



November 20, 2012

Supernus Announces Positive Phase IIb Results on SPN-810 and Decision to Advance to Late Stage Development

ROCKVILLE, Md., Nov. 20, 2012 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (Nasdaq:SUPN), a specialty pharmaceutical company, received positive topline results from its Phase IIb study on SPN-810 for the treatment of impulsive aggression in ADHD patients.

The study is a multicenter randomized, double-blind, placebo controlled clinical trial in children 6 to 12 diagnosed with Attention Deficit and Hyperactivity Disorder (ADHD) and characterized by impulsive aggression that is not controlled by optimal stimulant and psychosocial treatment. A total of 121 patients were randomized in the study across placebo and three doses of SPN-810.

The primary endpoints in the study were the effect in reducing impulsive aggression as measured with change in the score of the Retrospective - Modified Overt Aggression Scale "R-MOAS", and the rate of remission of aggression, after at least three weeks of treatment. Secondary endpoints included safety and tolerability of SPN-810 as well as the effect on the Clinical Global Impression and the Swanson, Nolan and Pelham Rating Scale (SNAP-IV) for ADHD. Patients who completed the study were offered the opportunity to continue into a six months open-label phase that is currently on-going. The study is a dose finding study with the primary objective of identifying effective doses in children of different weight groups.

Topline Results:

For all patients, low and medium doses of SPN-810 met the efficacy endpoint of rate of remission of aggression and showed statistical significance vs placebo with p-values of 0.009 and 0.043 and percent of patients with R-MOAS remission of 51.9% and 40.0%, respectively. The low and medium doses showed a reduction in score for the R-MOAS of 62.6% and 57.9%, respectively, with p-values of 0.071 and 0.115.

For patients of 30 kg or more in weight, the low and medium doses of SPN-810 showed statistical significance vs placebo on the change in R-MOAS primary endpoint with p-values of 0.024 and 0.049, and high percent reduction in the R-MOAS scores of 80.9% and 75.2%, respectively. In addition, both doses resulted in remission of aggression with statistical significance vs placebo with p-values of 0.004 and 0.021 with percent of patients with R-MOAS remission of 66.7% and 53.3%, respectively. The low dose also met the secondary endpoints of Clinical Global Impression for Severity and Improvement, and of the SNAP-IV rating for Oppositional Defiant Disorder with statistical significance vs placebo with p-values of 0.007, 0.017 and 0.039, respectively, and improvements of 41.3%, 34.5% and 49.3%. The high dose did not show statistically significant efficacy across any of these measures.

For patients under 30 kg in weight, while the low and medium doses showed improvements over placebo in the primary endpoints and the SNAP-IV rating for Oppositional Defiant Disorder, the studied doses did not show statistical significance vs placebo on efficacy measures. Coupled with the fact that the high dose did not show efficacy with statistical significance, this unexpected result leads us to believe that the most effective doses are those that achieve certain plasma concentrations (related to body weight) that do not exceed a level beyond which some sort of saturation threshold is reached.

Supernus will be conducting further analyses of the full dataset including analyzing the pharmacokinetic (PK) and pharmacodynamic (PD) relationship from the PK data generated from the study at various doses for patients in different weight groups.

"We are very excited about the positive results exhibited by SPN-810 at lower doses. The study accomplished its objectives of establishing a dose range at which the drug is effective and confirmed the efficacy of SPN-810 (molindone hydrochloride extended release formulation) in the treatment of impulsive aggression in ADHD patients," said Jack Khattar, Supernus president and CEO. "Because we have seen clear and consistent efficacy demonstrated by the low and medium doses in this study across several measures we have decided to advance the program into later stage development. We will be analyzing the full dataset in depth, and subsequently planning on meeting with the FDA to discuss next steps in the development program and the design and protocol for Phase III clinical trials."

SPN-810 was well tolerated throughout the study across all doses. The two serious adverse events that occurred were not drug related. One patient in the low dose arm and two patients in the medium dose arm had severe adverse events that were considered either possibly or definitely related to the drug. Six patients in total discontinued the study because of adverse events in the active treatment arms: one in low dose; two in medium dose; and three in high dose. Analysis of all safety and

clinical lab data has not yet been completed, though SPN-810 seemed to have a very good safety and tolerability profile with low incidence of adverse events, and no unexpected, life threatening, or limiting safety issues.

SPN-810 is a molecule that has been previously approved in the United States for treatment of other indications. It has a mechanism of action that Supernus believes is promising for the treatment of aggression and serious conduct problems. Approximately 25% of children with ADHD exhibit persistent conduct problems, such as impulsive aggression.

Currently there are no products approved for treating impulsive aggression in patients with ADHD and SPN-810 represents a novel approach to addressing this unmet medical need.

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, or CNS, diseases. The company has one approved product for epilepsy, Oxtellar XR™ (extended-release oxcarbazepine), and one tentatively approved product for epilepsy, Trokendi XR™ (extended-release topiramate). The company is also developing several product candidates in psychiatry to address large market opportunities in ADHD, including ADHD patients with impulsive aggression. These product candidates include SPN-810 for impulsive aggression in ADHD and SPN-812 for 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 achieve profitability; the Company's ability to raise sufficient capital to 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 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 respective PDUFA dates for 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 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 periodic reports and other filings made with the Securities and Exchange Commission. 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.

CONTACT: Jack Khattar, President & CEO

Gregory S. Patrick, Vice President and CFO

Supernus Pharmaceuticals, Inc.

Tel: (301) 838-2591

Source: Supernus Pharmaceuticals, Inc.

News Provided by Acquire Media