



NLS Pharmaceuticals Announces Issuance of Canadian Patent Covering its Novel Formulation of Controlled-Release Mazindol (Mazindol CR)

Claims encompass use in both attention deficit hyperactivity disorder (ADHD) & narcolepsy

Switzerland/Stans, March 29, 2021 - NLS Pharmaceuticals Ltd. (Nasdaq: NLSP, NLSPW) (“NLS” or the “Company”), a Swiss clinical-stage pharmaceutical company focused on the discovery and development of innovative therapies for patients with rare and complex central nervous system disorders, announces that it has been awarded Canadian Patent No. 3016852, entitled A MAZINDOL IR/SR MULTILAYER TABLET AND ITS USE FOR THE TREATMENT OF ATTENTION DEFICIT/HYPERACTIVITY DISORDER (ADHD). The patent provides intellectual property protection for oral formulations containing immediate-release and sustained-release layers of mazindol for use in treating attention deficit disorders (ADD or ADHD), related alertness of vigilance or excessive daytime sleepiness (EDS), narcolepsy, or idiopathic hypersomnia.

“We are very pleased to have obtained the first patent covering our novel formulation of controlled-release mazindol as we advance the development of Quilience® to treat narcolepsy and other potential sleep-wake disorders,” said Alex Zwyer, Chief Executive Officer of NLS. “Our application for a similar patent in Europe received notice of allowance in January, and our U.S. patent application is pending review. Most patients with narcolepsy remain unsatisfied with current treatment options, and we believe that Quilience has potential to fill a major need in the market given mazindol’s long history of safety and evidence of effectiveness in treating the symptoms of narcolepsy. We remain focused on initiating our prospective Phase 2 clinical study for Quilience in the second quarter of this year and bringing this treatment option to patients suffering from narcolepsy as soon as possible.”

About NLS Pharmaceuticals Ltd.

NLS Pharmaceuticals Ltd. is a Swiss-based clinical-stage biopharmaceutical company led by an experienced management team with a track record of developing and repurposing product candidates to treat rare and complex central nervous system disorders. The Company's lead product candidate, Quilience® is a proprietary controlled-release formulation of mazindol (mazindol CR), and is being developed for the treatment of narcolepsy. Mazindol is a triple monoamine reuptake inhibitor and partial orexin receptor 2 agonist, which was used for many years to treat patients diagnosed with narcolepsy in compassionate use programs. NLS completed a phase 2 study in the U.S. evaluating mazindol CR in adult subjects with ADHD. The study met all primary and secondary endpoints and was well-tolerated. Quilience has received Orphan Drug Designations both in the U.S. and in Europe for the treatment of narcolepsy.

Safe Harbor Statement

This press release contains express or implied forward-looking statements pursuant to U.S. Federal securities laws. For example, NLS is using forward-looking statements when it discusses its belief that Quilience has potential to fill a major need in the market given mazindol’s long history of safety and evidence of effectiveness in treating the symptoms of narcolepsy and the expected timing of the initiation of its Phase 2 clinical study for Quilience. These forward-looking statements and their implications are based on the current expectations of the management of NLS only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from

those described in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; NLS may encounter delays or obstacles in launching and/or successfully completing its clinical trials; NLS's products may not be approved by regulatory agencies, NLS's technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; NLS may be unable to retain or attract key employees whose knowledge is essential to the development of its products; unforeseen scientific difficulties may develop with NLS's process; NLS's products may wind up being more expensive than it anticipates; results in the laboratory may not translate to equally good results in real clinical settings; results of preclinical studies may not correlate with the results of human clinical trials; NLS's patents may not be sufficient; NLS's products may harm recipients; changes in legislation may adversely impact NLS; inability to timely develop and introduce new technologies, products and applications; loss of market share and pressure on pricing resulting from competition, which could cause the actual results or performance of NLS to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, NLS undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. More detailed information about the risks and uncertainties affecting NLS is contained under the heading "Risk Factors" in NLS' final prospectus, dated January 28, 2021, filed with the SEC, which is available on the SEC's website, www.sec.gov.

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