October 11, 2016

Supernus Announces Positive Results from Phase IIb Clinical Trial For SPN-812 in Children with ADHD

- ***Study confirms efficacy and tolerability of SPN-812, a novel non-stimulant product, in children with ADHD***
- ***Study meets primary endpoint with statistically significant reduction in ADHD symptoms***
- ***Conference call and webcast to discuss results at 9:00 a.m. ET, October 11, 2016***

ROCKVILLE, Md., Oct. 11, 2016 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (NASDAQ:SUPN), a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system diseases, today announced positive topline results from its Phase IIb dose-ranging clinical trial of SPN-812 in children for the treatment of attention deficit hyperactivity disorder (ADHD).

The trial was successful in meeting the primary endpoint, demonstrating that SPN-812 at daily doses of 400 mg, 300 mg and 200 mg achieved a statistically significant improvement in the symptoms of ADHD from baseline to end of study as measured by the ADHD Rating Scale-IV. All SPN-812 doses tested in the trial were well tolerated. Based on these positive results in children with ADHD and the positive Phase IIa results in adults with ADHD, Supernus plans to have an end-of-Phase II meeting with the U.S. Food and Drug Administration (FDA) after which it will initiate Phase III clinical testing.

"We are very excited about these results and that SPN-812 met the objectives of the study with an encouraging and strong clinical profile," stated Jack Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. "We believe SPN-812 has the potential of being a well differentiated treatment for ADHD that sets itself apart from current treatment options."

Phase IIb Study Design

The study was a randomized, double-blind, placebo controlled, multicenter, dose-ranging clinical trial in children 6 to 12 years of age diagnosed with ADHD. Each treatment was administered orally once a day over five weeks, after a three week titration phase. A total of 222 patients were randomized in the study across placebo and four doses of SPN-812 (100/200/300/400mg). The primary objective of the study was to assess the effect of SPN-812 in reducing the symptoms of ADHD in children. The primary outcome measure was the change from baseline to the end of the study in the ADHD-RS-IV total score. Safety and tolerability of SPN-812 were assessed by the monitoring of adverse events, 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

At the end of the study, SPN-812 400 mg, 300 mg and 200 mg doses were statistically significant compared to placebo in the primary endpoint. Patients receiving SPN-812 400 mg, 300 mg and 200 mg had a -19.0 point change (p=0.021), -18.6 point change (p=0.027) and a -18.4 point change (p=0.031) from baseline, respectively, in the primary endpoint vs. -10.5 for placebo.

This primary analysis using the Intent-To-Treat (ITT) population with last observation carried forward (LOCF) was confirmed with sensitivity analyses using the Per Protocol population and Mixed Model Repeated Measures (MMRM).

With respect to the effect size, patients receiving SPN-812 400 mg, 300 mg and 200 mg had a median effect size of 0.63, 0.60 and 0.55, respectively. Patients receiving SPN-812 100 mg had a -16.7 point change from baseline in the primary endpoint and a median effect size of 0.46, which did not quite reach statistical significance (p=0.089) in this relatively low number of patients.

In addition, SPN-812 400 mg, 300 mg and 200 mg met the Clinical Global Impression Severity (CGI-S) secondary endpoint with p- values of 0.014, 0.015 and 0.031, respectively, compared to placebo.

"These results exhibit a strong clinical efficacy profile with effect sizes that are typically not seen with non-stimulants. In addition, of the 160 patients who completed the trial, 87% or 139 patients chose to enter the open-label phase showing a

high level of confidence in SPN-812," stated Dr. Stefan Schwabe, Executive Vice President R&D, Chief Medical Officer of Supernus Pharmaceuticals.

SPN-812 was well tolerated in the study. All four active doses were well tolerated, with adverse events almost entirely mild or moderate in severity. Two subjects experienced three adverse events that were classified as severe and related to the medication; one on 400 mg with easy tearfulness and intermittent irritability and another on 200 mg with decreased appetite. There were no serious adverse events or deaths in the study. The most frequent adverse events across all the active doses were primarily somnolence, headache, decreased appetite, fatigue, vomiting and nausea. On average, the percentage of patients discontinuing the study due to adverse events for all active doses of SPN-812 was low at 6.7%.

"We believe this side effect profile compares very well with existing treatments in the market," added Dr. Schwabe.

Product Pipeline

SPN-812 is the company's second psychiatry product in late stage development. Supernus is also developing SPN-810 (molindone hydrochloride), a novel treatment for impulsive aggression in patients with ADHD. SPN-810 is currently in clinical development with two Phase III trials in children with ADHD.

"We are excited about our psychiatry pipeline, with two late-stage novel product candidates with positive Phase II clinical results. With SPN-812 now proceeding towards Phase III clinical testing, Supernus expects to have two product candidates in Phase III testing in 2017. We believe these two product candidates represent a significant platform for future growth for Supernus in multi-billion dollar markets," added Jack Khattar.

Conference Call Details

The Company will hold a conference call and webcast today, October 11, 2016, at 9:00 a.m. ET to discuss these topline results. The call will be hosted by Jack Khattar, President and Chief Executive Officer, and Greg Patrick, Vice President and Chief Financial Officer. Presentation slides will be available via this webcast link. A question and answer session with the Supernus management team will follow the company's remarks.

Please refer to the information below for conference call dial-in information and webcast registration. Callers should dial in approximately 10 minutes prior to the start of the call.

Conference dial-in: (877) 288-1043

International dial-in: (970) 315-0267

Conference ID: 93788624

Conference Call Name: Supernus Pharmaceuticals SPN-812 Phase IIb Topline Results

Webcast link: Click here

Following the live call, a replay will be available on the company's website, www.supernus.com, under ‘Investors'.

About SPN-812

SPN-812 is a selective norepinephrine reuptake inhibitor 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 more effective and have a better side effect profile than other non-stimulant treatments for ADHD due to its unique 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 specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system diseases. The Company has two marketed products for epilepsy, Oxtellar XR® (extended-release oxcarbazepine) and Trokendi XR® (extended-release topiramate). The Company is also developing several product candidates to address large market opportunities in psychiatry, including SPN-810 for the treatment of Impulsive Aggression in ADHD patients and SPN-812 for the treatment of ADHD.

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-812 and SPN-810; 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 SEC filings 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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