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Minerva Announces Outcome of End-of-Phase 2 Meeting With FDA

Pivotal Phase 3 trial design to include monotherapy administration of MIN-101 and primary endpoint of improvement in negative symptoms of schizophrenia

Planned initiation of MIN-101 Phase 3 development in second half of 2017

WALTHAM, Mass., May 15, 2017 (GLOBE NEWSWIRE) -- Following a recent "end-of-Phase 2" meeting with the U.S. Food and Drug Administration (FDA), 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 its plans to initiate Phase 3 development of MIN-101, a drug targeting negative symptoms in schizophrenia patients. A pivotal Phase 3 trial with MIN-101 is expected to be initiated in the second half of 2017.

The Phase 3 trial design will be a 12-week, double-blind, randomized, placebo-controlled, monotherapy study testing two doses of MIN-101 in patients with negative symptoms and a diagnosis of schizophrenia. To be eligible for this study, patients will be required to have stable negative and positive symptoms over several months prior to enrollment, with a specified minimum threshold baseline score on the Positive and Negative Syndrome Scale (PANSS) negative sub-scale.

After the double-blind phase, patients may enter a 36-week open label extension phase in which all patients will receive active treatment. This multi-center, international trial is expected to enroll approximately 500 patients at approximately 60 clinical sites across the U.S. and Europe.

The primary endpoint will be improvement in negative symptoms at 12 weeks as measured by the PANSS Marder negative factor score, a widely recognized instrument for quantifying severity of negative symptoms. Secondary efficacy endpoints will include the Clinical Global Impression of Severity (CGI-S) scale and Personal and Social Performance (PSP) total score. The overall design of the planned Phase 3 trial is similar to the Phase 2b trial completed in 2016, in which improvement was observed in schizophrenic patients with negative symptoms treated with MIN-101 compared to placebo.

The Company shared pre-clinical and clinical efficacy and safety data at the FDA meeting, and safety and tolerability of MIN-101 will continue to be assessed during the duration of the Phase 3 trial, including cardiac function via electrocardiograms (ECGs). Discontinuation criteria based on PANSS and cardiac electrophysiological criteria will be incorporated into the study protocol.

"Minerva is finalizing its plan for the Phase 3 development of MIN-101, an innovative investigational treatment for schizophrenia, following our recent meeting with the FDA," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "Our discussion with the agency has helped to confirm our Phase 3 trial design, which is similar to our previous Phase 2b trial design. We believe that positive data from the Phase 3 trial, along with the positive data from the Phase 2b trial, may form the basis for the future submission of a New Drug Application for MIN-101 to the FDA."

"The constructive feedback from the agency supports the further development of MIN-101 for schizophrenia," 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. "Negative symptoms currently continue to represent a significant unmet need and contribute substantially to poor quality of life and functional outcomes for the large worldwide population of patients with this disease."

Updates and further details regarding the Phase 3 trial, including anticipated timing of recruitment, participating centers and investigators will be provided later this year and posted on www.clinicaltrials.gov.

About schizophrenia and the impact of negative symptoms

Schizophrenia remains among the top ten disabling conditions worldwide for young adults and affects more than 21 million people worldwide. According to Datamonitor, an independent market research firm, in 2016 approximately 3.3 million people suffered from schizophrenia in the United States, Japan and the five major European Union markets of France, Germany, Italy, Spain and the United Kingdom.

Although positive psychotic symptoms are characteristic of schizophrenia, negative symptoms constitute one of the main sources of burden of illness, represent an important treatment target and are a major cause of the poor vocational and

social capabilities of these patients. These symptoms, which include a-motivation, avolition, lack of initiative, and restricted personal interaction, are associated with poor psychosocial functioning.

In the majority of schizophrenia patients, acute positive symptoms remit due to treatment with antipsychotics (dopamine-blocking drugs) or spontaneously. Antipsychotic drugs also reduce the risk for recurrence of psychosis. However, many patients maintain remission of psychosis without antipsychotic dopamine blocking drugs. Nevertheless, they continue to suffer negative symptoms, for which no FDA-approved treatments are specifically indicated.

About 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 alpha1-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.

The Phase 2b trial with MIN-101, announced in 2016 and presented at the annual meeting of the American College of Neuropsychopharmacology, met its primary endpoint of statistically significant improvement in negative symptoms as measured by the PANSS pentagonal structure model and in the higher dose showed statistically significant benefit in multiple secondary endpoints that included general psychopathology.

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-117, in clinical development for major depressive disorder (MDD); MIN-202 (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 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 potential for a single Phase 3 trial with supportive Phase 2b results to support the basis for an NDA; 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; 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, 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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