



December 5, 2016

Minerva Neurosciences' Clinical Data Featured at The American College of Neuropsychopharmacology Annual Meeting

Oral presentation highlights specific improvements in negative symptoms and cognition observed in schizophrenic patients treated with MIN-101 in Phase IIB trial

Data also presented from Phase IIA trials with MIN-101 and MIN-117

WALTHAM, Mass., Dec. 05, 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 data presentations at the 55th Annual Meeting of the American College of Neuropsychopharmacology (ACNP), December 4-8, 2016. Conclusions from these data analyses are summarized below. The posters will be available following the completion of the last of these presentations at the ACNP meeting at <http://ir.minervaneurosciences.com/events.cfm>.

"The presentations of data from the Phase IIB trial with MIN-101 at ACNP demonstrate broad internal consistency across multiple endpoints, supporting the direct effect of this compound in treating negative symptoms in schizophrenia," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "Beyond the significant improvement on negative symptoms observed in the core 12-week double blind phase of this trial, which was followed by continuous improvement experienced by patients over an additional 24-week extension phase, data presented at ACNP show the potential of treatment with MIN-101 in improving general psychopathology, cognition and sleep, as well as its marked impact on younger patients."

1. Abstract title: "Efficacy and Safety of MIN-101: A New Drug for the Treatment of Negative Symptoms in Schizophrenia" (Hot Topics oral presentation session and Poster Session I, Poster Board M218)

Data from the Phase IIB trial (top line results from which were first announced in May 2016) demonstrated a statistically significant improvement in negative symptoms as measured by both the pentagonal structure model of the Positive and Negative Symptom scale and the classic PANSS three factors negative symptoms subscale for both doses tested, 32 milligrams (mg) and 64 mg. The statistically significant superiority of MIN-101 over placebo was also observed on most secondary outcomes such as the PANSS total score, Clinical Global Impression of Improvement (CGI-I), Clinical Global Impression of Severity (CGI-S), Brief Negative Symptoms Scale (BNSS) total score, Personal and Social Performance (PSP) total score, and Calgary Depression Scale for Schizophrenia (CDSS).

The direct effect of MIN-101 on negative symptoms (rather than an indirect effect secondary to improvements in other symptoms) was underscored by the observed stability in positive symptoms, the absence of extra-pyramidal symptoms (EPS) and the persistence of this specific effect even after controlling for improvements in depressive symptoms. Researchers noted that since phenomena similar to negative symptoms are manifest in many psychiatric disorders and in brain degenerative disorders such as Alzheimer's disease and Parkinson's disease, future trials with MIN-101 could be designed to explore its potential benefit in these patient populations.

In post-hoc analysis, improvement in negative symptoms was shown to be greatest among younger patients, especially in the cohort of patients under 33 years of age. This finding supports the potential therapeutic intervention with MIN-101 in younger patients with schizophrenia who are beginning to manifest these symptoms. It is also consistent with research showing that chronic pharmacotherapeutic intervention in schizophrenia, which includes atypical antipsychotics to treat acute positive symptoms, becomes less effective as patients age and suffer long-term consequences of the disease and side effects of current treatment options.

With respect to safety and tolerability, no weight gain or clinically significant changes from baseline in vital signs, prolactin, routine laboratory values and EPS measurements were observed. As previously announced, two patients out of 162 who received MIN-101 in the core phase of the trial were discontinued based upon discontinuation criteria related to QTcF prolongation; both of these patients received the higher dose (64 mg). In the extension phase of the trial, no additional patients were discontinued.

2. Abstract title: "Effect of MIN-101 on Cognition in Schizophrenia Patients With Predominant Negative Symptoms: A 12-

Week Randomized, Double Blind, Placebo-Controlled Trial" (Poster Session II, Poster Board T167)

Results from the Phase IIB, double-blind, randomized, placebo-controlled study suggest a benefit of treatment with MIN-101 32 mg in improving cognitive function in schizophrenia patients with predominant negative symptoms. Cognitive function was evaluated using the Brief Assessment of Cognition in Schizophrenia (BACS) scale, and data analyses demonstrated statistically significant differences in the BACS scale between patients treated with MIN-101 at the 32 mg dose and those who received placebo. Cognitive dysfunction, a core feature of schizophrenia, affects up to 75 percent of patients and is viewed as a good predictor of functional outcome.

3. Abstract title: "MIN-101 Improves Sleep in Patients Suffering From Schizophrenia: A Randomized, Placebo-Controlled, Double Blind Study" (Poster Session III, Poster Board W192)

Results from a Phase IIA, double-blind, randomized, placebo-controlled study showed that treatment with MIN-101 as monotherapy was associated with significantly improved sleep induction and normalized slow wave sleep (SWS) ultradian distribution during the night, which are two key sleep parameters that are disturbed in schizophrenia. Such disturbances of sleep architecture and continuity may be associated with memory consolidation, which is impaired in schizophrenia. These effects on sleep parameters may help to improve the overall symptomatology observed in patients suffering from schizophrenia and treated with MIN-101.

4. Abstract title: "A Randomized, Double-Blind, Parallel-Group, Placebo- and Active-Controlled Study to Evaluate the Efficacy and Safety of MIN-117 in Patients With Major Depressive Disorder" (Poster Session II, Poster Board T132)

Results from a Phase IIA clinical trial demonstrated the dose-dependent superiority of MIN-117 over placebo in reducing symptoms of depression as measured by the Montgomery-Asberg Depression Rating Scale (MADRS). Twenty-four percent of patients treated with MIN-117 were observed to achieve remission as prospectively defined. In addition, MIN-117 was observed to preserve sleep continuity and architecture and therefore is not expected to have detrimental effects on rapid eye movement (REM) sleep distribution and duration. MIN-117 also demonstrated a favorable tolerability profile, and the incidence and types of side effects did not differ significantly from placebo. Treatment with MIN-117 was not associated with cognitive impairment, sexual dysfunction, suicidal ideation or weight gain.

MIN-101

MIN-101 is a drug candidate with equipotent affinities for sigma 2 and 5-hydroxytryptamine-2A (5-HT_{2A}) and lower affinity at α 1-adrenergic receptors. MIN-101 has no direct dopaminergic post-synaptic blocking effects, known to be involved in some side effects like extrapyramidal symptoms, sedation, prolactin increases and weight gain.

MIN-117

MIN-117 is an antidepressant drug candidate with a differentiated mechanism of action targeting adrenergic alpha 1a, alpha 1b, 5-HT_{1A}, 5-HT_{2A} receptors, serotonin and the dopamine transporters.

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, which has completed a Phase IIB clinical trial for schizophrenia; MIN-117, which has completed a Phase IIA clinical trial development for MDD; MIN-202 (JNJ-42847922), which has completed Phase IIA and Phase Ib clinical trials for insomnia and MDD, respectively; 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 with MIN-101 and MIN-117; the clinical and therapeutic potential of MIN-101 and MIN-117; our ability to successfully develop and commercialize MIN-101 and 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-101 and MIN-117 will advance further in the clinical trials process and whether and when, if at all, they 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-101 and MIN-117, if any, will be consistent with the results of past clinical trials; whether MIN-101 and MIN-117 will be successfully marketed if approved; whether our therapeutic product discovery and development efforts with MIN-101 and 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 September 30, 2016, filed with the Securities and Exchange Commission on November 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.

Contact:

William B. Boni

VP, Investor Relations/

Corp. Communications

Minerva Neurosciences, Inc.

(617) 600-7376

 [Primary Logo](#)

Source: Minerva Neurosciences, Inc.

News Provided by Acquire Media