



NLS PHARMA ANNOUNCES START OF ITS PHASE 2 TRIAL FOR MAZINDOL IN ADULT ADHD PATIENTS

Stans/Switzerland, August 29, 2016 - NLS Pharma Group (NLS) announced today that it has initiated enrollment for its "Double-Blind Placebo-Controlled Phase II Study to Determine the Efficacy, Safety, Tolerability and Pharmacokinetics of a Controlled Release (CR) Formulation of Mazindol in Adults with DSM-5 Attention Deficit Hyperactivity Disorder (ADHD)".

"The first patient in marks an important milestone in the development of a non-amphetaminic stimulant for ADHD" said Alex Zwyer, CEO at NLS Pharma Group.

About Mazindol

Mazindol is a wake-promoting agent, a norepinephrine and dopamine reuptake inhibitor which was previously approved as an immediate release (IR) formulation in Europe and in the USA for the short term treatment of obesity. It was taken off the market for reasons unrelated to its efficacy and safety.

Rebalancing dysfunctional central nervous system (CNS) noradrenergic and dopaminergic systems appears to be critical for the effective treatment of ADHD and narcolepsy. Given that the central nervous system (CNS) noradrenergic and dopaminergic systems appear to be dysfunctional in ADHD and that an open-label trial of Mazindol demonstrated efficacy in improving the symptoms of pediatrics with ADHD, NLS is developing a controlled release (CR) formulation of Mazindol to potentially treat this disorder.

The principal investigator of the study is Dr. Tim Wigal, who brings extensive experience in clinical research, diagnosis and treatment of ADHD to the project. Dr. Wigal has been author or co-author of over 125 journal articles about ADHD and related disorders. Seven clinical sites in the USA will participate in the study.

"As only a fraction of adults with ADHD are being treated with traditional stimulants, it is clear that alternatives are needed. ADHD can affect numerous aspects of a patient's life and the current Phase II study is examining functional outcomes in order to determine the impact of treatment", according to Dr. Tim Wigal, lead investigator. "Depending on the results in adults, this line of research may quickly expand to include younger patients. "

About ADHD

An major unmet medical need remains in the treatment of Attention Deficit Hyperactivity Disorder (ADHD). In recent studies the prevalence of ADHD is estimated to be 7 to 8% of school-age children and 4 to 5% of adults. In the US, pharmacological approaches to treatment are the most common, and typically consist of stimulant medication, such as methylphenidate, dexamethylphenidate, mixed amphetamine salts and lisdexamfetamine dimesylate. While stimulant medication is an effective treatment for many of the symptoms associated with ADHD, there are concerns about diversion of these medications for misuse and abuse, and some rare but serious cardiovascular side-effects can occur with the use of stimulant medication. Non-stimulants such as atomoxetine, clonidine, and guanfacine have also been found to be efficacious in treating ADHD but the efficacy of these agents may not be comparable to that seen with stimulants. Even with stimulant treatment, optimal functioning occurs in only roughly one in four children with ADHD. Despite considerable advances in our understanding and treatment of ADHD, the disorder remains difficult to manage and further treatment options need to be developed.

Nelson Handal, MD - Chief Medical Officer of NLS: "Clinicians and patients need effective and tolerable non-stimulant alternative medications to treat ADHD. Additionally, at risk populations need safe and non-addictive treatment options. This study creates a unique opportunity for the safe and successful treatment of ADHD in adults."

About NLS Pharma

NLS Pharma (NLS) is a Swiss based biotech group focusing on the repurposing of established and (cost-) effective drug/chemical compounds to treat ADHD, sleep disorders and cognitive impairment.

NLS is a fully privately owned enterprise managed by a top level team of experts who have demonstrated their value and experience with Big Pharma companies. They work closely with renowned AD-HD and sleep related disorders opinion leaders.

On July 11, 2016 NLS announced that the US Food and Drug Administration (FDA) had granted Orphan Drug Designation (ODD) for Mazindol for the treatment of Narcolepsy. On October 9, 2015, an ODD was granted by the European Commission to NLS for Mazindol within the same indication. Series-A financing was successfully completed on August 31, 2015, to secure full development of NLS-1 (Mazindol) up to Proof-of-Concept in ADHD.

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