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## **Minerva Neurosciences Announces Positive Top Line Results From Phase Ib Clinical Trial in Major Depressive Disorder With MIN-202**

**Treatment with selective orexin-2 receptor antagonist observed to be well tolerated and to improve symptoms of depression, independent from its effect on sleep**

WALTHAM, Mass., March 11, 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 positive top line results from a Phase Ib clinical trial in major depressive disorder (MDD) with MIN-202 (JNJ-42847922), a selective orexin-2 receptor antagonist under joint development with Janssen Pharmaceutica NV.

"Treatment with MIN-202 was observed to result in consistent improvements in the symptoms of depression in MDD patients in this trial," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "The results pave the way to initiate a Phase IIb trial in patients suffering from MDD. These improvements support the potential of MIN-202 to have a direct effect on mood independent from its effect on sleep. We previously observed that MIN-202 had a significant effect on sleep in our Phase IIa trial in patients suffering from insomnia disorder."

The Phase Ib trial was a randomized, multi-center, double-blind, parallel group, diphenhydramine- and placebo-controlled study to evaluate the effect of MIN-202 in MDD outpatients 18-65 years of age. Forty-eight participants were enrolled in three groups that received doses of 20 milligrams (mg) of MIN-202 daily, 25 mg of diphenhydramine daily (used as a positive control to induce sedation) or placebo over four weeks.

MIN-202 was observed to be well tolerated by study participants over a one-month treatment duration, with no new emerging safety signals and no serious adverse events.

Consistently greater improvements in depressive symptomatology were observed in patients randomized to receive MIN-202 compared to those randomized to receive placebo (PLA) or diphenhydramine (DPH), as measured by clinician administered rating scales, including the Hamilton Depression Rating Scale (HDRS<sub>17</sub>). Core symptoms of depression (as measured by the HAM-D<sub>6</sub>) were observed to be significantly improved in the MIN-202 arm when compared with the PLA arm.

The primary endpoint was safety and tolerability, and secondary endpoints included assessments of depressive symptomatology, cognition and sleep. The trial was conducted at seven clinical sites in Europe. Only top line results with respect to safety, tolerability and efficacy on depressive symptomatology are reported in this press release. Complete results are planned for peer-reviewed presentation in the future.

MIN-202 is also under development to treat primary insomnia disorder. Recently announced top line data from a Phase IIa trial in this indication included statistically significant improvements in sleep efficiency (SE) as measured by objective polysomnography, the primary endpoint of the trial, observed in study patients treated with MIN-202, with an acceptable safety and tolerability profile, compared to patients treated with placebo.

Minerva entered into a co-development and license agreement with Janssen in February 2014 covering MIN-202 and 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 IIb development for schizophrenia; MIN-202 (JNJ-42847922), in Phase IIa and Phase Ib development for insomnia and 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 [www.minervaneurosciences.com](http://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 Ib 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](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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