NLS Pharma Announces Submission of Investigational New Drug (IND) Application to FDA for its Controlled-Release Mazindol for the Treatment of Adults with attention-deficit/hyperactivity disorder (ADHD)

NLS Pharma Achieves Milestone in Potential Non-Amphetaminic Stimulant for ADHD

Paris/Stans, May 12th, 2016 - NLS Pharma Group announces the submission of an Investigational New Drug Application (IND) with the U.S. Food and Drug Administration (FDA) to initiate a Phase IIb clinical trial with its lead compound Mazindol. The study is entitled "A Double-Blind Placebo-Controlled Phase IIb 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 principal investigator of the study will be 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. 7 clinical sites in the USA will participate in the study.

ADHD is considered by OECD as one of the most frequently monitored developmental syndromes worldwide. In early adulthood, ADHD may be associated with depression, mood or conduct disorders 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.

Currently, first line treatments for ADHD mainly rely on the use of psychostimulants such as methylphenidates and amphetamines, along with the non-amphetamine-like stimulant modafinil. Certain adverse events have often been observed when using these types of products, impacting patients' everyday life, suggesting that better options for all patients are needed.

"With the submission of this IND, NLS Pharma has achieved an additional major milestone in its development program of NLS1001 for ADHD", stated Alex Zwyer, Chief Executive Officer of NLS Pharma.

NLS Pharma has been created to fulfill medical needs of patients with neurobehavioral and neurocognitive disorders, where there is unmet medical need. It is supported by a worldwide network of opinion leaders and academic institutions, relying on a team of experienced industry development experts and well-recognized pharmaceutical leaders.

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 Psychatry 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 Pharma

NLS Pharma – 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 develops innovative therapeutic solutions and prioritizes its work based on unmet medical needs, strong scientific understanding of neurobehavioral and neurocognitive disorders and their pharmacognosia.

NLS is a fully private owned enterprise managed by a top level team of experts who have proven their value and experience with Big Pharmas. They work closely with renowned ADHD 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 the clinical development of mazindol in ADHD.

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