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

September 5, 2017

WALTHAM, Mass., Sept. 05, 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) as adjunctive therapy to antidepressants in adult patients with major depressive disorder (MDD) who have responded inadequately to antidepressant therapy.

The primary objectives of this multi-center, double-blind, randomized, parallel group, placebo-controlled, adaptive-dose finding study are:

- to assess the dose-response relationship and antidepressant effects of up to three doses of seltorexant; and
- to assess the safety and tolerability of seltorexant compared to placebo as described in clinicaltrials.gov: NCT03227224.

“An important differentiator of seltorexant is its specificity for the orexin 2 receptor subtype, which is known to have a key role in controlling brain structures and pathways involved in mood and insomnia,” said Dr. Remy Luthringer, president and chief executive officer of Minerva. “This trial follows the observed improvements in mood in an earlier study carried out in depressed patients who received seltorexant.”

The trial consists of three phases: a screening phase lasting up to four weeks, a six-week double-blind treatment phase and a two-week post-treatment follow-up phase. Approximately 280 patients are planned to be enrolled at more than 85 clinical sites in the U.S., Europe, Russia and Japan.

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 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 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 June 30, 2017, filed with the Securities and Exchange Commission on August 3, 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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