Supernus Resubmits NDA for SPN-830 Apomorphine Infusion Device

October 9, 2023

ROCKVILLE, Md., Oct. 09, 2023 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (Nasdaq: SUPN), a biopharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases, today announced it has resubmitted its New Drug Application (NDA) for its apomorphine infusion device (SPN-830) for the continuous treatment of motor fluctuations (OFF episodes) in Parkinson's disease (PD).

Working closely with the U.S. Food and Drug Administration (FDA), Supernus believes it has addressed the FDA's questions related to a Complete Response Letter (CRL) issued in October 2022 for the SPN-830 New Drug Application (NDA). The CRL required additional information and analysis related to the infusion device and drug product across several areas of the NDA. In addition, the FDA mentioned at the time that approval of the NDA required inspections that could not be completed in a timely manner due to COVID-19 travel restrictions. The CRL did not request additional efficacy and safety clinical studies. Supernus will continue to work closely with the FDA as it reviews the SPN-830 NDA.

"SPN-830 represents a novel and less invasive therapy approach for PD patients who are seeking a convenient option in the form of a continuous subcutaneous infusion of apomorphine," said Jack Khattar, President and CEO of Supernus. "We look forward to continuing our effort with the FDA throughout the NDA review process to bring a promising alternative to patients and their families."

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.

CONTACT:

Jack A. Khattar, President and CEO
Timothy C. Dec, Senior Vice President and CFO
Supernus Pharmaceuticals, Inc.
Tel: (301) 838-2591

Or

INVESTOR CONTACT:

Peter Vozzo
ICR Westwicke
Office: (443) 213-0505
Email: peter.vozzo@westwicke.com

Source: Supernus Pharmaceuticals, Inc.