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Supernus Receives FDA Fast Track Designation for SPN-810

ROCKVILLE, Md., Aug. 14, 2014 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (Nasdaq:SUPN), a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system diseases, today announced that the United States Food and Drug Administration (FDA) has granted fast track designation for SPN-810 for the treatment of impulsive aggression in attention deficit hyperactivity disorder (ADHD). This product candidate is expected to enter Phase III testing, with patient dosing commencing during 2015.

Fast track designation is for products that are being investigated for treatment of serious conditions, and for which nonclinical or clinical data suggest that they may address an unmet medical need. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. The fast track designation allows for more frequent interactions between the FDA and the Company, allows for the early submission of some sections of the marketing application, and carries the potential for an expedited review category for the New Drug Application.

"We are pleased that the FDA has approved our application for a fast track designation for SPN-810," said Jack Khattar, President and Chief Executive Officer for Supernus Pharmaceuticals, Inc. "As a high-priority pipeline product, this designation reinforces our belief that SPN-810 can be a breakthrough product for treating patients with impulsive aggression. We look forward to working closely with the FDA to get this treatment to patients in an expedited manner."

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 (CNS) diseases. The Company has two marketed products for epilepsy, Oxtellar XR® (extended-release oxcarbazepine) and 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 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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