Minerva Neurosciences Screens First Patient in Phase 3 Trial Of MIN-101 to Treat Negative Symptoms in Schizophrenia

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Multi-center, international trial targets significant unmet need for which no treatments are approved

Approximately 500 patients to be enrolled at 60 clinical sites in U.S. and Europe

WALTHAM, Mass., Dec. 19, 2017 (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 the screening of the first patient in the pivotal Phase 3 clinical trial of MIN-101 (Study MIN-101C07) as monotherapy for negative symptoms in patients diagnosed with schizophrenia.

The trial is a multicenter, randomized, double-blind, parallel-group, placebo-controlled, 12-week study to evaluate the efficacy and safety of 32 milligrams (mg) and 64 mg of MIN-101 in adult patients with negative symptoms of schizophrenia. The 12-week study will be followed by a 40-week, open-label extension period during which patients on drug will continue receiving their original dose and patients on placebo will receive either 32 mg or 64 mg of MIN-101.

"The initiation of this pivotal Phase 3 trial is an important milestone for Minerva," said Dr. Remy Luthringer, chief executive officer of Minerva. "Patients with schizophrenia lack a treatment directed specifically toward negative symptoms, the key unmet need for these patients, which also helps stabilize positive symptoms. As no treatments are approved for negative symptoms, we believe this trial represents an exciting opportunity to make a significant impact on the therapeutic landscape for a debilitating disease affecting millions of patients in the U.S. and the rest of the world.

"Following discussion with the U.S. Food and Drug Administration (FDA) on the study's design and operational conduct, we are employing the same doses in monotherapy as used in the successful Phase 2b trial, as well as the same primary endpoint following the 12-week double-blind treatment period and the same patient recruitment criteria," said Dr. Luthringer. "We are looking forward to working with our investigators in the U.S. and Europe in the months ahead."

Approximately 500 patients will be enrolled at approximately 60 clinical sites in the U.S. and Europe, with about 30 percent of patients coming from the U.S. Patients will be initially randomized equally to receive one of the two doses of MIN-101 or placebo for 12 weeks. Thereafter, all patients will continue treatment with active drug for an additional 40 weeks, during which patients initially randomized to the two treatment groups will continue treatment with the same doses, while patients initially randomized to placebo will cross over to one of the two doses. Top-line results from the 12-week double blind phase of this trial are expected in the first half of 2019.

The primary endpoint of this trial will be improvement in negative symptoms in patients treated with MIN-101 compared to placebo as measured by the change in the Positive and Negative Syndrome Scale (PANSS) Marder negative symptoms factor score (NSFS) over the 12-week double-blind treatment period. The key secondary endpoint will be the effect of MIN-101 compared to placebo as measured by the Personal and Social Performance (PSP) total score over the same period. Additional secondary endpoints will be the effect of MIN-101 compared to placebo on the Clinical Global Impression of Severity (CGI-S) score and safety and tolerability.

Patients admitted into the trial must have a documented diagnosis of schizophrenia for at least one year and be symptomatically stable for at least 6 months with moderate to severe negative symptoms (> 20 on the PANSS negative symptom subscale) and stable positive symptoms. Patients without severe symptoms of suspiciousness, agitation, hostility, uncooperativeness or impulsivity will be recruited. These eligibility criteria are believed to represent the real-world patient population who may benefit when the drug is used in clinical practice[1]. In addition, patients treated with psychotropic agents will need to undergo wash-out before receiving study drug. These parameters were applied in screening the population treated in the Phase 2b trial.

About MIN-101

MIN-101 is a drug candidate with equipotent affinities for sigma $_2$ and 5?hydroxytryptamine-$_{2A}$ (5-HT$_{2A}$) and at lower affinity levels, ?1-adrenergic receptors. MIN-101 exhibits very low or no affinity for dopaminergic, muscarinic, cholinergic and histaminergic 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.

About Schizophrenia

As described by the National Institute of Mental Health, schizophrenia is a chronic and severe disorder that affects how a person thinks, feels and acts[2]. The disease affects more than 21 million people worldwide, according to the World Health Organization[3]. Schizophrenic patients suffer from positive, negative and cognitive symptoms. Negative symptoms are disruptions to normal emotions and behaviors that may signal social withdrawal. Patients may be socially inhibited, lack the ability to begin and sustain planned activities, or speak little even when forced to interact. Negative symptoms account for a substantial portion of the morbidity associated with schizophrenia[4]. They persist chronically throughout an individual patient's lifetime and increase with severity over time.

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; seltorexant (MIN-202 or 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; the Company's ability to successfully develop and commercialize MIN-101; the sufficiency of the Company's current cash position to fund operations; and management's ability to successfully achieve its goals. These forward-looking statements are based on the Company's 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; management's ability to successfully achieve its goals; its ability to raise additional capital to fund operations on acceptable terms; 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 the Company's filings with the Securities and Exchange Commission, including the Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed with the Securities and Exchange Commission on November 6, 2017. Copies of reports filed with the SEC are posted on the Company's website at www.minervaneurosciences.com. The forward-looking statements in this press release are based on information available to the Company as of the date hereof, and the Company disclaims any obligation to update any forward-looking statements, except as required by law.

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[1] Dunayevich, E., Chen, C.Y., Marder, S.R., and Rabinowitz, J. (2014). Restrictive symptomatic inclusion criteria create barriers to clinical research in schizophrenia negative symptoms: An analysis of the CATIE dataset. *Eur. Neuropsychopharmacol. 24* (10),1615-1621.

[2] https://www.nimh.nih.gov/health/topics/schizophrenia/index.shtml

[3] http://www.who.int/mediacentre/factsheets/fs397/en/

[4] Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, American Psychiatric Association.

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