of both citalopram studies.

* December 10, 2003 -- Study results from both citalopram pediatric depression trials, that were previously submitted by H. Lundbeck A/S to The Medicines and Healthcare Products Regulatory Agency in the U.K., were posted on their website: http://medicines.mhra.gov.uk/ [2].

* January 3, 2004 -- The British Medical Journal published an editorial titled, "Treatment of Major Depressive Disorder in Children and Adolescents." The editorial discussed the United Kingdom's Committee of Safety in Medicines evaluation of these studies.

* January 13, 2004 -- The U.S. Food and Drug Administration (FDA) posted on its public website a summary of their evaluation of these trials for inclusion in the February 2, 2004, meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee.

* April 22, 2004 -- The European study's principle investigator of the trial presented information about the European citalopram pediatric depression trial during the annual meeting of the Scandinavian College of Neuropsychopharmacology.

* April 24, 2004 -- The Lancet published an article titled, "Selective Serotonin Reuptake Inhibitors in Childhood Depression: systematic review of published versus unpublished data," which included a review of both citalopram pediatric depression studies.

(2) Celexa Labeling: Patients with major depressive disorder, both adult and pediatric, can experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality), whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Although no causal role for antidepressants in inducing such behaviors has been established, patients being treated with antidepressants should be observed closely for clinical worsening and suicidality, especially at the beginning of a course of drug therapy, or at the time of dose changes, either increases or decreases.

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