Minerva Neurosciences Screens First Patient in Phase 2b Trial of MIN-117 to Treat Major Depressive Disorder

April 9, 2018

Multi-center trial to enroll approximately 324 patients at approximately 40 clinical sites in U.S. and Europe

WALTHAM, Mass., April 09, 2018 (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 screening of the first patient in a Phase 2b trial of MIN-117 (Study MIN-117C03) to reduce the symptoms of patients diagnosed with major depressive disorder (MDD).

The primary objective of the trial is to evaluate the efficacy of two fixed doses of MIN-117, 5.0 milligrams (mg) and 2.5 mg, compared with placebo in reducing the symptoms of major depression as measured by the change in the Montgomery-Asberg Depression Rating Scale (MADRS) total score over six weeks of treatment. Secondary objectives include: (1) assessment of the change from baseline in symptoms of anxiety using the Hamilton Anxiety Scale (HAM-A); (2) the change in severity of illness using the Clinical Global Impression of Severity Scale (CGI-S) and Clinical Global Impression of Improvement Scale (CGI-I); and (3) safety over six weeks of treatment.

"While existing therapies for MDD are available, their effectiveness is limited due to unacceptable side effects, particularly cognitive impairment and sexual dysfunction," said Dr. Remy Luthringer, Chief Executive Officer of Minerva. "These shortcomings warrant the exploration of new treatment strategies with molecules such as MIN-117 that possess an innovative and rich pharmacological profile. In addition to the primary endpoint of reducing the symptoms of major depression, we plan to assess anxiety, cognition, sexual function, sleep, validated depression biomarkers and onset of action to further define the product profile of MIN-117 as an agent that can potentially address these shortcomings."

The study population will consist of adults with a diagnosis of moderate or severe MDD with anxious distress and without psychotic features. Based upon previous clinical observations, the Company believes that patients with MDD who also have symptoms of anxiety may benefit from treatment with MIN-117.

Approximately 324 patients are expected to be enrolled at approximately 40 sites in the U.S. and Europe. Patients will be randomized to one of three arms, including placebo and the two dosage arms, in a 2:1:1 ratio, resulting in approximately 162 patients in the placebo group and 81 patients in each of the two MIN-117 treatment groups. The study design includes a screening phase of up to three weeks, a six-week double-blind treatment phase and a two-week post-study follow-up period. Top line results of the trial are expected in the first half of 2019.

About MIN-117

The pharmacological effects of MIN-117 are related to serotonin and dopamine, two neurotransmitters in the brain. MIN-117 is meant to block a specific subtype of serotonin receptor called 5-HT1A. When 5-HT1A is blocked, anxiety and mood can be regulated. In addition, MIN-117 is meant to prevent the reuptake of serotonin and dopamine, which increases the amount of serotonin and dopamine in the brain, which is tied to an improvement in mood in individuals suffering from MDD. MIN-117 is also meant to modulate the levels of Alpha-1a and 1b, which further modulates serotonin and dopamine.

About Minerva Neurosciences:

Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of product candidates to treat CNS diseases. Minerva's proprietary compounds include: roluperidone (MIN-101), in Phase 3 clinical development for schizophrenia; seltorexant (MIN-202 or JNJ-42847922) in Phase 2b clinical development for insomnia and 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 scope of future clinical trials and results of clinical trials with MIN-117; the timing and scope of future clinical trials and results of clinical trials with this compound; the clinical and therapeutic potential of this compound; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies; our ability to successfully develop and commercialize our therapeutic products; 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 MIN-117 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 MIN-117 will be successfully marketed if approved; whether any of our therapeutic product discovery and development efforts will be successful; 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 Annual Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission on March 12, 2018. 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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