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Study Suggests Strattera(R) was Effective in Treating ADHD in Children and Adolescents with ADHD and Reading Disorders

INDIANAPOLIS, Oct 27, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- New data suggest that Strattera(R) (atomoxetine HCl) improved ADHD symptoms in children and adolescents who had both ADHD and a reading disorder, like dyslexia. Results were announced today at a meeting of child and adolescent psychiatrists.

The primary objective of the study was to measure Strattera's efficacy in treating the symptoms of ADHD in children and adolescents with ADHD and a comorbid reading disorder (ADHD+RD). Patients with ADHD alone were compared to patients with ADHD+RD. After taking Strattera for 16 weeks, both groups of patients aged 10 to 16 reported an improvement of nearly 50 percent in ADHD symptoms like inattentiveness, hyperactivity and impulsivity. Additionally, patients with ADHD+RD displayed an average reading composite improvement of approximately two years compared to 17 months for participants with ADHD alone. Reading composite is defined as the combined score for reading decoding and reading comprehension. Strattera is not approved to treat reading disorders.

"We are encouraged by the results of this study which highlight the importance of considering appropriate treatment options when treating ADHD in patients with ADHD and comorbid conditions," said Richard Rubin, M.D., clinical associate professor of psychiatry, University of Vermont College of Medicine. "Since ADHD is often combined with reading disabilities, considering treatment options that are effective in treating ADHD without having an adverse effect on reading performance may provide the best outcome."

The two most common developmental disabilities of school-age children are ADHD and learning disabilities, including a reading disorder, like dyslexia.(1,2) It is estimated that 15 - 30 percent of children with ADHD will also have a reading disorder.(2,3,4,5) While research suggests that students with both ADHD and a reading disorder are no more anxious, hyperactive or aggressive than students with ADHD only, the reading disorder does impact school performance, which may subsequently impact family and peer relationships.(6)

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Study Highlights
*  At the study endpoint, mean change from baseline to endpoint analyses
   revealed statistically significant improvement for both the patients
   with ADHD and the patients with ADHD and a comorbid reading disorder
   (ADHD+RD) on the ADHD RS Total Score (improved 52 percent and 49.2
   percent, respectively)
*  Age equivalence improvements (in months) were statistically significant
   for both groups on the following items:
   --  Total reading composite: improved 17.2 months for the ADHD group
       and 23.5 months for the ADHD+RD group
       --  Reading decoding (+17.8 months and +16.9 months, respectively)
       --  Reading comprehension (+17.0 months and +26.0 months,
           respectively)
   --  Spelling (+9.7 months and +8.7 months, respectively)
*  In this study, Strattera was well tolerated with no differences between
   groups and commonly reported adverse events similar to those reported
   in previous studies.  The most common adverse events (occurring in
   greater than 5 percent of patients taking Strattera) were somnolence,
   nausea, decreased appetite, headache, abdominal pain, vomiting,
   nasopharyngitis and cough.

Methods
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In this open-label, parallel-design pilot study conducted in the United States, patients received 1.0 to 1.4 mg/kg of Strattera once daily for approximately 16 weeks. Patients with ADHD (n = 20) were compared to patients with ADHD+RD (n = 36).

All patients were required to have an ADHD symptom severity score at least 1.5 standard deviations above age and gender

norms for at least one of the diagnostic subtypes: inattentive, hyperactive/impulsive, or the total score for the combined subtype as assessed by the Attention-Deficit/Hyperactivity Disorder Rating Scale-IV (ADHD RS). Patients diagnosed as ADHD+RD were also required to have at least a 22-point discrepancy between ability and achievement, based on intelligence quotient (K-BIT) and reading composite (K- TEA) scores. An IQ Composite score of >80 was required on the Kaufman Brief Intelligence Test (K-BIT) for the patient to participate in the study.

The ADHD RS was the primary efficacy measure. The second analysis measured patients' reading performance using the Kaufman Test of Educational Achievement (K-TEA) Reading Decoding, Comprehension and Spelling Subtests and Reading Composite Scale. The Working Memory Test Battery for Children (WMTB- C) and Life Participation Scale Investigator and Parent-Rated versions (LPS-C) were additional secondary measures. The patients were allowed to continue to receive educational services/assistance throughout the study.

About ADHD

ADHD is a complex disorder that often occurs in tandem with other conditions like reading disorders(7). Therefore, proper diagnosis of all a patient's symptoms is vital for choosing appropriate treatment and monitoring for both safety and efficacy.(8)

Untreated ADHD can have lifelong consequences, including poor peer relations, poor academic and work performance and increased risk-taking behaviors, such as substance abuse.(9)

About Strattera

Strattera is indicated for the treatment of Attention- Deficit/Hyperactivity Disorder (ADHD) in children, adolescents and adults.

Strattera, a selective norepinephrine reuptake inhibitor, is the first FDA-approved non-stimulant to treat ADHD. 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.(10) Since its first approval in the United States in 2002, more than 4.2 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

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 percent 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. Parents should call their doctor right away if their 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 at the same time as, or within two weeks of taking, a monoamine oxidase inhibitor (MAOI) or by patients with narrow angle glaucoma.

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. If you experience any cardiac symptoms, such as chest pain or fainting while taking Strattera, you should report them to your doctor right away.

In rare cases, Strattera can cause liver problems. Call your doctor right away if you have itching, dark urine, yellow skin/eyes, upper right-side abdominal tenderness, or unexplained "flu-like" symptoms. 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, if you are taking Strattera and experience priapism, a painful or prolonged erection lasting more than four hours, call your doctor right away. As with all ADHD medications, growth should be monitored during treatment, although height and weight data measured for up to three years indicates minimal, if any, long-term effects.

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.

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

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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) Goldman LS, Genel M, Bezman RJ, Slanetz PJ. 1998. Diagnosis and treatment of attention-deficit/hyperactivity disorder in children and adolescents. Journal of the American Medical Association; 279(14): 1100-1107.

(2) Shaywitz BA and Shaywitz SE. 1994. Learning disabilities and attention disorders. In: KF Swaiman (Ed.), Pediatric Neurology: Principles and practice, Vol II: 1119-1151; St. Louis, MO: CV Mosby.

(3) Barkley RA. 2002. Major Life Activity and Health Outcomes Associated with Attention-Deficit/Hyperactivity Disorder. J Clin Psychiatry; 63 (suppl 12): 10-15.

(4) Brown TE. 2000. Attention-Deficit Disorders and Comorbidities in Children, Adolescents, and Adults. Washington DC American Psychiatric Press.

(5) Semrud-Clikeman M, Biederman J, Sprich-Buckminster S, Lehman BK, Faraone SV, Norman D. 1992. Comorbidity between ADHD and learning disability: A review and report in a clinically referred sample. J Am Acad Child Adolesc Psychiatry 31 (3):439-48.

(6) ADHD and Coexisting Disorders, http://www.help4adhd.org/treatment/coexisting/WWK5

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

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

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

(10) Pliszka SR, et al. Journal of the American Academy of Child and Adolescent Psychiatry. 1996, 35(264-272).

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