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American Journal of Psychiatry Publishes Minerva Neurosciences' MIN-101 Phase 2b Trial Results for Treatment of Negative Symptoms in Schizophrenia

WALTHAM, Mass., July 31, 2017 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (NASDAQ:NERV), a clinical-stage biopharmaceutical company focused on the development of therapies to treat central nervous system disorders, today announced that the American Journal of Psychiatry has published online results from its previously reported Phase 2b clinical trial of MIN-101. MIN-101 is a novel compound with affinities for sigma$_2$ and 5HT$_{2A}$ receptors but no direct activity on dopamine receptors. In this regard, MIN-101 differs from drugs currently indicated for schizophrenia, all of which directly interfere with dopamine neurotransmission by antagonizing dopamine receptors.

The manuscript, entitled "Efficacy and Safety of MIN-101: A 12-Week Randomized, Double-Blind, Placebo-Controlled Trial of New Drug in Development for the Treatment of Negative Symptoms in Schizophrenia," and be found online at http://www.medical-reprints.com/US-MN-AJP-Davidson.

The key finding from the publication is that MIN-101 achieved its primary outcome in the trial, demonstrating statistically significant superiority over placebo in improving negative symptoms in schizophrenia patients as measured by the pentagonal negative symptoms cluster of the Positive and Negative Syndrome Scale (PANSS). The improvement in negative symptoms was shown for both doses tested: 32 milligrams (mg): p = 0.024 effect size = 0.45, and 64 mg: p = 0.004 effect size = 0.57.

Supporting these findings were similar and concomitant improvements on several secondary outcome measures, including PANSS cluster analyses of negative symptoms, the PANSS total score, the Clinical Global Impression (CGI) and the Brief Negative Symptom Scale (BNSS). Psychosis measured by the PANSS Positive symptoms subscale remained stable during the trial, suggesting that the improvement in negative symptoms associated with MIN-101 was specific and not a pseudo-effect secondary to improvements in psychosis.

MIN-101 also demonstrated good tolerability, with no weight gain or other metabolic abnormalities, no clinically significant changes in vital signs, routine laboratory values, sedation and extra-pyramidal symptoms (EPS). The lack of observed adverse effects associated with MIN-101 treatment as compared to placebo helped to preserve the blinding of the trial, further supporting the validity and specificity of the improvement observed in negative symptoms.

"Negative symptoms, which tend to persist even after psychosis improves, are the main impediment to social reintegration of schizophrenia patients," said Dr. Philip D. Harvey, Leonard M. Miller Professor of Psychiatry and Director of the Division of Psychology at the University of Miami Miller School of Medicine and an expert in the rehabilitation of schizophrenia patients. "No drugs in the U.S. are currently indicated for negative symptoms in schizophrenia, and a drug with specific effects on negative symptoms has a real chance to improve the day-to-day social and vocational functioning of patients affected by this disease."

"The findings published in the American Journal of Psychiatry are noteworthy in that MIN-101 was shown to improve negative symptoms without blocking dopamine receptors, unlike other drugs indicated for schizophrenia," said Dr. Harvey. "As such, it may be better tolerated by patients and may improve drug adherence, which is particularly problematic in treating schizophrenia." Dr. Harvey was not involved in the design or the conduct of the Phase 2b trial with MIN-101.

"The publication of these data by a prestigious journal like the American Journal of Psychiatry is important for Minerva because it reflects a peer-reviewed recognition by the scientific and medical community of a new and innovative potential approach to alleviating the most debilitating symptoms in patients suffering from schizophrenia," said Dr. Remy Luthringer, president and chief executive officer of Minerva.

Following a recent "end-of-Phase 2" meeting with the U.S. Food and Drug Administration (FDA), Minerva expects to initiate a pivotal Phase 3 trial with MIN-101 to treat negative symptoms in schizophrenia in the second half of 2017.

About the American Journal of Psychiatry

The American Journal of Psychiatry is the official journal of the American Psychiatric Association (APA), the oldest medical association in the country, founded in 1844. It is published monthly and is focused on a broad spectrum of issues and advances in the diagnosis and treatment of mental illness. The APA is the largest psychiatric association in the world with

more than 37,000 physician members specializing in the diagnosis, treatment, prevention and research of mental illness.

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 clinical development for schizophrenia; MIN-202 (JNJ-42847922), in clinical development for insomnia and major depressive disorder (MDD); MIN-117, in clinical 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 with MIN-101, including the planned Phase 3 trial of MIN-101, the timing and scope of future clinical trials and results of clinical trials with this compound; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies; our ability to successfully develop and commercialize MIN-101; 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 based on our current expectations and may differ materially from actual results due to a variety of factors including, without limitation, whether MIN-101 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-101, if any, will be consistent with the results of past clinical trials; whether MIN-101 will be successfully marketed if approved; whether any of our therapeutic product discovery and development efforts will be successful; 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, 2017, filed with the Securities and Exchange Commission on May 4, 2017. 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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