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Supernus Announces Issuance of First Use Patents Protecting SPN-812 as a Novel Non-Stimulant ADHD Product

ROCKVILLE, Md., Jan. 27, 2014 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (Nasdaq:SUPN), a specialty pharmaceutical company, today announced the issuance of a European patent (number 2341912) and Canadian patent (number 2,735,934) for SPN-812, its novel non-stimulant product candidate for the treatment of ADHD. These patents will provide protection for the product with expiration that is no earlier than 2029. Supernus has several additional patent applications for SPN-812 pending in other geographic regions, including the United States.

"These are the first patents to issue on SPN-812 covering its novel use as a non-stimulant for treatment of ADHD. We expect the product to have a highly differentiated clinical profile. Long term protection provided by the various patent applications coupled with its new chemical entity (NCE) status in the U.S. market is critical to realizing the full commercial value for this product," said Jack A. Khattar, President and CEO of Supernus.

About SPN-812

SPN-812 is a selective norepinephrine reuptake inhibitor that Supernus believes could be more effective and with an improved side effect profile compared to other non-stimulant treatments for ADHD due to its different pharmacological profile. The active ingredient in SPN-812 has an extensive safety record in Europe, where it was previously marketed for many years as an antidepressant. The product successfully completed a randomized, double-blind, placebo-controlled trial in 52 adults with a current diagnosis of ADHD (26 subjects per treatment group). SPN-812 met the study's primary endpoints of safety and tolerability, and achieved overall significant median reductions from baseline in investigator-rated CAARS total ADHD symptom scores by study end, -11.5 points vs. -6.0 for placebo (p=0.0414) and in self-rated CAARS total symptom scores by study end, -10.5 points vs. -1.0 for placebo (p=0.0349). Conners' Adult ADHD Rating Scale, or CAARS, is a commonly-used measurement for ADHD in adults.

We continue to progress SPN-812 and have completed the development of several extended release formulations that will be tested in a pharmacokinetic study in the first half of 2014 to select the final formulation for use in the Phase IIb trial.

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, or 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 contains forward-looking statements regarding the potential efficacy of SPN-812 and intellectual property protection of this product candidate. Actual results may differ materially from those in these forward-looking statements as a result of various factors, including, but not limited to, risks regarding the company's ability to obtain all required regulatory approvals of this product candidate, the Company's ability to commercialize the product candidate successfully, whether physicians will prescribe and patients will use the product candidate, and competition in the market. For a further description of these and other risks facing the Company, please see the risk factors described in the Company's Annual Report Form 10-K that was filed with the United States Securities and Exchange Commission on March 15, 2013 and under the caption "Risk Factors" and the updates to these risk factors in the Company's quarterly report form 10-Q that was filed with the Commission on August 14, 2013. Forward-looking statements speak only as of the date of this press release, and the company undertakes no obligation to update or revise these statements, except as may be required by law.

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