Supernus Submits NDA for SPN-830 for Continuous Treatment of ON-OFF Episodes in Adults with Parkinson's Disease Who Have Failed Two Treatments

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ROCKVILLE, Md., Sept. 14, 2020 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (Nasdaq: SUPN), a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases, today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its apomorphine infusion pump (SPN-830) for the continuous treatment of ON-OFF episodes in adults with Parkinson's disease (PD) whose motor control is unsatisfactory with oral levodopa and at least one other noninvasive PD therapy.

"We believe the continuous treatment of "OFF" episodes may offer PD patients an important alternative over currently available acute treatments," said Jack Khattar, President and CEO of Supernus. "Current alternatives to acute treatment often require continuous infusion of levodopa through a gastric tube or surgical intervention such as deep brain stimulation. SPN-830, if approved by the FDA, would offer patients a less invasive and a convenient option in the form of a continuous subcutaneous infusion of apomorphine."

The NDA for SPN-830 is based on data from an extensive development program, completed by Supernus' partners, US WorldMeds, LLC and Brittania Pharmaceuticals Ltd. The program includes the TOLEDO study, a pivotal Phase III study (conducted in Europe, ref. Katzenschlager et al, Lancet Neurology 2018; 17: 749–59) and a supportive safety and efficacy study (conducted in the US).

TOLEDO was a Phase III, multi-center, double-blind, placebo-controlled study that investigated the efficacy and safety of apomorphine subcutaneous infusion in PD subjects whose motor fluctuations were not adequately controlled on optimized treatment. The US study is an open label study which investigated the safety and effectiveness of SPN-830. The study eligibility criteria, apomorphine administration and dosing, study schedule, and efficacy and safety measures in both studies were similar. Both studies included PD subjects with average daily OFF time ≥3 hours. The primary efficacy endpoint in both studies was the change from baseline to Week-12 in mean daily OFF time over 24 hours recorded by the subject in a motor symptom diary. In TOLEDO, the reduction in mean daily OFF time with SPN-830 in comparison with placebo was statistically significant (SPN-830: 2.47 hours, n=53; placebo: 0.58 hours, n= 53; p=0.0025). In the US study, mean daily OFF time decreased from baseline to Week-12 by 3.0 hours (n=94, p<0.0001). Most of the treatment-related adverse events (AEs) were mild or moderate in severity. Infusion site AEs, nausea and dyskinesia were the most frequently reported AEs related to study treatment.

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals, Inc. is a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. The Company markets Trokendi XR® (extended-release topiramate) for the prophylaxis of migraine and the treatment of epilepsy; Oxtellar XR® (extended-release oxcarbazepine) for the treatment of epilepsy; APOKYN® (apomorphine hydrochloride injection) for the acute treatment of hypomobility in advanced Parkinson's disease (PD); MYOBLOC® (rimabotulinumtoxinB) for the treatment of cervical dystonia and treatment of chronic sialorrhea in adults; and XADAGO® (safinamide) as an adjunctive treatment to levodopa/carbidopa in PD patients with hypomobility. The Company is also developing several product candidates to address large market opportunities in the CNS market, including SPN-812 for the treatment of ADHD; SPN-830 for hypomobility in PD; SPN-820 for treatment-resistant depression; and SPN-817 for the treatment of epilepsy.

See full Prescribing Information for our products here: Trokendi XR, Oxtellar XR, APOKYN, MYOBLOC, and XADAGO.

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Forward-Looking Statements:
This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements do not convey historical information, but relate to predicted or potential future events that are based upon management's current expectations. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. In addition to the factors mentioned in this press release, such risks and uncertainties include, but are not limited to, the Company's ability to sustain and increase its profitability; the Company's ability to raise sufficient capital to fully implement its corporate strategy; the implementation of the Company's corporate strategy; the Company's future financial performance and projected expenditures; the Company's ability to increase the number of prescriptions written for each of its products; the Company's ability to increase its net revenue; the Company's ability to enter into future collaborations with pharmaceutical companies and academic institutions or to obtain funding from government agencies; the Company's product research and development activities, including the timing and progress of the Company's clinical trials, and projected expenditures; the Company's ability to receive, and the timing of any receipt of, regulatory approvals to develop and commercialize the Company's product candidates including SPN-830; the Company's ability to protect its intellectual property and operate its business without infringing upon the intellectual property rights of others; the Company's expectations regarding federal, state and foreign regulatory requirements; the therapeutic benefits, effectiveness and safety of the Company's product candidates; the accuracy of the Company's estimates of the size and characteristics of the markets that may be addressed by its product candidates; the Company's ability to increase its manufacturing capabilities for its products and product candidates; the Company's projected markets and growth in markets; the Company's product formulations and patient needs and potential funding sources; the Company's staffing needs; and other risk factors set forth from time to time in the Company's filings with the Securities and Exchange Commission made pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended. The Company undertakes no obligation to update the information in this press release to reflect events or circumstances after the date hereof or to reflect the occurrence of anticipated or unanticipated events.

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