PsychoGenics Announces Positive Phase-IIa for Its First-in-Class Partial 5-HT1A – 5-HT1B Receptor Agonist in ADHD : Statistically Significant Reductions in the ADHD RS IV in Adult Patients

PsychoGenics Inc. today announced positive data from its randomized, placebo controlled, multicenter, Phase IIa trial of eltoprazine, the company’s lead partial 5-HT1A – 5-HT1B receptor agonist, in adult patients with Attention Deficit/ Hyperactivity Disorder (ADHD). The primary objective of the exploratory study was to compare the effects of two doses of eltoprazine with placebo in a cross-over design on the symptoms of ADHD in adults using the total scores from the ADHD Rating Scale-Version IV.

TARRYTOWN, N.Y. (PRWEB) June 2, 2008 -- The compound achieved a reduction in the ADHD-RS-IV total score of 42% from baseline compared to placebo (p<0.051). Inattention (p< 0.041) and hyperactivity (p<0.047) were also significantly reduced when compared to placebo. Improvement was also observed in the Clinical Global Impression-Improvement Assessment with a significant decrease in the overall severity of symptoms (p<0.03).

Further analysis showed that a subset of patients, who shared higher screening and baseline scores at the beginning of the study, exhibited an even greater response to treatment in the ADHD-RS-IV total score (p<0.029).

Eltoprazine was well tolerated in this study and there were no serious adverse events. The most commonly reported treatment-emergent adverse events were related to GI-distress (nausea, constipation, diarrhea, pain) and fatigue and were usually mild or moderate in severity.

Based on these results, PsychoGenics plans to initiate further Phase-II studies in adults and children with ADHD.

"There is a need for a range of ADHD treatments, including novel stimulants and non-stimulant treatments so that patients can receive individualized and optimal care," stated Dr. Lenard Adler, Associate Professor of Psychiatry, Neurology and Child & Adolescent Psychiatry, NYU Langone Medical Center.

Dr. Sharon Wigal, Clinical Professor of Pediatrics and Director of Clinical trials at University of California, Irvine Child Development Center, a well-published author on ADHD and one of the investigators in this trial, said, "The responses observed in this clinical trial are promising, and clearly indicate that eltoprazine is worthy of further study."

About Eltoprazine

Unlike currently marketed medications for ADHD, eltoprazine is neither a psychostimulant nor a monoamine reuptake blocker. Eltoprazine was licensed from Solvay Pharmaceuticals where it had been previously studied for the treatment of pathological aggression. Solvay had studied numerous patients and healthy volunteers and showed that the compound was well tolerated at the doses employed in this trial. PsychoGenics, using its in
vivo behavioral approach to drug discovery, identified that the compound could be useful in the treatment of ADHD.

About Attention-Deficit Hyperactivity Disorder (ADHD)

ADHD is a neurobehavioral developmental disorder affecting about 3-5% of the world's population under the age of 19. It typically presents itself during childhood, and is characterized by a persistent pattern of inattention and/or hyperactivity, as well as forgetfulness, poor impulse control or impulsivity, and distractibility. There is a clear need for new non-stimulant therapies for ADHD, currently considered to be a persistent and chronic condition for which no medical cure is available. ADHD is one of the most common psychiatric disorders in children and adolescents with approximately 7.8 percent of all U.S. school-age children, or about 4.4 million children aged 4 to 17 years, having been diagnosed with ADHD at some point in their lives, according to the U.S. Centers for Disease Control and Prevention (CDC). Over 8 million adults in the US also exhibit the symptoms of ADHD, while only an estimated 600,000 are being treated. The ADHD market is valued at over $3.5 billion dollars, with approximately 35 million prescriptions written annually.

About PsychoGenics

PsychoGenics is a leader in preclinical behavioral neurobiology. The Company applies its behavioral expertise together with advances in robotics, computer vision, and informatics to provide innovative solutions for central nervous system drug discovery. PsychoGenics works with pharmaceutical and biotechnology companies, academic institutions, and not-for-profit research foundations to help discover treatments for such major neurological and psychiatric disorders as: ALS, anxiety, cognitive impairment, depression, Huntingtons Disease, psychosis/schizophrenia, and SMA. The Company's in house discovery efforts have focused on psychiatric indications.
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