NLS Presents Positive Phase 2 Study Results for Mazindol at APSARD

Switzerland, January 31, 2018 - NLS Pharma (NLS), a Swiss biotech group focusing on the development of novel treatments for Attention-Deficit/Hyperactivity Disorder (ADHD) and other cognitive disorders and impairments, announced positive results from their Phase 2 clinical trial of mazindol controlled release (CR), formerly used as an appetite suppressant, to treat ADHD at this month's APSARD conference. The poster was titled "Efficacy, Safety, Tolerability and PK of Mazindol Controlled Release (CR) in Adults with ADHD." The study was a randomized, double-blind, placebo-controlled, flexible dose trial of Mazindol CR vs. placebo (1:1) for 6 weeks in 85 participants with ADHD. Results showed that Mazindol CR has a robust effect on symptoms of ADHD with a placebo-adjusted effect size of 1.09. This effect size is similar to what is seen with C2 stimulants in the treatment for ADHD in other studies. Patients receiving mazindol CR responded quickly with a mean 30% reduction from Baseline in ADHD-RS-DSM5 score by 7 days (i.e., first assessment point) and a mean 50% reduction in the ADHD-RS-DSM5 score by 14 days.

"The results of the Adult Mazindol CR study are impressive, but most importantly, they may be a 'game changer' in the treatment of ADHD, if confirmed in Phase 3. The development of an effective, well-tolerated, fast acting, non-C2 stimulant, non-addictive medication has been the most important goal in the treatment of ADHD. The results of this study strongly suggest that Mazindol CR may meet that need," says Nelson Handal, MD, DFAPA, CMO of NLS.

About NLS Pharma

NLS Pharma is a privately owned, Swiss-based biotech group focusing on the development of first-in-class treatments for 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.

About Mazindol

Mazindol immediate release is an imidazo-isoindole agent, originally developed as an appetite suppressant in 1973, and classified at that time as a C4 controlled substance (low probability for misuse/abuse). It was withdrawn from US markets by 2002 due to commercial reasons unrelated to efficacy or safety. Mazindol controlled release is a novel formulation with a lower Cmax than the immediate release formulation and an equivalent AUC, designed for once daily dosing, which is under investigation for the treatment of ADHD and narcolepsy.

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