



May 18, 2005

## **Non-stimulant Strattera More Widely Available for Attention- Deficit/Hyperactivity Disorder in Children and Adolescents in Europe**

### **Europe's only approved non-stimulant ADHD medication offers a new treatment choice**

INDIANAPOLIS, May 18, 2005 /PRNewswire-FirstCall via COMTEX/ -- Eli Lilly and Company's Strattera(R) (atomoxetine HCl), the only approved non-stimulant medication proven clinically effective at treating the symptoms of attention- deficit/hyperactivity disorder (ADHD), is now more widely available in Europe, following marketing authorizations granted by regulatory authorities in Germany, The Netherlands and Norway. Strattera is approved for the treatment of ADHD in children and adolescents in these countries.

A selective norepinephrine reuptake inhibitor, Strattera represents the first new class of ADHD medications in the 50 years since stimulant medications first began being used. Strattera became available in Germany in March 2005 and became available in The Netherlands and Norway in April. Within Europe, Strattera was previously approved for use in the United Kingdom by the UK's Medicines and Healthcare Products Regulatory Agency in May 2004.

In clinical trials, Strattera demonstrated effective, continuous relief of core ADHD symptoms, including inattention and/or hyperactivity and impulsivity, from morning until late evening. Strattera treats ADHD without causing insomnia in most children and adolescents and can be used in patients who have other co-existing conditions such as tics and anxiety.

"Strattera provides physicians and families with something they've never had before -- a proven effective, non-stimulant option for the treatment of ADHD," said Dr. Jesus Hernandez, Executive Director of Clinical Research and Regulatory Affairs in European Operations at Eli Lilly and Company. "Through this new class of ADHD treatment, we are living up to Lilly's commitment to provide patients innovative new medications. We are very pleased that more doctors in Europe will be able to consider Strattera as a part of a comprehensive ADHD treatment program."

#### **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)

A biological, brain-based condition, ADHD is thought to be caused by an imbalance of some of the brain's neurotransmitters, which are the substances used to signal between nerve cells.(1) The condition is characterized by hyperactive/impulsive behaviors and/or attention-deficit problems that cannot be explained by any other psychiatric condition and are not in keeping with the child's intellectual ability or stage of development.(2)

Studies have shown that more than 50 percent of children with untreated ADHD have poor peer relationships and that families of children with ADHD experience greater stress.(3) If the disorder is not appropriately treated, these children are much less likely to finish college, and are more likely to develop drug use disorders (20-32 percent) and to hold less skilled jobs in adulthood.(3)

#### **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](http://www.lilly.com) . P-LLY

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. 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) Green C, Chee K. Understanding ADHD - The Definitive Guide to Attention Deficit Hyperactivity Disorder. The Random House Ballantine Publishing Group 1998.

(3) Barkley RA. Attention-Deficit Hyperactivity Disorder: A Handbook for Diagnosis and Treatment. 1998, Guilford Publications, New York.

(Logo: <http://www.newscom.com/cgi-bin/prnh/20031219/LLYLOGO> )

#### SOURCE Eli Lilly and Company

Jennifer Bunselmeyer of Eli Lilly and Company, +1-317-655-8808

<http://www.prnewswire.com>

Copyright (C) 2005 PR Newswire. All rights reserved.

News Provided by COMTEX