September 26, 2016

Minerva Neurosciences Provides Update on MIN-101 and MIN-117 Clinical Programs

Last patient completes extension phase of Phase IIb trial with MIN-101

Company receives FDA acceptance of Investigational New Drug Application for MIN-117

WALTHAM, Mass., Sept. 26, 2016 (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 recent progress in its clinical programs with MIN-101 for schizophrenia and with MIN-117 for major depressive disorder (MDD).

MIN-101

The last patient has completed the 24-week open-label extension period of the Company's Phase IIb clinical trial of MIN-101 in patients with negative symptoms of schizophrenia. Positive results from the prospective 12-week randomized, double-blind, placebo-controlled core phase of this trial were announced previously. These results from the core phase demonstrated statistically significant improvement of negative symptoms, the primary endpoint of the trial, in patients treated with both 32 milligrams (mg) and 64 mg daily doses of MIN-101 compared to placebo. Statistically significant benefit of MIN-101 was also demonstrated in multiple secondary endpoints.

Approximately 140 patients who completed the core phase of this trial entered the extension phase, during which all patients received one of the two doses of MIN-101. Patients who received placebo in the core study were randomized to one of these doses. As planned, the extension phase of the trial was completed in the third quarter of 2016, and the Company expects to announce top line results from this phase in the fourth quarter of 2016. The Company has submitted results from the core phase of the trial for peer-reviewed publication and presentations and plans to meet with regulatory authorities in the United States and Europe in preparation for Phase 3 testing of MIN-101, which is expected to begin in 2017.

MIN-101 is a drug candidate with equipotent affinities for sigma 2 and 5-hydroxytryptamine-2A (5-HT2A) and lower affinity at alpha1-adrenergic receptors. MIN-101 has no direct dopaminergic post-synaptic blocking effects, known to be involved in some side effects like extrapyramidal symptoms, sedation, prolactin increases and weight gain.

MIN-117

The U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug (IND) application to begin clinical testing of MIN-117 in the United States. This acceptance follows positive results from a randomized, double-blind, placebo- and positive-controlled Phase IIa clinical trial in MDD with MIN-117 in Europe announced earlier this year. Data from the study demonstrated the dose-dependent superiority of MIN-117 over placebo in reducing symptoms of depression and anxiety.

FDA acceptance of the IND for MIN-117 allows the Company to begin clinical trials with this compound in the U.S., building upon the results from the European trial. Planning is underway for these trials, which are expected to begin in 2017.

MIN-117 is an antidepressant drug candidate with a differentiated mechanism of action targeting adrenergic alpha 1a, alpha 1b, 5-HT1A, 5-HT2A receptors, serotonin and the dopamine transporters.

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, which recently completed a Phase IIb clinical trial for schizophrenia; MIN-117, which recently completed a Phase IIa clinical trial development for MDD; MIN-202 (JNJ-42847922), which recently completed Phase IIa and Phase Ib clinical trials for insomnia and MDD, respectively; 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-101 and MIN-117; the clinical and therapeutic potential of MIN-101 and MIN-117; our ability to successfully develop and commercialize MIN-101 and MIN-117; 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-101 and MIN-117 will advance further in the clinical trials process and whether and when, if at all, they 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 MIN-101 and MIN-117, if any, will be consistent with the results of past clinical trials; whether MIN-101 and MIN-117 will be successfully marketed if approved; whether our therapeutic product discovery and development efforts with MIN-101 and MIN-117 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, 2016, filed with the Securities and Exchange Commission on August 4, 2016. 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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