Minerva Neurosciences Announces Completion of Patient Enrollment in Phase 3 Trial of Roluperidone for the Treatment of Negative Symptoms in Schizophrenia

February 5, 2020

Data readout expected in the second quarter of 2020

WALTHAM, Mass., Feb. 05, 2020 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (NASDAQ: NERV), a clinical-stage biopharmaceutical company focused on the development of therapies addressing high unmet medical needs in the treatment of central nervous system (CNS) disorders, today announced the completion of patient randomization in the pivotal, Phase 3 multicenter trial of roluperidone, its lead product, for the treatment of negative symptoms in schizophrenia.

A total of 515 patients have been randomized in this trial, compared to the original goal of 501 patients. The trial, which is being conducted at clinical sites in the U.S. and Europe, is a randomized, double-blind, parallel-group, placebo-controlled, 12-week study to evaluate the efficacy and safety of 32 milligram (mg) and 64 mg doses of roluperidone as measured by the Marder negative symptoms factor score of the Positive and Negative Syndrome Scale, the primary endpoint. Secondary endpoints include the Personal and Social Performance Scale and Clinical Global Impression of Severity. Patients are being randomized 1:1:1 to the 32 mg and 64 mg doses of roluperidone and placebo. The core 12-week double-blind phase of the trial is followed by a 40-week, open-label extension period during which patients on the drug continue receiving their original dose and patients on placebo receive one of the two doses of roluperidone. Top-line results from the 12-week, double-blind portion of the trial are expected in the second quarter of 2020.

“The completion of patient enrollment marks a major milestone in the Phase 3 trial with roluperidone,” said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva. “We believe the data from this trial have the potential to lead to a significant new treatment option for schizophrenia, as no pharmacological agent is approved to treat negative symptoms, which is the single greatest unmet need for patients with this disease, their families and their physicians.”

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 clinical development for schizophrenia; seltorexant (MIN-202 or JNJ-42847922), in clinical development for insomnia and 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 roluperidone (MIN-101); 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 roluperidone 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 any of our therapeutic products 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, filed with the Securities and Exchange Commission on November 4, 2019. 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.

Contact:

William B. Boni
VP, Investor Relations
Corp. Communications
Minerva Neurosciences, Inc.
(617) 600-7376

Source: Minerva Neurosciences, Inc