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Lilly Announces Important Liver Safety Update to Strattera(R) Label

INDIANAPOLIS, Dec 17, 2004 /PRNewswire-FirstCall via COMTEX/ -- Eli Lilly and Company announced today that it has added a bolded warning to the product label for Strattera, an attention deficit/hyperactivity disorder (ADHD) medication. The bolded warning indicates that the medication should be discontinued in patients with jaundice (yellowing of the skin or whites of the eyes) or laboratory evidence of liver injury. This label change discusses two reported cases of severe liver injury out of the more than 2 million patients who have taken the medication since approval. Both patients have recovered with normal liver function after discontinuing the medication.

"Patient safety is our top priority at Lilly. When we learned of the first case, we reported it to the FDA and began a thorough investigation, including consultation with outside experts and a review of all the available data," said Douglas Kelsey, M.D., a pediatrician and a clinical research physician at Eli Lilly and Company. "We worked closely with the FDA to determine the best course of action, and as a result, are taking a number of measures to notify healthcare professionals and ultimately patients. In addition, our thorough review of the clinical trial and real-world data indicate that the benefit- risk profile for Strattera is positive, and the medication continues to be an important treatment option for patients with ADHD."

The company is in the process of notifying physicians, other health care providers and consumer advocacy and professionally focused associations about this label change so they can provide important information to patients. Lilly's outreach efforts include a "Dear Healthcare Professional" letter, sales force communications to prescribers and information on Strattera.com.

Liver Reactions in Medications

All prescription products have risks that physicians and patients should consider. While liver complications are rare, other medications across the broad spectrum of prescription and over-the-counter medications available today demonstrate the same type of liver effects and continue to be used safely. However, in a small percentage of patients, severe drug-related liver injury may progress to acute liver failure resulting in death or the need for a liver transplant.

Experts say that the signs and symptoms of liver effects can alert a patient to a potential problem. Patients should contact their doctor immediately if they develop:

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-- Pruritus (Itchy skin)
-- Jaundice
-- Dark urine
-- Upper right-sided abdominal tenderness
-- Or unexplained "flu-like" symptoms
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Strattera-Specific Information

The 6,000 patients taking Strattera in clinical trials experienced no evidence of liver injury. Real-world reports indicate that Strattera can cause severe liver injury in rare cases. Because of probable underreporting, it is impossible to provide an accurate estimate of the true incidence of these events. However, even when accounting for underreporting, real-world incidence of liver injury among patients taking the medication is less than the rate expected for the overall population.

If parents or patients have additional questions, please call the Lilly Answers Center at 1-800-LillyRx or log onto www.strattera.com. The updated Strattera label is on the Web site.

About ADHD

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) In addition, 60 percent of children with the disorder carry their symptoms into adulthood.(2) Experts estimate 4 percent of adults in the United States, more than 8 million people, have ADHD.(3,4)

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 .

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For full prescribing information visit www.strattera.com.

This press release contains forward-looking statements about the potential 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 in the process of commercialization. There is also no guarantee that the product will continue to be commercially successful. 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.

(1) American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, fourth edition, text revision, Washington, DC, American Psychiatric Association, 2000.
(2) Schweitzer JB, et al. Attention-deficit/hyperactivity disorder. Med Clin of North Am. 2001; 85(3): 757-777
(3) Murphy K, Barkley, RA. J Atten disord. 1996; 1:147-161.
(4) United States Census Summary File; 2000.

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SOURCE Eli Lilly and Company

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