Supernus Provides Regulatory Update on SPN-830

October 10, 2022

ROCKVILLE, Md., Oct. 10, 2022 (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 that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) for the SPN-830 New Drug Application (NDA). SPN-830 is an investigational apomorphine infusion device under review for the continuous treatment of motor fluctuations (OFF episodes) in Parkinson's disease (PD).

The CRL requires additional information and analysis related to the infusion device and drug product across several areas of the NDA including, but not limited to, labeling, product quality and manufacturing, device performance and risk analysis. In addition, the FDA mentions that approval of the NDA requires inspections that could not be completed in a timely manner due to COVID-19 travel restrictions. The CRL does not request additional efficacy and safety clinical studies. Supernus will continue to work closely with the FDA to address all questions, and when possible, to provide clarity regarding the potential timing of a resubmission of the NDA. The FDA has made an initial determination that the amendment to the Company's application in response to the CRL will be subject to a Class 2, or six-month, review timeline.

"SPN-830 remains a key priority for Supernus as there is a need to provide a minimally invasive therapy for PD patients who are experiencing motor fluctuations not adequately controlled with current treatment options," said Jack Khattar, President and CEO of Supernus. "We are committed to PD patients and to working with the FDA to address the CRL issues so that we can put the NDA back on track towards potential U.S. approval."

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals is a biopharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases.

Our diverse neuroscience portfolio includes approved treatments for epilepsy, migraine, ADHD, hypomobility in Parkinson's disease (PD), cervical dystonia, chronic sialorrhea, dyskinesia in PD patients receiving levodopa-based therapy, and drug-induced extrapyramidal reactions in adult patients. We are developing a broad range of novel CNS product candidates including new potential treatments for hypomobility in PD, epilepsy, depression, and other CNS disorders.

For more information, please visit www.supernus.com.

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 commercialize its products including Qelbree; 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-830; 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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