Supernus Provides Update on Results from Phase III Study (P301) of SPN-810 for Treatment of Impulsive Aggression (IA) in ADHD Patients

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ROCKVILLE, Md., Dec. 09, 2019 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (Nasdaq: SUPN), a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases, is providing an update on the results from the first Phase III study (P301) of SPN-810, a novel treatment of Impulsive Aggression (IA) in patients with ADHD.

In early November 2019, the Company reported topline results from the Phase III P301 trial in patients 6 to 11 years. The study was a randomized, double-blind, placebo controlled, multicenter, parallel group clinical trial in patients diagnosed with ADHD. Patients receiving SPN-810 36mg showed a median percent reduction of 58.6% in the average weekly frequency of impulsive aggression episodes from baseline that was not statistically significant (p=0.092) compared to placebo. These results are based on the combined analysis of data from stages 1 and 2 in the study. In stage 1 (interim analysis stage), the median percent reduction was 60.0%, which was statistically significant (p=0.029) compared to placebo. However, in stage 2 of the P301 study, post the interim analysis, the increase in variability in the 36mg treatment arm seems to have adversely impacted the results in the combined analysis.

After conducting further analysis on the P301 data, the Company believes that the high variability in the 36mg treatment arm was primarily due to 6 patients out of 135 that had a mild IA condition with a baseline score of 6 episodes or less per week. In the placebo arm, there were 7 patients with the same mild IA condition. By excluding these subjects from the placebo and the 36mg treatment arm, the primary analysis (combined stage 1 and 2 data) of the P301 data on the primary endpoint results in a p value of 0.017 for the treatment arm compared to placebo. This positive result is also confirmed by the sensitivity analysis on the primary endpoint with a p value of 0.044.

Percent Change from Baseline (CFB) in the Frequency of IA Behaviors
Treatment Period - Primary Analysis (ITT Population)

	Original Analysis		**Analysis Excluding Patients with Baseline Score of 6 or less Episodes per Week**	
Stage 1 - % CFB	**Placebo**	**SPN-810 36mg**	**Placebo**	**SPN-810 36mg**
N	52	45	50	44
Mean (SD)	-42.9 (35.9)	-56.6 (34.1)	-44.8 (29.9)	-55.6 (33.8)
Median	-48.6	-60.0	-48.6	-57.8
P-value		0.029		0.039
Stage 2 - % CFB				
N	73	90	68	85
Mean (SD)	-43.8 (36.3)	-44.0 (43.5)	-42.0 (35.3)	-49.1 (36.6)
Median	-47.2	-58.5	-46.2	-59.2
P-value		0.5370		0.119
Stages 1 & 2 Combined - % CFB				
N	125	135	118	129
Mean (SD)	-43.4 (36.0)	-48.2 (40.9)	-43.2 (33.0)	-51.3 (35.7)
Median	-48.2	-58.6	-47.2	-59.2
P-value		0.092		0.017

The Company plans on finalizing the statistical plan (SAP) for the second Phase III P302 study in patients 6 to 11 years old taking into consideration the exclusion of patients with 6 or less episodes of IA per week. The Company will be submitting the SAP to the Food and Drug Administration (FDA) and expects data from the P302 study in the first quarter of 2020.

The P503 adolescent Phase III study in patients 12 to 17 years old had been designed from the outset with an exclusion criterion that excludes patients with a baseline score of 6 or less episodes per week.

“Based on this new analysis, we are hopeful that the second Phase III study will be positive, and if so, that future discussions with the FDA will be productive in progressing this potential novel treatment,” said Jack Khattar, President and CEO of Supernus. “While there are no assurances that SPN-810 will eventually progress forward and obtain FDA approval, we continue to believe that with a clinically meaningful reduction of approximately 60% in IA episodes, it can be a real treatment option for patients who currently have no proven products to help them manage their condition,” added Mr. Khattar.

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals, Inc. is a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. The Company currently markets Trokendi XR® (extended-release topiramate) for the prophylaxis of migraine and the treatment of epilepsy, and Oxtellar XR® (extended-release oxcarbazepine) for the treatment of epilepsy. The Company is also developing several product candidates to address large market opportunities in the CNS market, including SPN-812 for the treatment of ADHD and SPN-604 for the treatment of bipolar disorder.

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 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 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 including SPN-810; 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 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.

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