FDA Approves Strattera(R) for Maintenance of ADHD in Children and Adolescents

First Medication Indicated for Maintenance Treatment for ADHD

INDIANAPOLIS, May 8, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) announced today that the United States Food and Drug Administration (FDA) has approved Strattera(R) (atomoxetine HCI) for maintenance treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children and adolescents. Strattera, a selective norepinephrine reuptake inhibitor, is the first FDA-approved non-stimulant to treat ADHD in children, adolescents and adults.

"The approval provides physicians and their patients with the first treatment option that is indicated for maintenance of ADHD" said Thomas J. Spencer, M.D., Associate Professor of Psychiatry, Harvard Medical School. "This is critical as ADHD may be a life-long disease and effective long-term control of symptoms may mean improved outcomes in children and adolescents."

The safety and efficacy of Strattera in the maintenance of ADHD was demonstrated in one of the largest relapse prevention studies ever conducted in ADHD, which is one of the most common mental health disorders in children and adolescents. (1)

The 18-month trial of about 600 children and adolescents aged six to 15 years, who met DSM-IV (Diagnostic and Statistical Manual of Mental Disorders) criteria for ADHD, showed Strattera was superior to placebo in maintaining continuous efficacy in patients, as measured by the ADHD Rating Scale (ADHD-RS). Additionally, at the end of the trial, patients taking Strattera had lower relapse rates (2.5 percent) as compared to patients taking placebo (12.2 percent).

Strattera provides uninterrupted relief from ADHD symptoms throughout the day into the evening. This is important since the symptoms of ADHD go beyond the work and school day. ADHD patients can experience frustration, low self-esteem, difficulty with relationships and increased lifestyle risks.

"In the past, our understanding of ADHD treatment was limited to clinical data on short-term use, meaning a few weeks or a couple of months," said A.J. Allen, M.D., Ph.D., Strattera global medical director for Eli Lilly and Company. "For the first time, clinicians have guidance that Strattera is effective for up to a year in patients who respond well to initial treatment."

The long-term, international, multi-center study, which was reviewed by the FDA as part of its decision to grant this approval, employed a treatment discontinuation design (3 months of acute open-label treatment followed by up to 15 months of placebo controlled maintenance treatment) that enabled investigators to test the efficacy of Strattera as maintenance therapy. In the study, 604 patients initially received acute open label treatment with Strattera. After 10-weeks, 69% of patients qualified as responders and were re-randomized to double-blind treatment with either Strattera or placebo for nine months. A second six-month randomization occurred after approximately one year of treatment with 81 patients taking Strattera and 82 patients in the placebo group.

Results of both randomization phases showed that patients treated with Strattera had significantly greater continuous response rates versus patients taking placebo. For child and adolescent ADHD patients with a good initial response to Strattera and who continued to respond well for 1 year, 97.5% maintained response on Strattera vs. 87.8% on placebo (relapse rates 2.5% for Strattera vs. 12.2% for placebo). Additionally, relapse rates for those discontinuing treatment after one year were lower than the relapse rates for patients who discontinued treatment during the 6 months following the open label treatment phase (Strattera, 61/292 [20.9%]; placebo, 46/124 [37.1%]).

Strattera was generally well-tolerated. The most common side effects reported in the study were headache and the common cold (nasopharyngitis). In the study, the mean final dose of Strattera was approximately 1.54 mg/kg/day after 12 months and 18 months treatment. There were no significant differences in standardized height change between groups during the post-randomization period.

About ADHD

ADHD is the most common psychiatric disorder to appear in childhood. If left untreated, ADHD can have long-term effects on a child's emotional well-being and social skills, like making friends or doing well at school or at work.(2) ADHD can also have lifelong consequences, including poor peer relations, poor academic and work performance and increased risk-taking behaviors, such as substance abuse.(3)

About Strattera

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.(4) Since its first approval in the United States in 2002, more than 5 million patients have taken Strattera worldwide. It has been studied in more than 6,000 patients in clinical trials, some for as long as three years.

Important Safety Information for Strattera(R) (atomoxetine HCl)

In some children and teens, Strattera increases the risk of suicidal thoughts. A combined analysis of 12 studies of Strattera showed that in children and teens this risk was 0.4% for those taking Strattera compared to none for those taking a sugar pill. A similar analysis in adults treated with Strattera did not reveal an increased risk of suicidal thoughts. Call your doctor right away if your child has thoughts of suicide or sudden changes in mood or behavior, especially at the beginning of treatment or after a change in dose.

Strattera should not be taken if you or your child: are taking or have taken within the past two weeks a medicine for depression called a monoamine oxidase inhibitor (MAOI); have an eye problem called glaucoma; are allergic to anything in STRATTERA.

Tell your doctor if you or a family member has a history of high or low blood pressure, increased heart rate, heart or blood vessel disease or structural heart defects. When on Strattera, tell your doctor right away if you have chest pain, shortness of breath, or fainting, as these may be signs of heart-related conditions that may be life threatening.

In rare cases, Strattera can cause severe liver problems. Call your doctor right away if you or your child has itching, dark urine, yellow skin/eyes, upper right-side abdominal tenderness, or unexplained "flu-like" symptoms.

Tell the doctor about any family history of or if you or your child: has bipolar illness (manic-depressive illness); or has suicidal thoughts or actions before starting Strattera.

If your child develops new psychological symptoms such as abnormal thoughts/behaviors and/or extreme elevated or irritable moods, while taking Strattera you should report them to your child's doctor right away.

For male patients, call your doctor right away if you or your child experience priapism, a painful or prolonged erection lasting more than 4 hours.

Other rare but serious side effects include: serious allergic reactions including swelling, hives, or other allergic reactions; problems passing urine; and slowing of growth in children. As with all ADHD medications, growth should be monitored during treatment although height and weight data for Strattera measured up to 3 years indicates minimal, if any, long-term effects.

Tell your doctor about all prescription and nonprescription medicines that you or your child takes, including vitamins, and herbal supplements. Do not start any new medicine while taking STRATTERA without talking to your doctor first.

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breastfeeding.

In children, the most common side effects were upset stomach, decreased appetite, nausea or vomiting, tiredness, and drowsiness. 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. Most people in clinical studies who experienced side effects were not bothered enough to stop using Strattera. Strattera has not been tested in children under 6 years of age or in geriatric adults.

For Medication Guide, visit www.Strattera.com.

For full Prescribing Information, including Boxed Warning information, visit http://www.Strattera.com/.

About Eli Lilly and Company

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

This press release contains forward-looking statements about 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 development and commercialization, including the risk of side effects and other safety concerns. There is 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) National Resource Center on ADHD. "Statistical Prevalence." Available at" http://www.help4ADHD.org/en/about/statistics. Accessed on March 28, 2007.
(2) National Institute of Mental Health. "NIMH research on treatment for attention deficit disorder (ADHD): The multimodal treatment study -- questions and answers." Available at: http://www.nimh.nih.gov/childhp/mtaqa.cfm. Accessed on May 2, 2008
(3) Faraone S, Beiderman J, et al. ADHD in adults: an overview. Biol Psychiatry 2000; 48:9-20.
(4) Pliszka SR, et al. Journal of the American Academy of Child and Adolescent Psychiatry. 1996., 35 (264-272).

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

SOURCE Eli Lilly and Company