

## FDA accepts IND for Phase II Study of Mazindol in Adults with ADHD

### Critical step towards the development of a non-amphetaminic stimulant for ADHD

Stans/Switzerland, June 16, 2016 - FDA has accepted an investigational new drug (IND) submitted by NLS Pharma, a Swiss biotech group developing next-generation ADHD therapies for a phase II proof-of-concept clinical trial evaluating the use of Mazindol in adults with Attention Deficit Hyperactivity Disorder (ADHD).

The lead investigator of the double-blind placebo-controlled Phase II study is Dr. Tim Wigal. Dr. Wigal has been author or co-author of over 125 peer-reviewed articles about ADHD and related disorders. 7 clinical sites in the USA have been selected to participate in the study.

ADHD is considered by the Organisation for Economic Co-operation and Development (OECD) as one of the most frequently monitored developmental syndromes worldwide. In early adulthood, ADHD may be associated with depression, anxiety, sleep difficulties, deficit of alertness and substance abuse. Adults with ADHD often cope with difficulties at work and in their personal and family lives related to ADHD symptoms. ADHD is still far from being well addressed.

Alex Zwyer, CEO of NLS Pharma: "The FDA's acceptance of our first IND marks a major development milestone for our novel compound NLS-1 to treat ADHD. It allows us to commence our U.S. based Phase II study in adult patients with ADHD, and we expect to enroll the first patients this summer. The IND will also pave the way for additional studies for other related indications, including narcolepsy, a life-long and rare sleep disorder. "

#### About ADHD

Attention Deficit Hyperactivity Disorder (ADHD) is a group of behavioral symptoms that include inattentiveness, hyperactivity and impulsiveness.

The worldwide prevalence, for those under the age of 18, is estimated to be 5.3% to 12% (American Journal of Psychiatry 2007). In the USA, approximately 6.4 million people under the age of 18 have been diagnosed with ADHD at some point in their lives. It is estimated that well over 10 million adults in the USA have ADHD (Journal of the American Academy of Child & Adolescent Psychiatry 01/2014).

ADHD Treatment market value is expected to rise with a Compound Annual Growth Rate (CAGR) of 5.3%. ADHD therapeutics market value will rise from \$ 6.9 billion in 2013 to \$ 9.9 billion by 2020. (GBI Research 08/2014).

### **About NLS-1**

NLS-1 (Mazindol) is a norepinephrine and dopamine reuptake inhibitor which was previously approved as an immediate release (IR) formulation in Europe and in the US for the short term treatment of obesity. Rebalancing dysfunctional central nervous system (CNS) noradrenergic and dopaminergic systems appears to be critical for the effective treatment of ADHD. An open-label trial of mazindol has indicated efficacy in improving the symptoms of pediatric subjects with ADHD and thus NLS Pharma is developing a controlled release (CR) formulation of mazindol to potentially treat this disorder and is conducting a placebo controlled phase II study in adults to further lend evidence to the potential efficacy of this compound in ADHD across all ages.

### **About NLS Pharma**

NLS/NLS-1 Pharma (NLS) - NLS is a Swiss based biotech group focusing on the repurposing of established and (cost-) effective drug/chemical compounds to treat Attention Deficit/HyperActivity Disorder (ADHD), sleep disorders and cognitive impairment.

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

Series-A financing was successfully completed for \$ 8.5 million on August 31, 2015, to secure proof of concept of mazindol in ADHD.

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