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Minerva Neurosciences Announces Top Line Data From MIN-202 Phase I Clinical Study in Japanese Patients

Treatment With Selective Orexin-2 Receptor Antagonist Observed to be Well Tolerated

WALTHAM, Mass., Feb. 01, 2016 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (NASDAQ:NERV), a clinical-stage biopharmaceutical company focused on the development of therapies for central nervous system (CNS) disorders, today announced top line results from a Phase I clinical trial conducted in Japan with MIN-202 (JNJ-42847922), a selective orexin-2 receptor antagonist under joint development with Janssen Pharmaceutica NV.

It was observed that single dose morning administration of MIN-202 was well tolerated at all three dose levels tested, 5 milligrams (mg), 20 mg and 40 mg. The observed plasma pharmacokinetic features were comparable to those observed in previous studies carried out in healthy non-Asian study participants. No clinically relevant safety concerns were observed based on the assessment of multiple safety endpoints. Somnolence was the most frequently reported adverse event at the two higher doses, an expected finding as this compound is being developed as a treatment for patients suffering from insomnia disorder and as adjunctive treatment to concomitant antidepressant drug therapy in major depressive disorder (MDD).

"These findings are an important step in the global development of MIN-202," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "They add to the expanding database of study participants treated with this compound worldwide and support further clinical testing in an important part of the world."

This trial was a single center, double blind, placebo-controlled randomized single ascending dose study to investigate the safety, tolerability and pharmacokinetics of MIN-202 in 24 healthy Japanese adult male study participants.

Minerva entered into a co-development and license agreement with Janssen in February, 2014 covering MIN-202 and any other orexin-2 compounds. Under this agreement, Minerva has an exclusive license to these compounds in the European Union, Switzerland, Liechtenstein, Iceland and Norway. Janssen has exclusive rights to these compounds worldwide outside of these territories.

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 2B development for schizophrenia; MIN-202 (JNJ-42847922), in Phase 2A and Phase 1B development for insomnia and adjunctive treatment of MDD, respectively; MIN-117, in Phase 2A 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 regarding MIN-202; the timing of future clinical trials and results of clinical trials regarding MIN-202; the clinical and therapeutic potential of MIN-202; our ability to successfully develop and commercialize MIN-202; 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 only predictions and may differ materially from actual results due to a variety of factors including, without limitation, whether final data from the Phase 2A MIN-202 trial will be consistent with the preliminary results, whether MIN-202 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-202 will be successfully marketed if approved; whether our therapeutic product discovery and development efforts will be successful for MIN-202; 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 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.

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