Supernus Announces Promising Data from Open-Label Phase 2a Study of SPN-820 in Adults with Major Depressive Disorder

October 17, 2024

Phase 2a study demonstrated rapid and substantial decrease in depressive symptoms

SPN-820 was well-tolerated with few adverse events

SPN-820 is a novel, first-in-class intracellular modulator of mTORC1 for the treatment of depression

Company to host webcast today at 4:30 p.m. ET to discuss the topline data

Topline results from Phase 2b randomized double-blind placebo-controlled study of SPN-820 in adults with treatment-resistant depression expected first-half 2025

ROCKVILLE, Md., Oct. 17, 2024 (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 data from its exploratory open-label Phase 2a clinical study of SPN-820 in adults with major depressive disorder. The study examined the safety and tolerability of SPN-820 2400 mg given once every 3 days as an adjunctive treatment to the current baseline antidepressant therapy, as well as assessed the rapid onset of improvement in depressive symptoms. The analysis is based on 40 enrolled subjects, of which 38 completed the 10-day treatment period.

Summary of the Data

- Clinically meaningful improvement of –6.1 at two hours and –9.6 at Day 10 on the Hamilton Depression Rating Scale-6 Items (HAM-D6) total score.
- Clinically meaningful improvement of –16.6 at four hours and –22.9 at Day 10 on the Montgomery Åsberg Depression Rating Scale (MADRS) total score.
- Suicidal ideation decreased by 80% (12.5% with suicidal ideation at baseline decreased to 2.6% with suicidal ideation at Day 10).
- SPN-820 was well-tolerated with few adverse events (AEs) and had acceptable tolerability with a discontinuation rate of 2.5% due to AEs.
- Most common AEs related to the drug included headache, nausea, somnolence, and dizziness. Additional AEs such as cognitive disorder, dry mouth, fatigue, nasal decongestion, and paresthesia oral were observed.

“These Phase 2a data underscore our belief that SPN-820 has the potential as a novel treatment option for patients with depression, with the opportunity to decrease symptoms quickly and without certain burdensome side effects,” said Jack Khattar, President and CEO of Supernus. “We expect to complete enrollment in the Phase 2b randomized double-blind placebo-controlled study of SPN-820 in adults with treatment-resistant depression in November of this year, with topline results expected in the first half of 2025.”

Webcast Details

Supernus will host a conference call and webcast today, October 17, 2024, at 4:30 p.m. ET to discuss these topline results. A live webcast with presentation slides will be available via this webcast link or in the Events & Presentations section of the Company’s Investor Relations website at www.supernus.com/Investors. Following management’s prepared remarks and discussion of the interim trial results, the call will open for questions.

Participants may also pre-register any time before the call here. Once registration is completed, participants will be provided a dial-in number with a personalized conference code to access the call. Please dial in 15 minutes prior to the start time.

Following the live call, a replay will be available on the Company's Investor Relations website at www.supernus.com/Investors. The webcast will be available on the Company’s website for 60 days following the live call.

About SPN-820

SPN-820 is a first-in-class, orally active small molecule that increases the brain mechanistic target of rapamycin complex 1 (mTORC1) mediated synaptic function intracellularly. SPN-820 is being developed to provide a rapid-onset antidepressant response via oral administration for adult patients with depression. The compound has a novel mechanism of action that enhances synaptic activity and cellular metabolism in the brain and has demonstrated a rapid onset of action (signal at two hours) in early clinical studies. SPN-820 is expected to provide rapid antidepressant efficacy without potential dissociative side effects. A Phase 2b clinical study of SPN-820 in approximately 227 adult patients with treatment-resistant depression is ongoing.

About the SPN-820 Phase 2a Clinical Study

The study is a Phase 2a open-label study in 40 subjects with major depressive disorder (MDD). The primary objective of the study is to assess efficacy in MDD, as well as onset of efficacy and safety.

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, and dyskinesia in PD patients receiving levodopa-based therapy. 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 reporting on preliminary and exploratory open label clinical study on SPN-820, 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 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 ability to conduct and progress 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-820; 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-820; 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-820; 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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