Supernus Provides Regulatory Updates for SPN-812 and SPN-830

November 9, 2020

ROCKVILLE, Md., Nov. 09, 2020 (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, today announced regulatory updates for SPN-812 (viloxazine hydrochloride) for the treatment of attention-deficit hyperactivity disorder (ADHD) in pediatric patients 6 to 17 years of age, and SPN-830 (apomorphine infusion pump) for the continuous treatment of motor fluctuations ("on-off" episodes) in Parkinson's disease (PD).

SPN-812 - Novel non-stimulant for the treatment of ADHD

The U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for SPN-812 for the treatment of ADHD in pediatric patients 6 to 17 years of age. The FDA issued a CRL to indicate that the review cycle for the application is complete and that the application is not ready for approval in its present form.

The primary issue cited in the SPN-812 CRL relates to the Company's in-house laboratory that conducts analytical testing, which recently moved to a new location. The Company plans to discuss with the FDA the contents of the CRL and clarify to the FDA that the application does not rely solely on this facility for product release. We plan to discuss with the agency the steps required for the resubmission of the NDA for SPN-812. Importantly, no clinical safety or efficacy issues were identified during the review.

SPN-830 (apomorphine infusion pump) - Continuous treatment of motor fluctuations ("on-off" episodes) in PD

The Company received a Refusal to File (RTF) letter from the FDA regarding its NDA for SPN-830 (apomorphine infusion pump) for the continuous treatment of motor fluctuations ("on-off" episodes) in Parkinson's disease (PD). In its review of the NDA, which was submitted in September 2020, the FDA determined that the NDA was not sufficiently complete to permit a substantive review. In the letter, the FDA requested certain documents and reports to be submitted in support of the application.

The Company plans to seek guidance from the FDA, including a Type A meeting, to discuss the contents of the RTF letter and clarify the steps required for the resubmission of the NDA for SPN-830.

"On SPN-812, we look forward to collaborating with the FDA to clarify and resolve the facility matter and put SPN-812 back on track to help the millions of children and adolescents in the U.S. with ADHD," said Jack Khattar, President and CEO of Supernus. "Regarding SPN-830, we remain confident in the data package for SPN-830 and its promise as an important treatment option for PD patients who experience motor fluctuations associated with on-off episodes. We are fully committed to working with the FDA to address its letter and successfully refile our SPN-830 NDA."

The Company plans to provide updates on the NDA status and expected launch timing for both SPN-812 and SPN-830 once it has had further discussions with the FDA and has agreed on the path forward for each program.

Full Year 2020 Financial Guidance

The Company reiterates its full year 2020 net product sales and research and development expenses guidance and provides an update to its full year 2020 selling, general and administrative expenses and operating earnings (GAAP) guidance to reflect the expected impact of the SPN-812 CRL on the fourth quarter of 2020. SPN-812 commercial launch preparation activities continue and Supernus expects to achieve the following financial objectives in 2020:

Full Year 2020 Financial Objectives	**Full Year 2020 Guidance** ***($ in millions)***
Net product sales	$500 - $525
Research and development expense	Approximately $75
Selling, general and administrative expenses	$205 – $215, as compared to prior guidance of $215 - $225
Amortization of intangible assets	$16
Operating earnings (GAAP)[(1)]	$155 - $170, as compared to prior guidance of $145 - $160

[(1)] Generally accepted accounting principles (GAAP). Operating earnings including amortization of intangible assets.

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 markets Trokendi XR® (extended-release topiramate) for the prophylaxis of migraine and the treatment of epilepsy; Oxtellar XR® (extended-release oxcarbazepine) for the treatment of epilepsy; APOKYN® (apomorphine hydrochloride injection) for the acute treatment of hypomobility in advanced Parkinson's disease (PD); MYOBLOC® (rimabotulinumtoxinB) for the treatment of cervical dystonia and treatment of chronic sialorrhea in adults; and XADAGO® (safinamide) as an adjunctive treatment to levodopa/carbidopa in PD patients with hypomobility. 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; SPN-830 (apomorphine infusion pump) for the continuous treatment of motor fluctuations ("on-off" episodes) in PD; SPN-820 for treatment-resistant depression; and SPN-817 for the treatment of epilepsy.

See full Prescribing Information for our products here: Trokendi XR, Oxtellar XR, APOKYN, MYOBLOC, and XADAGO.

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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. These forward-looking statements include expectations regarding the Company's future interactions and communications with the FDA, including its expectation to discuss with the FDA the issues raised in the CRL regarding the NDA for SPN-812 for the treatment of ADHD in pediatric patients 6 to 17 years of age and the Company's plans to address them, the Company's future resubmission of the NDA for SPN-812, the potential approval of the NDA for SPN-812 following resubmission and the potential benefits and commercialization of SPN-812, and the Company's expectation to discuss with the FDA the issues raised in the RTF letter relating to the NDA for SPN-830 (apomorphine infusion pump) and the Company's plans to address them, the Company's future resubmission of the NDA for SPN-830, the potential approval of the NDA for SPN-830 following resubmission and the potential benefits and commercialization of SPN-830. 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 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 products and 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; 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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