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Minerva Neurosciences Announces Completion of Patient Enrollment in Phase IIa Trial of MIN-117 in Major Depressive Disorder

WALTHAM, Mass., Feb. 22, 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 the completion of patient enrollment in a randomized, placebo-controlled double-blind European Phase IIa clinical trial of MIN-117 in major depressive disorder (MDD).

The primary objective of this trial is to evaluate the efficacy of MIN-117 compared to placebo in reducing the symptoms of a major depressive episode as measured by the change from baseline in the Montgomery-Asberg Depression Rating Scale (MADRS) total score over six weeks of treatment. Additional objectives include the assessment of onset to response, severity of illness, sexual function, executive function, working memory, and safety and tolerability. Eighty-four patients have been enrolled across the four treatment arms of this study (0.5 and 2.5 mg daily of MIN-117, placebo, and 20 mg daily of paroxetine). Top line results are expected in the second quarter 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 the adjunctive treatment of MDD, respectively; MIN-117, in Phase IIa 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 <u>www.minervaneurosciences.com</u>.

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-117; the clinical and therapeutic potential of MIN-117; and our ability to successfully develop and commercialize MIN-117. 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 our therapeutic product discovery and development efforts with 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 guarter 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 forwardlooking 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.

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