NLS PHARMA ANNOUNCES NEW INFORMATION IN SUPPORT OF THE MECHANISM OF ACTION OF ITS LEAD COMPOUND NLS-1 MAZINDOL CR

Stans/Switzerland, May 26, 2017 – NLS Pharma Group (NLS Pharma), a Swiss biotech group focusing on the development of novel treatments for attention deficit hyperactivity disorder (ADHD), sleep disorders, and cognitive impairments, announced today that studies investigating the mechanism of action of mazindol—a dual pan-monoamine reuptake inhibitor/orexin-2 receptor agonist (dual pMRI/OX_2R agonist)—may indicate a unique profile for treating ADHD.

Alex Zwyer, CEO of NLS Pharma: "This is exciting information that expands the knowledge of the mechanism of action for potentially more effective and safer treatments for ADHD compared to existing standard of care."

NLS Pharma is investigating NLS-1 mazindol CR (Controlled Release) as a potential alternative to conventional psychostimulants first-line in ADHD. Recently completed in vitro binding studies suggest that mazindol appears to play a direct role on the pathophysiology of ADHD by its affinity, measured as the percentage inhibition or stimulation of binding primarily for serotonin (5-HT), dopamine, and norepinephrine transporters with a reuptake inhibition greater than 98%, but also with an affinity for μ-opioid (MOP) and above all for $5HT_{1A}$, which is involved in neuroprotection, anxiety, mood disorders, and in motor control effects of drug abuse.

In a second part study, it was confirmed that the binding activity of NLS-1 mazindol CR for the orexin receptor 2 (OX_2R) found was moderated sufficiently to produce a direct relevant agonist effect.

These in vitro binding studies were conducted at concentrations that may exceed the concentrations in the brain following administration of NLS-1 mazindol CR to patients with ADHD. However, if activity can be confirmed, NLS-1 mazindol CR may represent a unique and novel profile for treating ADHD.

The contribution of the metabolite will be determined by the blood levels relative to mazindol and its transport into the central nervous system.

A recently completed Phase 2 trial showed promising results of NLS-1 mazindol CR for the treatment of ADHD in adults (NLS-1001).

The clinical potential of mazindol to improve ADHD symptoms was first observed in an open label pilot study which assessed the efficacy, safety, and pharmacokinetics of mazindol in children with ADHD (MAZDAH study).

About ADHD

A 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, dexmethylphenidate, 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 extended-release 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.

About NLS Pharma

NLS Pharma Group (NLS Pharma) is a privately owned, Swiss-based biotech group focusing on the development of first-in-class treatments for attention deficit hyperactivity disorder (ADHD), sleep disorders, cognitive impairment, and other neurological disorders that remain largely underdiagnosed and for which unmet medical needs are significant. NLS Pharma has built a large portfolio of promising clinical-stage medicines being developed by an experienced team of proven experts in ADHD and sleep-related disorders and working closely with key opinion leaders.

Media

Wendy Ryan, MSLGROUP

Danae McKenzie, MSLGROUP

781-684-0770

nlspharma@mslgroup.com

NLS Pharma Contacts

Alex Zwyer, CEO, az@nls-pharma.com

Hervé Girsault, Head of M&A and Business Development, hg@nls-pharma.com

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