Supernus Announces FDA Acceptance for Review of New Drug Application for SPN-812 for the Treatment of ADHD

January 21, 2020

SPN-812 (viloxazine hydrochloride), a once-daily novel serotonin norepinephrine modulating agent (SNMA), demonstrates a reduction in ADHD-RS-5 total score as early as Week 1 and continuing until the end of the pivotal clinical studies

ROCKVILLE, Md., Jan. 21, 2020 (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 the U.S. Food and Drug Administration (FDA) has found the New Drug Application (NDA) for SPN-812 for the treatment of children and adolescents with attention deficit hyperactivity disorder (ADHD) acceptable for review. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of November 8, 2020.

“SPN-812, if approved by the FDA, will be the first truly new therapy to treat ADHD in a decade,” said Jack A. Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. “This is critical for the nearly 6.1 million children and adolescents in the U.S. who are diagnosed with the condition and are in need of a treatment that is a non-controlled substance and that works differently from currently available treatments.”

The NDA for SPN-812 is based on 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, a long-term open label extension study, preclinical testing, and drug manufacturing data. Each of the four pivotal clinical trials showed a reduction in ADHD-RS-5 total score as early as Week 1 and continuing until the end of the clinical study, as well as improvement in both hyperactivity/impulsivity and inattention subscales. The effect was statistically significant for the studies for 100mg, 200mg, and 400mg doses. SPN-812 had an acceptable safety profile with low incidence of adverse events and low discontinuation rates.

In addition, during the fourth quarter of 2019, the Company 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, SPN-810 for the treatment of impulsive aggression, 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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