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# Lilly Announces Important Strattera(R) Label Update

INDIANAPOLIS, Sept 29, 2005 /PRNewswire-FirstCall via COMTEX/ -- Eli Lilly and Company (NYSE: LLY) today announced that it will update the product label globally for its attention-deficit/hyperactivity disorder (ADHD) medication, Strattera, to communicate new information regarding uncommon reports of suicidal thoughts among children and adolescents. In conjunction with a request from the U.S. Food and Drug Administration (FDA), Lilly submitted to regulatory agencies an analysis of adverse event data from its Strattera clinical trials database that identified a small but statistically significant increased risk of suicidal thoughts among Strattera-treated children and adolescents (5 cases out of 1357 patients or 0.4 percent vs. 0 cases out of 851 patients taking placebo). There also was one case of a suicide attempt in a patient taking the medication (out of 1357 patients). There were no suicides among children, adolescents or adults on the medication during any Strattera clinical trials, and there was no indication of an increased risk of suicidal thinking in the adult population. As part of the FDA's continuing focus on patient safety, the agency and its Pediatric Advisory Committee plan to complete an ongoing review of adverse event data for all ADHD medications by early 2006.

In the United States, Lilly will add a boxed warning to the product label and is working with the FDA to finalize the product label content as well as information for healthcare professionals. Lilly is also working with other regulatory agencies where the product is currently approved regarding this safety information. In Europe, the information will be provided under the special warnings and precautions section of the product label. In Australia, it will appear as a precaution.

"Lilly's top priority is to help doctors, patients and their families make informed treatment decisions, so we are reaching out extensively to educate physicians and the public about this product label change," said Alan Breier, M.D., vice president and chief medical officer at Lilly. "While suicidal thinking was uncommon in patients on the medication during clinical trials, it is important for parents to be aware it can occur, and to discuss any unusual symptoms with a physician. Also important for parents to know," he said, "is that Lilly continues to view Strattera as a safe and effective treatment option, and those doing well on the medication should be able to continue their treatment with confidence."

Investor Information

Lilly is confirming its prior sales and earnings guidance for the year. Lilly expects reported full-year 2005 earnings per share of $1.90 to $1.96. Eliminating the second-quarter 2005 product liability charge of $.90 per share, the adjusted full-year 2005 earnings per share would be $2.80 to $2.86. For the full year of 2005, the company continues to expect sales growth of 6 to 8 percent.

ADHD and Suicide

ADHD affects 3-7 percent of school-age children and manifests itself in levels of attention, concentration, activity, distractibility and impulsivity that are inappropriate to the child's age.(1) ADHD is a serious disorder that can have lifelong consequences, including poor peer relations, poor academic and work performance and increased risk-taking behaviors such as substance abuse.(2,3,4) Sixty percent of children with the disorder carry their symptoms into adulthood.(5) Experts estimate 4 percent of adults in the United States, more than 8 million people, have ADHD.(6,7)

"ADHD is a complex disorder and many patients who are managing it are often dealing with other co-existing psychiatric disorders," said Christopher Kratochvil, M.D., associate professor of psychiatry at the University of Nebraska Medical Center. "As a physician, I believe strong communication between the doctor, parents, caregivers and patients is vital to successful mental health treatment."

The FDA's request for clinical trial data is part of the agency's ongoing review of psychiatric medicines, reflecting the scientific community's growing understanding of suicide-related behaviors and how to analyze them. The analysis was based on criteria developed by Columbia University and the FDA last year, and uses a rigorous classification system to assess any risk of suicide-related events in clinical trials.

According to the World Health Organization, suicidal thoughts or behaviors have a large number of complex, underlying causes that can make it difficult to determine why some people experience these feelings. Suicidal thoughts occur in children and adolescents and are not always associated with other features of mental illness. There is evidence that those suffering from ADHD are at greater risk of suicide than the general population.(8,9)

Information for Patients and Physicians

Lilly is working in concert with regulatory agencies worldwide to notify physicians about this important update. In addition, the company is notifying consumer advocacy and professionally focused associations about these findings so they can provide important information to patients. In the U.S., Lilly's outreach efforts will include a "Dear Healthcare Professional" letter, sales force communications to prescribers and updated label information on the product web site, www.Strattera.com.

All medications have side effects. No medication works for everyone. As with any medication, patients or parents should consult their doctors with any questions or concerns regarding treatment. This allows physicians and patients to make the most informed treatment decisions. Patients or caregivers with questions may also call the Lilly Answers Center at 1-800-LillyRx.

About Strattera

Strattera, a selective norepinephrine reuptake inhibitor, is the first FDA-approved non-stimulant to treat ADHD and provide full-symptom relief. It is not known precisely how Strattera reduces ADHD symptoms, but scientists believe it works by blocking or slowing reabsorption of norepinephrine, a chemical in the brain considered important in regulating attention, impulsivity and activity levels. This keeps more norepinephrine at work in the spaces between neurons in the brain. Improved efficiency in the norepinephrine system is associated with improvement in symptoms of ADHD (Pliska, 1996).

Strattera should not be taken at the same time as, or within two weeks of taking, a monoamine oxidase inhibitor (MAOI) or by patients with narrow angle glaucoma. Patients with a history of high or low blood pressure, increased heart rate, or any heart or blood vessel disease should tell their doctor before taking Strattera. Strattera has not been tested in children less than 6 years of age or in geriatric patients. Some children may lose weight when starting treatment with Strattera. As with all ADHD medications, growth should be monitored during treatment. Strattera can cause liver damage in rare cases. Patients should tell their doctor right away if they have itching, dark urine, yellow skin/eyes, upper right-sided abdominal tenderness, or unexplained "flu-like" symptoms.

Most people in clinical studies who experienced side effects were not bothered enough to stop using Strattera. The most common side effects in children and adolescents in medical studies were upset stomach, decreased appetite, nausea and vomiting, dizziness, tiredness and mood swings. In adults, the most common side effects were constipation, dry mouth, nausea, decreased appetite, dizziness, problems sleeping, sexual side effects, problems urinating and menstrual cramps.

About Lilly

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and 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. P-LLY

For full prescribing information visit www.strattera.com.

This press release contains forward-looking statements about the use of Strattera for the treatment of ADHD and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties, including risk of side effects and other safety concerns; and there is no guarantee regarding the future commercial success of the product. The company's results may also be affected by such factors as competitive developments affecting current products; rate of sales growth of recently launched products; the timing of anticipated regulatory approvals and launches of new products; other regulatory developments and government investigations; patent disputes and other litigation involving current and future products; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals; changes in tax law; and the impact of exchange rates. For additional information about the factors that affect the company's business, please see Exhibit 99 to the company's latest Form 10-Q filed August 2005. The company undertakes no duty to update forward-looking statements.

(1) American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, fourth edition, text revision, Washington, DC, American Psychiatric Association, 2000.

(2) Greenhill LL. Diagnosing attention-deficit/hyperactivity disorder in children. J Clin Psychiatry 1998; 59 (Suppl 7): 31-41.

(3) Faraone S, Biederman J, et al. ADHD in adults: an overview. Biol Psychiatry 2000; 48:9-20.

(4) Barkley. ADHD: A Handbook for Diagnosis and Treatment. New York: Guilford Press; 1998.

(5) Schweitzer JB, et al. Attention-deficit/hyperactivity disorder. Med Clin of North Am. 2001; 85(3): 757-777

(6) Murphy K, Barkley, RA. J Atten disord. 1996; 1:147-161.

(7) United States Census Summary File; 2000.

(8) Swensen A, Kruesi M, Allen A, et al. Self injury and suicide in patients with attention deficit hyperactivity disorder. Program and abstracts of the American Academy of Child and Adolescent Psychiatry 49th Annual Meeting; October 22-27, 2002; San Francisco, California. New Research F27.

(9) James A, Lai FH, Dahl C. Attention deficit hyperactivity disorder and suicide: a review of possible associations. Acta Psychiatr Scand 2004;110:408-415.

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