September 18, 2017

Supernus Provides Update on SPN-810 Phase III Clinical Trials

ROCKVILLE, Md., Sept. 18, 2017 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (NASDAQ:SUPN), a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases, today announced the outcome of the planned interim analysis from the first Phase III clinical trial on SPN-810.

The Company is developing SPN-810 as a novel treatment for impulsive aggression (IA) in patients aged 6 to 12 years who have attention deficit hyperactivity disorder (ADHD). SPN-810 is being tested in two Phase III clinical trials at total daily doses of 18 mg and 36 mg against placebo. The two trials are being conducted using an agreed-upon novel scale to measure IA that was developed by the Company with the FDA under a Special Protocol Assessment (SPA). The two trials are of the same design except that under the SPA, an interim analysis was planned in the first trial when one-half of the patients (146 patients) reached randomization.

The purpose of the interim analysis is to assess the doses being tested and allow for optimization of the trial design of both trials. The interim analysis was conducted by an independent third party statistician with clear and strict guidelines that do not compromise the quality or blinding of the trials and that were predefined under the SPA prior to the initiation of the trials. The benefit of structuring the first trial with an interim analysis is to enable the Company to implement certain actions that would maximize the probability of success. These actions include, but are not limited to: terminating the trials due to an expectation of futility; dropping one of the dose arms; increasing the number of patients to be recruited; or simply continuing the trials unchanged.

The interim analysis has been completed and both trials will continue through to completion. Based on the predefined criteria for dropping a dose arm, the lower dose of 18 mg will be eliminated. Moving forward, all patients will be randomized to either the 36 mg dose arm or placebo until the predetermined total number of patients are enrolled without changing the size of the trials. The Company believes that this will maximize the probability of reaching a statistically significant outcome for the 36 mg dose. Implementation of these changes will start immediately. We continue to expect enrollment through mid-2018.

Current enrollment is at approximately 64% for the first trial and 56% for the second trial. Enrollment in the open label extension study continues to be very encouraging at a high level of 90%.

"We are pleased to have included an interim analysis in the design of the first trial that allows us to implement predefined measures to optimize the trials and better position them for success. We are committed to bringing this novel treatment to patients who currently have no proven and approved options," said Jack Khattar, President & CEO of Supernus Pharmaceuticals.

Conference Call Details

The Company will hold a conference call hosted by Jack Khattar, President and Chief Executive Officer, and Stefan Schwabe, Executive Vice President and Chief Medical Officer at 5:00 p.m. ET, on Monday, September 18, 2017. An accompanying webcast also will be provided.

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: 88391639

Conference Call Name: Supernus Pharmaceuticals SPN-810 Conference Call

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

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 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 psychiatry, including SPN-810 for the treatment of IA 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 successfully complete the development of its product candidates including SPN-810; 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 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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Source: Supernus Pharmaceuticals, Inc.