Minerva Neurosciences Announces Enrollment of First Patient in Phase 2b Trial Comparing Seltorexant (MIN-202) Versus Quetiapine as Adjunctive Therapy to Antidepressants in Patients With Major Depressive Disorder

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WALTHAM, Mass., Dec. 21, 2017 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (NASDAQ:NERV), a clinical-stage biopharmaceutical company focused on the development of therapies to treat central nervous system (CNS) disorders, today announced the enrollment of the first patient in a Phase 2b clinical trial (NCT03321526) comparing seltorexant (MIN-202) versus quetiapine as adjunctive therapy in patients with major depressive disorder (MDD) who have responded inadequately to antidepressant therapy.

The primary objective of this multi-center, double-blind, randomized, flexible-dose, parallel-group study is to assess the efficacy of flexibly dosed seltorexant compared to flexibly dosed quetiapine as adjunctive therapy to a baseline antidepressant drug in delaying time to all-cause discontinuation of study drug over a 6-month treatment period. Time to all-cause discontinuation is defined as the number of days from administration of the first dose of study drug to administration of the last dose of study drug.

"Preclinical studies have demonstrated that inhibition of orexin 2 receptors diminishes stress-induced activation of the HPA (hypothalamic-pituitary-adrenal) axis, a major part of the neuroendocrine system that is implicated in the pathophysiology of mood disorders and controls reactions to stress," said Dr. Remy Luthringer, chief executive officer of Minerva. "We expect that this trial will provide important clinical data on the potential role of an orexin 2 inhibitor in treating major depressive disorder."

The trial consists of three phases: a screening phase lasting up to four weeks, a six-month double-blind treatment phase and a two-week follow-up phase. Approximately 100 patients 18 to 64 years of age are planned to be randomized at approximately 34 sites in the U.S. to receive either flexibly dosed seltorexant, 20 milligrams (mg) or 40 mg, or flexibly dosed quetiapine XR, 150 mg or 300 mg. Subjects will continue to take their baseline antidepressant therapy of either an SSRI (selective serotonin reuptake inhibitor) or an SNRI (serotonin-norepinephrine reuptake inhibitor) at the same dose throughout the screening, double-blind and follow-up phases.

About Seltorexant (MIN-202)

Seltorexant is a selective orexin 2 receptor antagonist under co-development by Janssen Pharmaceutica NV and Minerva as adjunctive therapy for MDD and for the treatment of insomnia disorder. The orexin system in the brain is involved in the control of several key functions, including metabolism, stress response and wakefulness.

About Minerva Neurosciences

Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of products to treat CNS diseases. Minerva's product portfolio includes: MIN-101, in clinical development for schizophrenia; seltorexant (MIN-202), in clinical development for insomnia and major depressive disorder (MDD); MIN-117, in clinical development for MDD; and MIN-301, in pre-clinical development for Parkinson's disease. Minerva's common stock is listed on the NASDAQ Global Market under the symbol "NERV." For more information, please visit www.minervaneurosciences.com.

Forward-Looking Safe Harbor Statement

This press release contains forward-looking statements which are subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts, reflect management's expectations as of the date of this press release, and involve certain risks and uncertainties. Forward-looking statements include statements herein with respect to: the timing and results of future clinical milestones with seltorexant in major depressive disorder, including the timing and scope of future clinical trials and results of clinical trials with this compound; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies; our ability to successfully develop and commercialize seltorexant; the sufficiency of our current cash position to fund our operations; and management's ability to successfully achieve its goals. These forward-looking statements are based on our current expectations and may differ materially from actual results due to a variety of factors including, without limitation, whether seltorexant will advance further in the clinical trials process and whether and when, if at all, it will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether the results of future clinical trials of seltorexant, if any, will be consistent with the results of past clinical trials; whether seltorexant will be successfully marketed if approved; whether any of our therapeutic product discovery and development efforts will be successful; our ability to achieve the results contemplated by our co-development agreements; management's ability to successfully achieve its goals; our ability to raise additional capital to fund our operations on terms acceptable to us; and general economic conditions. These and other potential risks and uncertainties that could cause actual results to differ from the results predicted are more fully detailed under the caption "Risk Factors" in our filings with the Securities and Exchange Commission, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed with the Securities and Exchange Commission on November 6, 2017. Copies of reports filed with the SEC are posted on our website at www.minervaneurosciences.com. The forward-looking statements in this press release are based on information available to us as of the date hereof, and we disclaim any obligation to update any forward-looking statements, except as required by law.

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