Supernus Presents Promising Data from Open-Label Phase 2a Study of SPN-820 Data in Major Depressive Disorder at Psych Congress 2024

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Participants in the Phase 2a study experienced rapid and meaningful decreases in depressive symptoms

Suicidal ideation decreased by 80%

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

ROCKVILLE, Md., Oct. 31, 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, announced data in a poster presentation at Psych Congress 2024 with new data from its exploratory open-label Phase 2a clinical study of SPN-820 in adults with major depressive disorder (MDD). The study examined the safety and tolerability of 2400 mg of SPN-820 given once every three days as an adjunctive treatment to the current baseline antidepressant therapy and assessed the rapid onset of improvement in depressive symptoms. The study included 40 enrolled subjects, of which 38 completed the 10-day treatment period.

In the Phase 2a study, SPN-820 demonstrated a 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), as well as a clinically meaningful improvement of -16.6 at four hours and -22.9 at Day 10 on the Montgomery Åsberg Depression Rating Scale (MADRS).

New data from the Phase 2a study presented at Psych Congress 2024 demonstrate a rapid MADRS response rate (≥50% reduction) and remission (MADRS ≤10), reaching 50.0% and 35.0% of participants, respectively, at 4 hours, with additional improvement to 84.2% and 63.2% by Day 10.

Suicidal ideation decreased by 80% (from 12.5% with suicidal ideation at baseline 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 low discontinuation rate due to AEs (2.5%). Most common AEs related to the drug were mild to moderate and included headache, nausea, somnolence, and dizziness. Additional AEs such as cognitive disorder, dry mouth, fatigue, nasal decongestion, and paresthesia oral were observed and considered mild to moderate. There were no severe AEs and no serious AEs reported.

“The data shared at the Psych Congress suggest the promise of SPN-820 as a potential first-in-class, novel treatment option for patients with depression, in which it demonstrated rapid acting antidepressant properties, a favorable tolerability profile and convenient, oral at home administration,” said Jonathan Rubin, M.D., Chief Medical Officer and Senior Vice President, Research & Development, Supernus Pharmaceuticals. “By decreasing symptoms safely and effectively without certain burdensome side effects, with a majority of patients reaching a remission threshold in just 10 days, SPN-820 exhibited meaningful improvements on the main depression rating scales, and we remain very excited about its potential to make a difference in the lives of those suffering from depression.”

About SPN-820

SPN-820 is a first-in-class, orally active small molecule that modulates the brain mechanistic target of rapamycin complex 1 (mTORC1), increasing synaptic function via an intracellular mechanism. 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 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, first in class 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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