Supernus Submits New Drug Application for SPN-812 for the Treatment of ADHD

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SPN-812 (viloxazine hydrochloride), a novel serotonin norepinephrine modulating agent (SNMA)

ROCKVILLE, Md., Nov. 11, 2019 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (Nasdaq: SUPN), a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases, today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for SPN-812 for the treatment of patients with attention deficit hyperactivity disorder (ADHD).

SPN-812 is a well differentiated product candidate that, if approved by the FDA, can become a unique multi-symptom treatment option for many patients with ADHD. It is a non-controlled substance that is easy to use and that has shown in clinical studies a reduction in ADHD symptoms observed as early as week one and continued until the end of the studies.

“This NDA submission is an important milestone in the development of SPN-812, which if approved by the FDA, has the potential of becoming the first novel treatment to be introduced in the ADHD market in more than a decade,” said Jack A. Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. “In addition, SPN-812 represents the foundation on which we will be building a strong presence in psychiatry.”

The NDA for SPN-812 includes data from an extensive development program consisting of four Phase III clinical trials that studied the pediatric patient population from the age of 6 to 17 years, two Phase II clinical trials, several Phase I trials, long-term open label extension study, preclinical testing, and drug manufacturing data.

In addition, we announced last week that we initiated a Phase III program to study SPN-812 in the adult ADHD patient population.

About SPN-812

SPN-812 is a serotonin norepinephrine modulating agent (SNMA) 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 treatments for ADHD due to its novel mechanism of action and 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 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-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 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; 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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