Supernus Resubmits New Drug Application for SPN-812 for the Treatment of ADHD in Pediatric Patients

February 8, 2021

ROCKVILLE, Md., Feb. 08, 2021 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (Nasdaq: SUPN), a biopharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases, today announced it has resubmitted its New Drug Application (NDA) for SPN-812 for the treatment of ADHD in pediatric patients. The U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding the NDA in November 2020 indicating that the review cycle for the application was incomplete and that the application was not ready for approval in its present form. Supernus and the FDA held a Type A meeting in January 2021 to discuss the CRL and the requirements for the NDA resubmission.

The primary issue cited in the SPN-812 CRL relates to the Company's in-house laboratory that conducts analytical testing, which recently moved to a new location. In the NDA resubmission Supernus removed reference to its in-house laboratory and addressed other contents of the CRL.

The FDA will classify the NDA resubmission as Class I or Class II upon acceptance of the resubmission. Generally, a Class I review constitutes a two-month review from the date of resubmission and a Class II review constitutes a six-month review from the date of resubmission.

In December 2020, Supernus announced positive results from a Phase III study for SPN-812 in adults with ADHD. The Company plans to submit a supplemental NDA to the FDA for SPN-812 in adults in the second half of 2021, assuming approval for pediatric patients.

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals, Inc. is a biopharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases.

Our diverse neuroscience portfolio includes approved treatments for epilepsy, migraine, hypomobility in Parkinson's Disease, cervical dystonia and chronic sialorrhea. We are committed to developing a broad range of novel CNS product candidates to address high unmet medical needs. Our development programs include new potential treatments for attention-deficit hyperactivity disorder, hypomobility in Parkinson's Disease, epilepsy, depression, and rare CNS disorders. For more information, please visit https://www.supernus.com/.

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. These forward-looking statements include expectations regarding the Company's recent and future interactions and communications with the FDA, the potential approval of the NDA for SPN-812 following resubmission, the planned submission of an sNDA to the FDA for SPN-812 in adults and the potential benefits and commercialization of SPN-812. 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 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 products and 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; 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.

CONTACTS:

Jack A. Khattar, President and Chief Executive Officer
Jim Kelly, EVP & Chief Financial Officer
Supernus Pharmaceuticals, Inc.
Tel: (301) 838-2591

or

INVESTOR CONTACT:
Peter Vozzo
Westwicke/ICR
Office: (443) 213-0505
Mobile: (443) 377-4767
Email: peter.vozzo@westwicke.com

Source: Supernus Pharmaceuticals, Inc.