Minerva Neurosciences Presents Pre-Clinical Data Suggesting a Mechanistic Role of Roluperidone in Addressing Negative Symptoms of Schizophrenia

April 11, 2019

Findings show roluperidone increases release and gene expression of BDNF, as well as release of GDNF

Data presented at 2019 Congress of the Schizophrenia International Research Society

WALTHAM, Mass., April 11, 2019 (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 presentation of a poster at the 2019 Congress of the Schizophrenia International Research Society in Orlando, Florida entitled *Roluperidone increases in-vitro Brain-Derived Neurotrophic Factor (BDNF) release: a possible mechanistic role in negative symptoms?*

Findings to be presented in Poster #T145 during Poster Session 1 on April 11, 2019, 12:00 p.m. – 2:00 p.m., demonstrate that administration of roluperidone significantly increased BDNF release by astrocytes and hippocampal neurons obtained from the cerebral cortex of newborn rats, as well as the release of GDNF (Glial cell derived neurotrophic factor) in cultured astrocytes. Furthermore, data showed that roluperidone enhanced BDNF gene expression at drug concentrations similar to those observed in humans at tested doses.

Based on these results, researchers suggested that the effect of roluperidone on BDNF and GDNF may indicate the potential of this investigational compound for disease modification and improved neuroplasticity, in addition to its observed effects on the $sigma_2$ and serotoninergic $5\text{-}HT_{2A}$ neurotransmitter pathways.

BDNF is a member of a family of proteins called neurotrophins that plays an important role in the formation and function of neural connections. BDNF is the most widely distributed neurotrophin in the brain and has been associated with neurogenesis, neuroplasticity, neuroprotection, synapse regulation, learning, and memory.[1] Its involvement in schizophrenia has also been described.[2] GDNF is another neurotrophin that is known to promote the survival of different types of brain cells and has been shown to be essential for the maintenance and survival of dopamine neurons.[3]

About Roluperidone

Roluperidone is a drug candidate with equipotent affinities for 5-hydroxytryptamine-$_{2A}$ ($5\text{-}HT_{2A}$) and $sigma_2$ and at lower affinity levels, α1-adrenergic receptors. Roluperidone exhibits no affinity for dopaminergic, muscarinic, cholinergic and histaminergic receptors. Roluperidone 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.

A pivotal Phase 3 clinical trial is ongoing with roluperidone as monotherapy for negative symptoms in patients diagnosed with schizophrenia. Approximately 500 patients are expected to be enrolled at approximately 60 clinical sites in the U.S. and Europe. Top-line results from the 12-week double blind phase of this trial are expected in mid-2019.

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 future clinical trials and results of clinical trials with roluperidone, seltorexant, MIN-117 and MIN-301; the timing and scope of future clinical trials and results of clinical trials with these compounds; the clinical and therapeutic potential of these compounds; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies; our ability to successfully develop and commercialize our therapeutic products; 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, seltorexant, MIN-117 and MIN-301 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 any of our therapeutic products will be successfully marketed if approved; whether any of our therapeutic product discovery and development efforts will be successful; 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 Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission on March 12, 2019. 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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[1] BDNF and schizophrenia: from neurodevelopment to neuronal plasticity, learning and memory, R. Nieto et al, Frontiers in Psychiatry, June 2013, Volume 4 Article 45, https://doi.org/10.3389/fpsyt.2013.00045

[2] Childhood trauma interacted with BDNF Val66Met influence schizophrenic symptoms, Xiao-jiao Bi et al, Medicine, http://dx.doi.org/10.1097/MD.0000000000010160

[3] ScienceDirect, https://www.sciencedirect.com/topics/biochemistry-genetics-and-molecular-biology/glial-cell-line-derived-neurotrophic-factor

Source: Minerva Neurosciences, Inc