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# Minerva Neurosciences Provides Update on Clinical Development Program With MIN-202, Selective Orexin-2 Receptor Antagonist

## Patient Recruitment Ongoing in Trials in Insomnia Disorder and Adjunctive Major Depressive Disorder

WALTHAM, Mass., Sept. 24, 2015 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (NASDAQ:NERV), a clinical-stage biopharmaceutical company focused on the development of innovative therapies to treat central nervous system (CNS) disorders, today provided an update on two ongoing clinical trials with MIN-202 (JNJ-42847922), a selective orexin-2 receptor antagonist under joint development with Janssen Pharmaceutica NV. Patient recruitment is ongoing in both trials, which include a Phase 2a trial in insomnia disorder and a Phase 1b trial in adjunctive major depressive disorder (MDD).

"We are pleased with the progress that is being made in the development of MIN-202 in insomnia and adjunctive MDD," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "The ongoing trials in these indications are designed to provide assessments of the effects of this compound in sleep and major depressive disorder. We believe that MIN-202 has the potential to physiologically regulate biological rhythm and control of the wake drive based on its unique mechanism of action as a selective orexin-2 receptor antagonist."

Insomnia trial (clinicaltrials.gov identifier: NCT02464046):

The Phase 2a trial in insomnia disorder is a randomized, placebo-controlled double-blind study to evaluate treatment with MIN-202 in subjects with insomnia disorder without psychiatric co-morbidity. It is estimated that 26 patients will be enrolled. Half of these patients will receive MIN-202 for five days, followed by a washout period and then placebo for five days. The other half will receive placebo first, followed by a washout period and then MIN-202 under the same schedule.

The primary endpoint of this trial is sleep efficiency as measured by polysomnography, and secondary endpoints include additional assessments of sleep, mood and cognition, as well as safety. The trial is being conducted at clinical sites in the U.S. and Europe, and the data readout is expected in the first half of 2016.

Adjunctive MDD trial (clinicaltrials.gov identifier: NCT02476058):

The Phase 1b trial in adjunctive MDD is a randomized, diphenhydramine- and placebo-controlled double-blind study to evaluate treatment with MIN-202 in subjects with MDD. It is estimated that 48 patients will be enrolled in three groups, which will be treated with MIN-202, diphenhydramine and placebo, respectively, while maintained on their antidepressant regimens.

The primary endpoint of this trial is safety, and secondary endpoints include assessments of depressive symptomology, cognition and sleep. The trial is being conducted at clinical sites in Europe, and the data readout is 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 development for the treatment of schizophrenia; MIN-202 (JNJ-42847922), in development for the treatment of insomnia; MIN-117 in development for the treatment of major depressive disorder; and MIN-301 in development for the treatment of 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 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 June 30, 2015, filed with the Securities and Exchange Commission on August 5, 2015. Copies of reports filed with the SEC are posted on our website at [www.minervaneurosciences.com](http://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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