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Minerva Neurosciences Announces Positive Results in Phase IIA Trial of MIN-117 in Major Depressive Disorder

MIN-117 meets primary and secondary endpoints

- **Reduction in depressive symptoms demonstrated**
- **Good tolerability and safety profile observed**
- **Positive effect on sleep architecture shown**
- **Differentiated mechanism of action**

WALTHAM, Mass., May 26, 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 positive top line results from a Phase IIa clinical trial in major depressive disorder (MDD) with MIN-117, an antidepressant drug candidate with a differentiated mechanism of action targeting adrenergic alpha 1a, alpha 1b, 5-HT1A, 5-HT2A receptors, serotonin and the dopamine transporter.

Results demonstrated dose-dependent superiority of MIN-117 over placebo as measured by change in the Montgomery-Asberg Depression Rating Scale (MADRS). Data show that MIN-117 at the 0.5 milligrams (mg) daily dose had an effect size (magnitude of difference) as compared to the placebo group of 0.23 while the 2.5 mg daily dose had an effect size of 0.33. This magnitude of effect size is similar to those observed with currently marketed antidepressants. Improvement in MADRS with MIN-117 against placebo was observed at two weeks. Furthermore, data also show that 24 percent of the patients treated with 2.5 mg of MIN-117 achieved remission as prospectively defined.

Both doses of MIN-117 demonstrated a favorable tolerability profile, and the incidence and types of side effects did not differ significantly between the MIN-117 group and the placebo group. No unexpected adverse events were reported. Preliminary analysis shows that treatment with MIN-117 is not associated with cognitive impairment, sexual dysfunction, suicidal ideation or weight gain.

Pharmacodynamic measurements based on sleep recordings show that MIN-117 preserved sleep continuity and architecture and therefore is not expected to have detrimental effects on rapid eye movement (REM) sleep distribution and duration unlike most marketed antidepressants.

"We believe these results show a meaningful clinical benefit and support further development of MIN-117, an antidepressant with a differentiated mechanism of action and a favorable tolerability profile," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "These promising results, combined with the drug's distinctive pharmacology, lay the foundation to potentially address unmet needs not currently served by existing therapies in the treatment of mood disorders and other central nervous system indications."

About this study (https://www.clinicaltrials register.eu, EudraCT Number: 2015-000306-18)

This study was a four-arm, parallel-group, randomized double-blind, placebo- and positive-control trial which tested two daily administered doses of MIN-117: 0.5 mg and 2.5 mg. The study included 84 patients (21 per arm) with moderate to severe MDD in four European countries. The goals of the trial were to test efficacy, safety and tolerability of MIN-117 over six weeks of treatment. The antidepressant paroxetine was used as an active control and confirmed assay sensitivity. Change on the MADRS, a scale measuring severity of depression, was used as the main outcome measurement. As established prospectively in the statistical analysis plan, this trial was designed for signal detection and effect size estimation. As such, the study was not powered to demonstrate statistically significant differences between MIN-117 and placebo.

About Major Depressive Disorder

Major depressive disorder (also referred to as major depression) is one of the most common mental disorders worldwide, with an estimated 350 million people affected. According to the World Health Organization, it is the leading cause of disability worldwide and a major contributor to the overall global disease burden. In the U.S. in 2014, an estimated 15.7 million adults aged 18 or older, representing 6.7 percent of all adults, had at least one major depressive in the past. Shortcomings of many current antidepressant therapies include a large number of treatment non-responders, delayed onset of action, sexual dysfunction and weight gain, all potentially leading to poor compliance with therapy.

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), which has completed Phase IIa and Phase Ib clinical trials in insomnia and the adjunctive treatment of major depressive disorder (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 visitwww.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 with MIN-117; the clinical and therapeutic potential of MIN-117; our ability to successfully develop and commercialize MIN-117; 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, 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 the results of future clinical trials of MIN-117, if any, will be consistent with the results of past clinical trials; 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 quarter ended March 31, 2016, filed with the Securities and Exchange Commission on May 3, 2016. 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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