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Study Suggests Atomoxetine Significantly Improved Functioning in Children with Both ADHD and Anxiety Disorders

TORONTO, May 24, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Data from a recent clinical study suggest that atomoxetine HCl significantly improved measures of psychosocial functioning (the impact of ADHD on various aspects of your life such as quality of relationships with family and peers) in children and adolescents who also had anxiety disorders. The results of the 12-week study were presented today at the 159th annual meeting of the American Psychiatric Association.

The functioning assessment was part of a larger trial, of which the primary endpoint was to examine atomoxetine's ability to treat ADHD in children and adolescents with ADHD and anxiety disorders. At the end of the study, atomoxetine significantly reduced ADHD symptoms such as inattention, hyperactivity and impulsivity by 39 percent, compared to a four percent improvement in patients taking sugar pill. Atomoxetine also significantly reduced anxiety symptoms like excessive worry, sweating and trembling by 32 percent, compared with 19 percent of patients taking sugar pill.

The secondary analysis examined atomoxetine's affect on patient functioning. At the end of the study, patients taking atomoxetine saw a significant improvement in functioning compared to sugar pill as measured on the following scales, Multidimensional Anxiety Scale for Children (MASC), 9 percent improvement for atomoxetine vs. 4 percent worsening for sugar pill; Life Participation Scale for ADHD-Revised (LPS-ADHD-R), 31 percent improvement for atomoxetine vs. 10 percent improvement for sugar pill and the Child Health Questionnaire-Parent Completed Full Length (CHQ-PF50) 23 percent improvement for atomoxetine vs. 11 percent improvement for sugar pill.

"Treating ADHD in children is challenging, because of the complexity of the disease and the presentation of underlying issues such as anxiety," said Daniel Geller, MD, director of the Pediatric Obsessive Compulsive Disorder program at Massachusetts General Hospital in the Division of Pediatric Psychopharmacology. "This study suggests that atomoxetine improved ADHD and anxiety symptoms in children with both ADHD and anxiety disorders."

Up to 35 percent of children with ADHD also suffer from anxiety disorders(1) like separation anxiety, generalized anxiety or social phobia. Children with ADHD and anxiety report more school, family and social/peer problems than children who only have ADHD. Children with ADHD accompanied by anxiety are less likely to appear hyperactive and disruptive, but instead appear more slowed down or inefficient.(2)

Study Highlights

* At the study endpoint, 12 weeks, the response rate for improvement in ADHD symptoms for eligible patients was significantly higher for atomoxetine relative to sugar pill (hyperactivity /impulsivity: -4.5 vs. -0.8; inattention: -4.6 vs. 0.1 on the ADHD Rating Scale-IV - Parent Version (ADHDRS-IV-PI))

-- Mean change from baseline also showed greater improvement for atomoxetine-treated patients than those taking sugar pill (decreases of 10.5 points vs. 1.4 respectively, or 39 percent vs. 4 percent)

* Atomoxetine patients also experienced significantly greater improvement in anxiety symptoms on the Pediatric Anxiety Rating Scale (PARS) compared with sugar pill (decreases of 5.5 points vs. 3.2 respectively, or 32 percent vs. 19 percent)

-- Secondary analyses also showed significant improvement in anxiety

(a decrease of -4.6 vs. an increase of 2.1 on the MASC)

* In this study, the most common adverse events (occurred at a rate of greater than or equal to 5 percent and at least twice the rate of placebo) were decreased appetite, upper abdominal pain, vomiting, nausea and influenza

* There were no clinically significant baseline-to-endpoint treatment differences in electrocardiogram (ECG) or laboratory measures, nor were there significant differences in the incidence of clinically important or treatment-emergent abnormal ECG

or laboratory measures

Methods

In this randomized, double-blind, placebo-controlled study of patients who met the DSM-IV criteria for ADHD and either separation anxiety, generalized anxiety or social phobia, 87 atomoxetine-treated (dosage increased from 0.8 mg/kg/day to a target dose of approximately 1.2 mg/kg/day and not exceeding 120 mg/day), and 89 treated with a sugar pill, participated in a 12-week comparison. A total of 66 patients in each group completed the study.

In the study, which comprised six visits over approximately 12 weeks, patients were assessed according to the 18-item ADHDRS-IV-PI scale and total patient- and parent-reported PARS score. The secondary analysis examined patient functioning on the MASC, LPS-ADHD-R and CHQ-PF50 scales. This study was designed to examine atomoxetine's ability to improve symptoms of ADHD and comorbid anxiety in children with both ADHD and anxiety. It was not designed to study the effects of atomoxetine on ADHD or anxiety alone.

Sample sizes in this study were not sufficient to detect uncommon safety differences between treatments. Because of the 12-week duration, long term efficacy and safety conclusions cannot be drawn from this data. Additionally, generalizability is limited since the patients in this study were clinically referred, and results do not indicate whether atomoxetine is independently beneficial for treatment of any single anxiety disorder.

About ADHD(3,4,5)

ADHD is a complex disorder that can be difficult to diagnose and often occurs in tandem with other psychiatric diagnoses like anxiety or depression. Therefore, proper diagnosis of all a patient's symptoms is vital for choosing appropriate treatment and monitoring for both safety and efficacy.

ADHD is a serious disorder that can have lifelong consequences, including poor peer relations, poor academic and work performance, and increased risk- taking behaviors such as substance abuse.

About Atomoxetine

Atomoxetine, a selective norepinephrine reuptake inhibitor, is the first FDA-approved non-stimulant to treat ADHD. It is not known precisely how atomoxetine 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.(6)

Since its first approval in the United States in 2002, more than 3.7 million patients have taken atomoxetine 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, atomoxetine increases the risk of suicidal thoughts. A combined analysis of 12 studies of atomoxetine showed that in children and teens this risk was 0.4 percent for those taking atomoxetine compared to none for those taking a sugar pill. A similar analysis in adults treated with atomoxetine 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. Atomoxetine 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 atomoxetine. Atomoxetine has not been tested in children less than 6 years of age or in geriatric patients. As with all ADHD medications, growth should be monitored during treatment although height and weight data measured for up to 3 years indicates minimal, if any, long-term effects. Atomoxetine 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 atomoxetine. 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.atomoxetine.com.

For full Prescribing Information, including Boxed Warning, visit <http://www.atomoxetine.com/>.

About Eli Lilly and Company

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This press release contains forward-looking statements about atomoxetine 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) Biederman J: Comorbidity of attention-deficit/hyperactivity disorder with conduct, depressive, anxiety and other disorders. *Am J Psych* 1991; 148:564-577

(2) ADHD and Coexisting Disorders,
<http://www.help4adhd.org/en/treatment/coexisting/WWK5>

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

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

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

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

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