



June 3, 2004

First Non-Stimulant ADHD Medication Available in the United Kingdom

June 03, 2004

UK is the First Country in the European Union to Make Strattera Available

Strattera® (atomoxetine HCl), a non-stimulant treatment for attention-deficit hyperactivity disorder (ADHD), is now approved for use in the United Kingdom and will be available by mid-July. Strattera is the first and only non-stimulant approved for the treatment of ADHD in children, adolescent and adults. Before Strattera's approval, the stimulant methylphenidate was the only licensed treatment for ADHD in the United Kingdom (U.K).

"Health care professionals involved in the care of children with ADHD have long expressed a desire to be able to offer parents an alternative to stimulant treatment," said Dr. Val Harpin, consultant pediatrician from Sheffield Children's Trust located in the U.K. "We will now be able to offer parents and their children an effective alternative treatment."

"Since it first became available in the United States in January 2003, more than 1.5 million patients have been treated with it," A.J. Allen, M.D., Ph.D., Lilly Research Labs, Eli Lilly and Company. "In addition to being a non-stimulant, Strattera is an important treatment option because it reduces ADHD symptoms at school and during family time in the evenings."

According to the National Center of Clinical Excellence (NICE), 5 percent of children¹ or 500,000² children, are estimated to suffer from ADHD in the U.K. Strattera, a highly selective norepinephrine reuptake inhibitor (NRI), demonstrated significant efficacy in six out of six double-blind, randomized, placebo-controlled clinical trials submitted to Medicines and Healthcare products Regulatory Agency (MHRA). Strattera demonstrated improvements in the symptoms of ADHD including: inattention, hyperactivity, and/or impulsivity in children, adolescents, and adults.

This marks the first European approval of Strattera. Strattera is also currently approved in: the United States, Australia, Mexico, Argentina, and additional Latin American countries.

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.³ In addition, 60 percent of children with the disorder carry their symptoms into adulthood.⁴ Experts estimate 4 percent of adults in the United States, more than 8 million people, have ADHD.^{5,6}

About Strattera

Prior to the U.K. approval, the U.S. Food and Drug Administration approved Strattera on Nov. 26, 2002, for the treatment of ADHD in children, adolescents and adults.

Strattera, a selective norepinephrine reuptake inhibitor, works differently than other FDA-approved treatments for the disorder, all of which are stimulants. 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 six 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.

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 Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of 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. More information about Lilly is available at www.lilly.com.

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.

References

1. National Institute of Clinical Excellence. Technology Appraisal Guidance- No. 13. *Guidance on Use of Methylphenidate (Ritalin, Equasym) for Attention Deficit/Hyperactivity Disorder (ADHD) in Childhood*. October 2000.
2. Population projections by the Government Actuary. United Kingdom, 2003.
3. American Psychiatric Association: *Diagnostic and Statistical Manual of Mental Disorders, fourth edition, text revision*, Washington, D.C., American Psychiatric Association, 2000.
4. Schweitzer JB, et al. Attention-deficit/hyperactivity disorder. *Med Clin of North Am*. 2001; 85(3):757-777
5. Murphy K, Barkley, RA. *J Atten disord*. 1996; 1:147-161.
6. United States Census Summary File; 2000.



Strattera 25 mg Dosage