Supernus Announces Positive Results from Phase III Study For SPN-812 in Adolescents with ADHD

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- ***Met primary endpoint with robust statistical significance***
- ***Third positive Phase III study for SPN-812 in patients with ADHD***
- ***Showed efficacy on both hyperactivity/impulsivity and inattention subscales with statistical significance***
- ***Showed statistically significant onset of action as early as week 1 on 400 mg dose***
- ***SPN-812 was well-tolerated with low incidence of adverse events and low discontinuation rates***

ROCKVILLE, Md., Dec. 20, 2018 (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 pivotal Phase III study of SPN-812 in adolescents (P302) for the treatment of attention deficit hyperactivity disorder (ADHD).

At daily doses of 200 mg and 400 mg, the trial met the primary endpoint with robust statistical significance in improvement in the symptoms of ADHD from baseline to end of study as measured by the ADHD Rating Scale-5. Both active doses were well tolerated.

The Company expects to announce topline data from the final Phase III trial of SPN-812, study P304 in adolescents, by the end of the first quarter of 2019. The Company expects to submit a New Drug Application for SPN-812 in the second half of 2019, and to launch it, pending U.S. Food and Drug Administration approval, in the second half of 2020.

“These data further reinforce the effectiveness of SPN-812 in patients with ADHD, showing a clinically meaningful reduction in the symptoms of ADHD, with a favorable safety and tolerability profile,” stated Jack Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. “We now have positive data proving the efficacy and safety of SPN-812 in all ADHD patient populations; positive Phase III data in children 6-11 years old and adolescents 12-17 years old, and positive Phase IIa data in adults.”

About the P302 Study

The study is a randomized, double-blind, placebo controlled, multicenter, parallel group clinical trial in adolescents 12 to 17 years of age diagnosed with ADHD. Each treatment was administered orally once a day over six weeks, including the titration phase of the 400 mg dose group.

A total of 310 patients were randomized across placebo and two doses of SPN-812 (200mg/400mg). The primary objective was to assess the effect of SPN-812 in reducing the symptoms of ADHD in adolescents 12-17 years old. The primary outcome measure was the change from baseline to the end of the study in the ADHD-RS-5 total score. 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 open-label phase that is currently on-going.

Topline Results

P302 Study

At the end of the study, SPN-812 200 mg and 400 mg doses reached statistical significance compared to placebo in the primary endpoint. Patients receiving SPN-812 200 mg and 400 mg had a -16.0 point change (p=0.0232) and a -16.5 point change (p=0.0091) from baseline, respectively, in the primary endpoint vs. -11.4 for placebo at week 6.

This primary result, based on Mixed Model Repeated Measures (MMRM) analysis in the Intent-To-Treat (ITT) population, was confirmed by sensitivity analyses using Analysis of Covariance (ANCOVA) (200 mg, p=0.0163; 400 mg, p=0.0055). With respect to the effect size, patients receiving 200 mg and 400 mg had an effect size of 0.47 and 0.50, respectively, within the range of 0.46 to 0.63 observed in the first two Phase III studies and the Phase IIb study.

The study demonstrated fast onset of action, reaching statistical significance for the 400 mg dose as early as week 1 with a p-value of 0.0085, and maintaining statistical significance on a weekly basis through the end of the trial at week 6. Onset of action for the 200 mg dose showed clear differences compared to placebo starting by week 1, reaching statistical significance at week 3, which was sustained through the rest of the trial.

Similar to the P301 and P303 studies, at the end of the P302 study, SPN-812 200 mg and 400 mg reached statistical significance compared to placebo on the hyperactivity/impulsivity and inattention subscales of the ADHD-RS-5 scale with p-values ranging from 0.0005 to 0.0424.

In addition, SPN-812 200 mg and 400 mg met the Clinical Global Impression-Improvement secondary endpoint with p-values of 0.0042 and 0.0003, respectively, compared to placebo.

Safety and tolerability

Overall, the trial exhibited favorable tolerability and safety profiles with low incidence of AEs across all doses. AEs were mild leading to low discontinuation rates due to AEs of 1.9% to 4.1%. Treatment related AEs that reported at more than or equal to 5% for SPN-812 were somnolence,

fatigue, decreased appetite, headache and nausea.

“We are pleased with the positive topline results of the P302 study, in which SPN-812 showed statistical significance on the primary endpoint and main secondary endpoint. It’s exciting to see a consistency in the data across the first three Phase III studies,” stated Dr. Stefan Schwabe, Executive Vice President R&D, Chief Medical Officer of Supernus Pharmaceuticals.

Additional topline data for the P302 study can be accessed by visiting ‘Events & Presentations’ in the Investor Relations section on the Company’s website at www.supernus.com.

About SPN-812

SPN-812 is a norepinephrine reuptake inhibitor with selective serotonin modulation activity that Supernus is developing as 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 compared to other non-stimulant treatments for ADHD 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 currently markets Trokendi XR® (extended-release topiramate) for the prophylaxis of migraine and the treatment of epilepsy, and Oxtellar XR® (extended-release oxcarbazepine) for the treatment of epilepsy. The Company is also developing several product candidates to address large market opportunities in the CNS market, including SPN-810 for the treatment of Impulsive Aggression in ADHD patients, SPN-812 for the treatment of ADHD and SPN-604 for the treatment of bipolar disorder.

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 successfully complete the development of its product candidates including SPN-812, obtain regulatory approval and commercially market them; 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; 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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