December 3, 2014

Minerva Neurosciences Announces Completion of Development and Final Selection of Once-Daily Dose Formulation of MIN-101 for Its Schizophrenia Program

New Formulation to be Used in Planned Phase 2b Clinical Trial Has Been Developed to Offer Improved Safety, Tolerability and Pharmacokinetic Profile

WALTHAM, Mass., Dec. 3, 2014 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (Nasdaq:NERV), a clinical-stage biopharmaceutical company focused on the development of innovative therapies to treat neuropsychiatric diseases and disorders, today announced the completion of development and final selection of a once-daily dose formulation of MIN-101**,** an antagonist on 5-HT2A and Sigma2 receptors for the treatment of schizophrenia**.** The new formulation will be used in the Company's planned Phase 2b clinical trial in schizophrenia, scheduled to begin recruiting in the first half of 2015.

"The development and final selection of this once-daily formulation of MIN-101 represents an important milestone in our plan to develop a formulation of MIN-101 to achieve optimal efficacy, safety, tolerability and pharmacokinetic profiles," said Dr. Remy Luthringer, chief executive officer and president of Minerva. "We are especially encouraged by the pharmacokinetic parameters of this formulation and believe it has the ability to address significant areas of unmet need in the treatment of negative symptoms, cognitive impairments and sleep disorders."

The administration trial objectives were to develop a formulation of MIN-101 to allow for chronic daily administration by maintaining daily exposure of the compound and keeping the maximum plasma concentration (Cmax) and its two active metabolites (BFB-520 and BFB-999) below a level based on previous pharmacokinetic/pharmacodynamics analyses. The trial results show that the final formulation of MIN-101 lowers levels of BFB-520, which has been previously associated with prolongation of QT intervals at supra-therapeutic levels.

"We believe that this new once-daily formulation will be able to maintain plasma levels of MIN-101 over the course of one day while reducing BFB-520 levels and increasing levels of BFB-999 associated with sleep improvements due to its affinity to 5-HT2A and histaminergic H1 receptors," added Dr. Luthringer.

About The Study

The new formulation was assessed in a single-center, open-label trial to evaluate the safety, tolerability and pharmacokinetic profiles of several formulations of MIN-101 in a single dose administration setting. Plasma levels of parent compound MIN-101 as well as of the two main metabolites (BFB-520 and BFB-999) were assessed in 12 young healthy volunteers, who received three different formulations of MIN-101. Six adverse reactions of mild to moderate intensity were reported in five subjects: sleepiness (2); headache (3); and blurred vision (1). QTc measures stayed in the recommended values as given by ICH-E14 on Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs.

About Schizophrenia

Patients suffering with schizophrenia can present with a range of symptoms, including: positive symptoms, such as delusions, hallucinations, thought disorders, and agitation; negative symptoms, such as mood flatness and lack of pleasure in daily life; cognitive symptoms, such as the decreased ability to understand information and make decisions, difficulty focusing, and decreased working memory function; and sleep disorders. Most currently approved therapies for schizophrenia show efficacy primarily in the management of positive symptoms. An estimated 4.2 million people suffered from schizophrenia in 2012 in the United States and the five major European Union markets. Of those, an estimated 48% experienced predominantly negative symptoms and 80% suffered from cognitive impairment. In addition, about 50% of patients with schizophrenia experience sleep disorders, which can further exacerbate both positive and negative symptoms.

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 neuropsychiatric diseases. Minerva is developing a portfolio of first-in-class proprietary compounds, including lead compound MIN-101, which is in Phase 2 trials for schizophrenia, and additional candidates targeting major depressive disorder (MDD), insomnia and other CNS disorders. Minerva's common stock is listed on the NASDAQ Global Market where it trades 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 benefits, efficacy and safety of the new once-a-day formulation of MIN-101; timing and results of future clinical milestones; the timing of future clinical trials and results of such clinical trials regarding MIN-101; clinical and therapeutic potential of MIN-101 and our ability to successfully develop and commercialize MIN-101; and management's ability to successfully achieve its goals. These forward-looking statements are only predictions and may differ materially from actual results due to a variety of factors including, without limitation, whether MIN-101 or any of our other therapeutic products 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 MIN-101 and our other therapeutic products will be successfully marketed if approved; whether any of our other 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 September 30, 2014, filed with the Securities and Exchange Commission on November 6, 2014. Copies of reports filed with the SEC are posted on our website. 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: Media Contact:

David Salisbury

Berry & Company Public Relations

Tel: 212-253-8881

dsalisbury@berrypr.com

Investor Contact:

Renee Leck

Stern Investor Relations

Tel: 212-362-1200

renee@sternir.com

Source: Minerva Neurosciences, Inc