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Minerva Neurosciences Reports Positive Data Showing an Analog of Minerva's MIN-301 Compound Improves Symptoms of Parkinson's Disease in Primates

Results provide further support for research involving use of neuregulin-1 compounds in treatment of Parkinson's and other neurodegenerative disorders

WALTHAM, Mass., Jan. 5, 2015 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (Nasdaq:NERV) today announced that results from a Primomed (use of PRIMate MOdels to support translational MEDicine) non-human primate study showed that treatment with an analog of MIN-301, the company's investigational neuregulin-1 compound, resulted in improvements in a range of symptoms associated with Parkinson's disease in primates. MIN-301 is a recombinant form of the neuregulin-1β1 extracellular domain. The analog used in the Primomed study differs from MIN-301 by a single amino acid.

"We believe that MIN-301 and its analog are functionally identical and that this data provides further support for advancing MIN-301 into clinical trials for the treatment of Parkinson's disease in humans," stated Dr. Rémy Luthringer, Ph.D., president and CEO of Minerva. "We believe MIN-301 and other peptides from our neuregulin platform may represent the next generation of therapies with neuroprotective activities in Parkinson's and other neurodegenerative disorders."

In the pre-clinical study, Parkinson's disease symptoms were induced in marmosets by a standard protocol using subcutaneous injections of MPTP neurotoxin. Daily treatment with either the analog or saline vehicle was initiated one week prior to Parkinson's induction with MPTP and continued for eight weeks. In both treatment groups, disease-modifying efficacy was measured as it related to changes in clinical signs, motor symptoms and motor function. Clinical signs were scored on a semiquantitative scale of clinical Parkinsonian symptoms. Motor symptoms were assessed using the abnormal involuntary movements scale (AIMS), which includes assessments of extremity and trunk movements, facial expressions, and movements of the lips, peri-oral area, tongue and jaw. Motor function was evaluated using the Bungalow test, which records the number of compartment changes as a measure of locomotor activity.

Subjects treated with a daily subcutaneous injection of the MIN-301 analog showed greater improvements in Parkinsonian clinical score, AIMS and locomotor activity (Bungalow test) compared to vehicle. The strongest improvements in the analog-treated population were obtained during periods of slower disease progression. Previous research in rodent models of Parkinson's disease has shown that MIN-301 has the potential to restore motor function. Results from the Primomed study involving an analog of MIN-301 were consistent with these previous results.

Neuregulins play key roles in myelination, neuronal integrity and cognition-related signaling. Neuregulin-1 has been shown to have neurotrophic and neuroprotective effects on dopaminergic neurons. A number of studies have also demonstrated the association of neuregulin-1 with brain pathologies including schizophrenia, Alzheimer's disease and Parkinson's disease. These features, combined with the ability to cross the blood-brain barrier, make neuregulin-1 and its variants attractive for therapeutic purposes in Parkinson's.

In previous research both MIN-301 and its analog have been found to have the same level of activity *in vitro* in phosphorylation of ErBB3 receptors. Research involving multiple pre-clinical models mimicking Parkinson's symptoms has been carried out with MIN-301. The non-human primate MPTP model used in the Primomed study is the only animal model of early Parkinson's that replicates the progressive development of symptoms alongside progressive neurodegeneration.

About the Primomed Project

Primomed, sponsored by the European Union, is a research project involving the use of PRIMate MOdels to support translational MEDicine and advance disease modifying therapies to address a range of unmet medical needs in the treatment of chronic inflammatory and degenerative disorders. The project works to provide clinically relevant proof of concept regarding efficacy for drug candidates and to characterize the immune responses in biological samples generated by research activities, when appropriate. Further details are available at: http://primomed.fp7sme.eu/

About Parkinson's disease

Parkinson's disease is a widespread and progressive neurodegenerative disorder resulting in disabling motor impairment. Parkinson's is the most common neurodegenerative disease after Alzheimer's disease, and currently has no cure. The average age at which symptoms begin to develop is 55-60 years. While a range of medications and surgical interventions is available to treat some of the symptoms of Parkinson's disease, no therapy has been shown to either prevent or cure the disease. Parkinson's disease is associated with a range of medical and societal costs, including frequent medical interventions and hospitalizations, loss of productivity, inability to work, and diminished quality of life for patients and care partners.

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 central nervous system (CNS) diseases. Minerva is developing first-in-class proprietary compounds, including MIN-301, which is in preclinical development for the treatment of Parkinson's disease, and additional candidates targeting major depressive disorder, 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 whether the results of the study of the analog of MIN-301 are applicable to MIN-301; the timing and results of future clinical milestones; the timing of future clinical trials and results of clinical trials regarding MIN-301; clinical and therapeutic potential of MIN-301; our ability to successfully develop and commercialize MIN-301; 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 the analog of MIN-301 is a good predictor of clinical efficacy of MIN-301; whether MIN-301 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-301 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 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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