Minerva Neurosciences Announces Enrollment of First Patient in Phase 2b Trial of Seltorexant (MIN-202) in Patients With Insomnia Disorder

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WALTHAM, Mass., Dec. 06, 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 of seltorexant (MIN-202) in patients with insomnia disorder.

This multicenter, double-blind, randomized, parallel-group, active- and placebo-controlled dose finding study is designed to assess the efficacy and safety of seltorexant in both adult and elderly subjects with insomnia disorder. The primary objective of this trial is to assess the dose-response of three doses of seltorexant (5, 10 and 20 milligrams daily) compared to placebo on sleep onset as measured by the latency to persistent sleep (LPS) using polysomnography (PSG). The key secondary objective is to assess the dose-response of these three doses compared to placebo on wake after sleep onset (WASO) over the first six hours using PSG. In addition, the effects of seltorexant on sleep and cognition will be compared to those effects of zolpidem to determine potential differences between the compounds.

"Activation of the orexin-2 receptor pathway is believed to contribute to the maintenance of wakefulness, and the blockade of this pathway represents a novel pharmacologic approach for the treatment of insomnia," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "Patients treated with seltorexant in the Phase 2a trial were observed to have statistically significant improvements in key sleep parameters, compared to patients who received placebo. Data from the Phase 2a trial indicate that seltorexant may accelerate sleep induction, restore sleep duration and preserve key phases of sleep, thus enabling restorative sleep."

A total of approximately 360 patients 18 to 85 years of age will be randomized in this study at clinical sites in the United States, European Union and Japan. The duration of participation in this study for an individual subject will be up to 61 days, including screening and follow-up.

About Seltorexant (MIN-202)

Seltorexant is a selective orexin 2 receptor antagonist under co-development by Janssen Pharmaceutica NV and Minerva for the treatment of insomnia disorder and as adjunctive therapy for MDD. 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 proprietary compounds include: 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 (MIN-202) in insomnia and 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 agreements with Janssen related to seltorexant; 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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