Supernus Pharmaceuticals Initiates Phase IIb Clinical Trial for SPN-810 in Impulsive Aggression

Study Measures Efficacy, Safety and Tolerability of Novel Therapy for Treatment of Impulsive Aggression in Children with ADHD

Rockville, MD, November 28, 2011 — today announced the initiation of a Phase IIb U.S. clinical trial of its product candidate SPN-810 in the treatment of impulsive aggression in the setting of ADHD. The study is a multi-center randomized, double-blind, placebo controlled clinical trial in children 6 to 12 diagnosed with Attention Deficit and Hyperactivity Disorder (ADHD) and characterized by impulsive aggression that is not controlled by optimal stimulant and psychosocial treatment.

The primary objective of the study is the effect of SPN-810, given at three different dose levels, in reducing impulsive aggression (measured with the Modified Overt Aggression Scale), after at least three weeks of treatment. Secondary objectives include safety and tolerability of SPN-810 as well as the effect on the Clinical Global Impression and the SNAP-IV Questionnaire to monitor the underlying ADHD condition. Patients who complete the study are offered the opportunity to continue into an open-label phase of six months duration.

SPN-810 is a molecule that has been previously approved in the United States for treatment of other indications. It has a mechanism of action that is promising for the treatment of aggression and serious conduct problems. Approximately 25% of children with ADHD exhibit persistent conduct problems, such as impulsive aggression. Currently there are no products approved for treating impulsive aggression in patients with ADHD.

"The initiation of this study demonstrates our commitment to developing SPN-810 as a novel approach to addressing this unmet medical need," said Jack Khattar, Supernus president and CEO. "We are excited about the progress we have achieved on SPN-810 since we received positive Phase IIa results in 2010. We look forward to continuing to advance SPN-810 in the clinic and potentially bringing its unique benefits to children diagnosed with ADHD with impulsive aggression."

About Supernus

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's extensive expertise in product development has been built over the past 20 years: initially as a stand alone development organization, then as a U.S. subsidiary of Shire plc and, upon its acquisition of substantially all the assets of Shire Laboratories Inc. in late 2005, as Supernus Pharmaceuticals. The company is developing several product candidates in neurology and psychiatry to address large market opportunities in epilepsy, ADHD and depression. In addition to its two ADHD product candidates, Supernus is developing two late stage epilepsy product candidates, SPN-538 (extended release topiramate), and SPN-804 (extended release oxcarbazepine).

Supernus' proprietary technologies have been used in the following approved and marketed products: Carbatrol®, Equetro®, Adderall XR®, Sanctura XR®, Oracea® and Intuniv®.

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