Journal of Clinical Psychiatry Publishes Positive Results of Cognitive Performance From Phase 2B Trial of Roluperidone, Under Development by Minerva Neurosciences for the Treatment of Negative Symptoms in Schizophrenia

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WALTHAM, Mass., May 17, 2018 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (NASDAQ:NERV), a clinical-stage biopharmaceutical company focused on the development of therapies to treat central nervous system disorders (CNS), today announced that The Journal of Clinical Psychiatry has published online results demonstrating cognitive improvements in patients with schizophrenia treated with roluperidone (MIN-101). The results also demonstrated that cognitive improvements correlate with previously reported improvements in negative symptoms.

The manuscript, entitled "Cognitive Effects of MIN-101 in Patients with Schizophrenia and Negative Symptoms: Results from a Randomized Controlled Trial," can be found online at https://doi.org/10.4088/JCP.17m11753.

Roluperidone is a novel compound with affinities for $5HT_{2A}$ and $sigma_2$ receptors and no direct binding to dopamine receptors. In this regard, roluperidone differs from drugs currently indicated for schizophrenia, all of which directly interfere with dopamine neurotransmission.

Results presented in this publication suggest a benefit of roluperidone on cognitive performance in schizophrenia patients with stable positive symptoms and moderate to severe negative symptoms. Researchers hypothesized that because roluperidone lacks the detrimental effects associated with currently available medications that do not benefit cognitive performance in patients with schizophrenia, the potential beneficial effects on cognition induced by $5HT_{2A}$ antagonism and $sigma_2$ antagonism would not be disrupted or diminished by other aspects of the compound's mechanism of action.

"Currently available dopamine-blocking antipsychotic drugs have very little impact on cognitive impairment associated with schizophrenia," said Dr. Richard Keefe, Professor of Psychiatry and Behavioral Sciences at Duke University School of Medicine, CEO of NeuroCog Trials, which provided quality assurance of the cognitive data in the study, and an author of the publication. "The data from this study suggest that roluperidone, which combines $5HT_{2A}$ and $sigma_2$ antagonism without dopamine blockade, in addition to improving negative symptoms may improve cognitive deficits in schizophrenic patients."

Cognitive impairment is one of the primary drivers of functional disability in schizophrenia and an unmet medical need. Cognitive impairment in patients with this disease has been consistently associated with various aspects of diminished functioning, including unemployment, limited social interaction and poor quality of life.

Cognitive abilities in this study were measured by the Brief Assessment of Cognition in Schizophrenia (BACS) scale at baseline and after 4 and 12 weeks of treatment. In the analysis of the changes from baseline to the study endpoint (Week 12), scores on a motor test and on a test of verbal fluency were statistically significantly better than placebo. BACS composite *z* scores (*z* score distribution $p = .05$) showed statistically significant improvement in the roluperidone 32 milligram (mg) group compared to the placebo group. The *T* score for the BACS composite was close to significance ($p = .06$). There were no significant intergroup differences in the changes in the other BACS domains.

Additional analyses illustrate the correlations between the change in the BACS scores and the change in the Positive and Negative Syndrome Scale (PANSS) negative factor score.

Previously announced results from this trial, published in the American Journal of Psychiatry, showed that roluperidone 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 PANSS. The improvement in negative symptoms was shown for both doses tested: 32 mg: p = 0.024 effect size = 0.45, and 64 mg: p = 0.004 effect size = 0.57.

About The Journal of Clinical Psychiatry

The Journal of Clinical Psychiatry is the official journal of the American Society of Clinical Psychopharmacology (https://www.ascpp.org), which was founded in 1992 to advance the science and practice of clinical psychopharmacology.

About Minerva Neurosciences

Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of product candidates to treat CNS diseases. Minerva's proprietary compounds include: roluperidone (MIN-101), in clinical development for schizophrenia; MIN-117, in clinical development for major depressive disorder (MDD); seltorexant (MIN-202 or JNJ-42847922), in clinical development for insomnia and 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 scope of current clinical trials and results of clinical trials with roluperidone; the timing and scope of future clinical trials and results of clinical trials with roluperidone; the clinical and therapeutic potential of roluperidone; our ability to successfully develop and commercialize roluperidone; 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 roluperidone 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 roluperidone will be successfully marketed if approved; 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, 2018, filed with the Securities and Exchange Commission on May 3, 2018. 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

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