Supernus Pharmaceuticals Announces Positive Results from Phase IIa Clinical Trial for SPN-812 in Adults with ADHD

Study Shows Statistically Significant Reduction in ADHD Symptoms for Novel Non-Stimulant Therapy

SPN-812 Represents Second Program in ADHD Area with Positive Phase IIa Results, Following Positive Phase IIa Results for SPN-810

Rockville, MD, March 11, 2011 – Supernus Pharmaceuticals, Inc. today announced that its Phase IIa U.S. clinical trial of SPN-812 in adults for the treatment of attention deficit hyperactivity disorder (ADHD) met the primary endpoints of safety and tolerability, and showed statistically significant median reduction versus placebo in both investigator-rated and patientrated ADHD symptom scores. The trial was a randomized, double-blind, placebo-controlled trial in 52 adults with a current diagnosis of ADHD (26 subjects per treatment group).

"We are very excited about these positive results as we advance our second ADHD portfolio product candidate in development and continue to make steady progress across all of our pipeline product candidates," said Jack Khattar, Supernus president and CEO. "About 13 million Americans are estimated to suffer from ADHD, and about 30% of patients do not adequately respond to or cannot tolerate stimulant ADHD treatments. The pharmacological profile of SPN-812 is promising for the treatment of ADHD and could represent an alternative to existing ADHD regimens in the United States."

Patients in the active arm were administered SPN-812 at a single dose level three times a day over five weeks, after a one-week titration phase. The primary endpoint was safety, and SPN-812 was shown to be safe and well tolerated by patients. The secondary endpoints included: the efficacy of SPN-812 as measured by Total ADHD Symptom Score on the Conners' Adult ADHD Rating Scale, or CAARS, a commonly-used measurement for ADHD in adults, as rated by each of the investigators and the patients; and the effectiveness of SPN-812 when compared to placebo as determined by changes in the Clinical Global Impressions—Improvement, or CGI-I, score. Subjects in the active group 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). With respect to the secondary endpoint of CGI-I scores, patients exhibited a trend, although not statistically significant, toward larger median reductions in scores from baseline vs. placebo.

"Because this proof-of-concept study was not designed to show a definitive statistical significant separation from placebo on the primary efficacy outcome, we are extremely pleased to have observed such a strong signal in such a small study," said Paolo Baroldi, senior vice president and chief medical officer of Supernus. "The results are also encouraging because we used an immediate-release formulation in the study, which we believe to be less than optimal when compared to an extended-release formulation. With an extended-release formulation of SPN-812, we believe we could achieve a much better release profile and therefore optimize this clinical outcome."

SPN-812 is the company's second ADHD-related program. Supernus is also developing SPN-810 (molindone hydrochloride), a novel treatment for impulsive aggression in patients with ADHD. In 2010, Supernus reported positive results from the Phase IIa trial of SPN-810, its investigational candidate for treatment of children with ADHD and persistent serious conduct problems. SPN-810 met the primary endpoints of safety and tolerability, and showed statistically significant reduction versus baseline in serious persistent conduct problems across all doses. The company is currently planning to initiate a phase IIb trial for SPN-810.

About ADHD in Children and Adults

ADHD is a common CNS disorder characterized by developmentally inappropriate levels of inattention, hyperactivity, and impulsivity. ADHD affects an estimated 6% to 9% of all school-age children and 3% to 5% of adults in the United States. An estimated 60% to 80% of children with ADHD continue to meet criteria for ADHD into adolescence. In 2008, the U.S. market for ADHD prescription drugs was more than $4 billion.

About SPN-812

SPN-812 is a selective norepinephrine reuptake inhibitor that Supernus believes could be more effective and have a better side effect profile than 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.

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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