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Minerva Provides Year-End Update on Clinical Trials With Three Central Nervous System Product Candidates

Patient Enrollment Progress During 2015 Confirms Timeline Expectations for Topline Data Availability From Four Trials in First Half of 2016

WALTHAM, Mass., Dec. 9, 2015 (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 provided a year-end update on clinical trials testing MIN-101 for schizophrenia, MIN-202 for insomnia disorder and adjunctive treatment of major depressive disorder (MDD) and MIN-117 for MDD.

"Our primary focus during 2015 has been on clinical trial execution, and we are pleased with the pace of patient recruitment that has taken place in all four ongoing trials," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "The progress achieved during the past year paves the way for a series of topline data readouts during the first six months of 2016."

MIN-101

In the randomized, placebo-controlled double-blind Phase IIb trial with MIN-101 for schizophrenia, the Company has reached its patient screening target and expects to achieve its enrollment target of 234 patients in late December, 2015. The primary objective of this trial is to evaluate the efficacy of MIN-101 compared to placebo in improving the negative symptoms of schizophrenic patients over 12 weeks of treatment. Patients who respond positively to treatment with MIN-101 will have the opportunity to enter an extension period of six months, during which all patients will be on active treatment. Topline results for the core 12-week treatment evaluation period are expected in the second quarter of 2016.

MIN-202 (JNJ-42847922)

Patient enrollment has been completed in two trials with MIN-202, under joint development with Janssen Pharmaceutica NV. These include a Phase IIa trial in insomnia disorder and a Phase Ib trial in adjunctive treatment of MDD.

The Phase IIa trial in insomnia disorder is a randomized, placebo-controlled double-blind study to evaluate treatment with MIN-202 in 26 patients with insomnia disorder without psychiatric co-morbidity. The primary endpoint is sleep efficiency as measured by polysomnography, with secondary endpoints including additional assessments of sleep, mood and cognition, as well as safety.

The Phase Ib trial in adjunctive treatment of MDD is a randomized, diphenhydramine- and placebo-controlled double-blind trial to evaluate treatment with MIN-202 in 48 patients with MDD. The primary endpoint is safety, and secondary endpoints include assessments of depressive symptomology, cognition and sleep.

MIN-117

The Company is continuing to screen and randomize patients in a Phase IIa trial with MIN-117 to treat MDD. The trial is comparing the therapeutic impact of two doses of MIN-117 to paroxetine and placebo. Target enrollment is 80 patients, with 20 patients expected in each of the four groups. The primary endpoint is the efficacy of MIN-117 versus placebo in reducing depressive symptoms. Topline results are expected in the first half of 2016.

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 Phase IIb development for schizophrenia; MIN-202 (JNJ-42847922), in Phase IIa and Phase Ib development for insomnia and adjunctive MDD, respectively; MIN-117, in 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; the timing of future clinical trials and results of clinical trials; the clinical and therapeutic potential of our compounds; 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, our ability to successfully enroll patients in ongoing and future clinical trials; the safety and efficacy of our product candidates observed in clinical development; our ability to accurately forecast the costs associated with ongoing and future clinical trials; and our ability to raise additional capital to fund our operations on terms acceptable to us or at all. 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, 2015, filed with the Securities and Exchange Commission on November 5, 2015. 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

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