Supernus Provides Regulatory Update for SPN-830

ROCKVILLE, Md., April 8, 2024 – 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 a regulatory update for SPN-830. SPN-830 is an investigational apomorphine infusion device for the continuous treatment of motor fluctuations ("off" episodes) in Parkinson's disease (PD) under U.S. Food and Drug Administration (FDA) review.

The FDA has issued a Complete Response Letter (CRL) in response to the Company's New Drug Application (NDA) for SPN-830. The CRL indicates that the review cycle for the application is complete, but that the application is not ready for approval in its present form.

The CRL mentions two areas that require additional review by the FDA or additional information to be provided to the FDA. The first area relates to product quality. The Company recently submitted additional product quality data to the FDA which it has not yet reviewed. The second relates to the master file for the infusion device which is proprietary to the device manufacturer. The Company plans to discuss with the device manufacturer the provision of the requested information and the steps required for the resubmission of the NDA for SPN-830. No clinical safety or efficacy issues were identified as a requirement for approval. The FDA completed in February 2024 a successful preapproval inspection of the device manufacturer's facility.

"We remain committed to bringing SPN-830 to the market as an important treatment option for PD patients who experience motor fluctuations associated with off episodes. We will work with the FDA to address the CRL and to successfully resubmit our SPN-830 NDA," said Jack Khattar, President & CEO of Supernus.

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals, Inc. 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 and the products of its subsidiaries; the Company's ability to increase its net revenue; the Company's ability to commercialize its products and the products of its subsidiaries; 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 the intellectual property of its subsidiaries 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 including SPN-830; 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 including SPN-830; 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; the Company's ability to increase the number of prescriptions written for each of its products and the products of its subsidiaries; the Company's ability to increase its net revenue from its products and the products of its subsidiaries; 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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