NLS Pharmaceuticals Obtains License to Full Regulatory Data Package and Proprietary Know-How for Sanorex® (Mazindol)

Agreement provides exclusive rights to all available data included in the original new drug application ("NDA") for mazindol in the U.S.

Switzerland/Stans, March 12, 2021 - NLS Pharmaceutics 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 entered into a License Agreement (the "Agreement") with Novartis Pharma AG, whereby the Company has obtained, on an exclusive basis in the United States, all of the available data referred to and included in the original NDA for Sanorex® (mazindol) submitted to the United States Food and Drug Administration in February 1972. The Agreement encompasses all preclinical and clinical studies, data used for manufacturing including stability and other chemistry manufacturing and controls data, formulation data and know-how for all products containing mazindol as an active substance, and all post-marketing clinical studies and periodic safety reports from 1973 forward.

Under the Agreement, NLS has obtained the same rights on an non-exclusive basis in all territories outside of the U.S, except for Japan, with the right to cross-reference the Sanorex NDA with non-U.S. regulatory agencies in the licensed territories. The Agreement includes the right to sublicense or assign the license to third parties, subject to such third parties meeting certain obligations.

"We are very pleased to have obtained rights to this important clinical and regulatory package for mazindol, as well as proprietary know-how that may save us time, reduce our clinical budget, and enhance our clinical/regulatory programs to advance Quilience®, our controlled release formulation of mazindol, through development," said Alex Zwyer, Chief Executive Officer of NLS. "Quilience's unique mechanism of action, including its partial agonism of the orexin-2 receptor, has potential to provide significant benefits to patients suffering from narcolepsy, which remains a major unmet medical need. Other disorders related to sleep-wake cycle disturbances, such as idiopathic hypersomnia and obstructive sleep apnea, may also benefit from Quilience, and we remain focused on bringing this enhanced formulation of mazindol to the market."

About NLS Pharmaceutics Ltd.

NLS Pharmaceutics Ltd. is a Swiss-based clinical-stage pharmaceutical 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 the benefits of the Agreement, including the potential to save time, reduce its clinical budget, and enhance its clinical/regulatory programs to advance Quilience®; Quilience's potential to provide significant benefits to patients suffering from narcolepsy; the possibility that other disorders related to sleep-wake cycle disturbances, such as idiopathic hypersomnia and obstructive sleep apnea, may also benefit from Quilience; and bringing its enhanced formulation of mazindol to the market. 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' Registration Statement on Form F-1 filed with the SEC, which is available on the SEC's website, www.sec.gov.

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