Supernus Announces Topline Results from Phase 2b Study in Adults with Treatment Resistant Depression

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- *Study did not demonstrate statistically significant improvement on primary endpoint of reduction in depressive symptoms as measured by MADRS total score compared to placebo*
- *SPN-820 was well-tolerated with few adverse events, consistent with previously reported studies*

ROCKVILLE, Md., Feb. 18, 2025 (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, announced today that the Phase 2b study of SPN-820 in adults with treatment-resistant depression (TRD) did not demonstrate a statistically significant improvement on the primary endpoint of change from baseline in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score to Week 4 (SPN-820 [LS mean ± Standard Error]: -12.3 ± 0.96 vs. placebo: -11.9 ± 0.96; p = not significant). There was no treatment difference between SPN-820 and placebo in the change from baseline to Week 4 for the secondary endpoints. The safety profile of SPN-820 was consistent with previous clinical trials, showing few adverse events.

“We are disappointed that the trial did not meet its primary endpoint in this patient population,” said Jack Khattar, President and CEO of Supernus. “We will continue to analyze these data and discuss the future of the program with our development partner, Navitor Pharmaceuticals. I’d like to thank the patients, coordinators and investigators, as well as the development team at Supernus, for their time and efforts in conducting this trial.”

About the SPN-820 Phase 2b Clinical Study
The Phase 2b study was a multi-center, randomized, double-blind, placebo-controlled trial of SPN-820 in adults with TRD. The study examined the efficacy and safety of SPN-820 over a course of four weeks of treatment and then a week of blinded placebo-washout in approximately 250 patients from approximately 40 clinical sites. The primary outcome measure was the change from baseline to end of treatment period on the MADRS Total Score.

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 attention-deficit hyperactivity disorder (ADHD), dyskinesia in Parkinson’s disease (PD) patients receiving levodopa-based therapy, hypomobility in PD, epilepsy, migraine, cervical dystonia, and chronic sialorrhea. We are developing a broad range of novel CNS product candidates including new potential treatments for 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 including ONAPGO; 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; 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, including ONAPGO, 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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