Supernus Announces Positive Results from Phase III Study for SPN-812 in Adults with ADHD

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- ***Met primary endpoint with robust statistical significance***
- ***Showed efficacy on both hyperactivity/impulsivity and inattention subscales with statistical significance***
- ***Showed statistically significant onset of action as early as week 2***
- ***Had a good safety and tolerability profile throughout the study***
- ***Topline data confirm positive results from prior Phase IIa study in adults and Phase III studies of SPN-812 in children and adolescents***

ROCKVILLE, Md., Dec. 22, 2020 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (Nasdaq: SUPN), a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system diseases, today announced positive topline results from a Phase III study of SPN-812 in adults (P306) for the treatment of attention deficit hyperactivity disorder (ADHD).

At a daily dose of up to 600mg, the trial met the primary endpoint with robust statistical significance (p=0.0040) compared to placebo in improving the symptoms of ADHD from baseline to end of study as measured by ADHD Investigator Symptom Rating Scale (AISRS). In addition to meeting the primary efficacy endpoint, the Phase III study met the key secondary efficacy endpoint with statistical significance (p=0.0023) in the change from baseline of the Clinical Global Impression – Severity of Illness (CGI-S) Scale at week 6. The active dose was well tolerated.

SPN-812 is under review by the U.S. Food and Drug Administration (FDA) for the treatment of ADHD in pediatric patients 6 to 17 years of age. As announced in November, 2020, the FDA issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for SPN-812 for the treatment of ADHD in pediatric patients to indicate that the review cycle for the application was complete and that the application is not ready for approval in its present form. The Company will be meeting with the FDA in January 2021 to discuss the CRL. Assuming approval for pediatrics, the Company plans to submit a supplemental NDA (sNDA) to the FDA for SPN-812 in adults in the second half of 2021.

“These compelling data in adults will be important for our planned sNDA submission to make this treatment option available, if approved by the FDA, to the adult ADHD patient population, which represents approximately half of the total ADHD market in the U.S.,” stated Jack Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. “We now have positive Phase III data proving the efficacy and safety of SPN-812 in a broad range of ADHD patient populations; children 6-11 years old, adolescents 12-17 years old, and adults.”

About the P306 Study

The study was a randomized, double-blind, placebo controlled, multicenter, parallel group clinical trial in adult patients diagnosed with ADHD. The study had a two-arm flexible dose design where treatment was administered orally once a day over six weeks, including the titration phase up to a total daily dose of 600mg SPN-812 or matched placebo.

A total of 374 adult patients were randomized across placebo and a daily dose of SPN-812 starting with 200mg with flexible dose administration up to 600mg. The primary objective was to assess the effect of SPN-812 in reducing the symptoms of ADHD. The primary outcome measure was the change from baseline to the end of the study in the AISRS. Safety and tolerability of SPN-812 were assessed by the monitoring of adverse events (AEs), clinical laboratory tests, vital signs, ECGs, suicidality and physical examinations. Patients who completed the study were offered the opportunity to continue into an ongoing open-label safety extension study.

Topline Results

At the end of the study, SPN-812 reached statistical significance compared to placebo in the primary endpoint. Patients receiving SPN-812 had a -15.5 point change from baseline in the primary endpoint compared to -11.7 for placebo at week 6 (p=0.0040).

This primary result, based on a Mixed Model Repeated Measures (MMRM) analysis using the Full Analysis Set (FAS) population, was confirmed by sensitivity analysis with a p-value of 0.0085.

The study demonstrated fast onset of action, reaching statistical significance as early as week 2 with a p-value of 0.0397, and maintaining statistical significance through the end of the trial at week 6.

Similar to the previously reported studies in pediatric patients 6 to 17 years of age, at the end of the P306 study, SPN-812 reached statistical significance compared to placebo on the hyperactivity/impulsivity and inattention subscales of the AISRS with p-values of 0.0380 and 0.0015, respectively.

In addition, SPN-812 met the CGI-S secondary endpoint with a p-value of 0.0023 compared to placebo at week 6 and showed significant improvement as early as week 2 with a p-value of 0.0203.

Safety and tolerability

Overall, the trial exhibited a good safety and tolerability profile. Adverse events (AEs) were primarily mild to moderate leading to a low placebo-

adjusted discontinuation rate due to AEs in the SPN-812 group of 4.1% (9.0% for SPN-812 compared to 4.9% in the placebo group). Treatment related AEs that reported at more than or equal to 5% for SPN-812 were insomnia, fatigue, decreased appetite, nausea, headache, and dry mouth.

Topline data for the P306 study can be accessed by visiting 'Events & Presentations' in the Investor Relations section of the Company's website at www.supernus.com.

About SPN-812

SPN-812 is a novel non-stimulant for the treatment of ADHD. Based on data generated to date, the Company believes SPN-812 could be a well-differentiated ADHD treatment due to its different pharmacological and pharmacokinetic profile. The active ingredient in SPN-812, viloxazine hydrochloride, has an extensive safety record in Europe, where it was previously marketed for many years as an antidepressant.

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 (apomorphine infusion pump) for the continuous treatment of motor fluctuations ("on-off" episodes) 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. These forward-looking statements include expectations regarding the Company's future interactions and communications with the FDA, including its expectation to discuss with the FDA the issues raised in the CRL regarding the NDA for SPN-812 for the treatment of ADHD in pediatric patients 6 to 17 years of age and the Company's plans to address them, the Company's future resubmission of the NDA for SPN-812, the potential approval of the NDA for SPN-812 following resubmission, the planned submission of an sNDA to the FDA for SPN-812 in adults and the potential benefits and commercialization of SPN-812. 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 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; 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 products and 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; 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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