January 20, 2017

Additional Data Analyses From Phase IIb Trial of MIN-101 in Schizophrenia Underscore Benefit in Multiple Measurements of Cognitive Function

WALTHAM, Mass., Jan. 20, 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 results of additional data analyses related to cognitive function from its 12-week, randomized, double-blind, placebo-controlled Phase IIb clinical trial of MIN-101 as monotherapy in patients with negative symptoms of schizophrenia. Data from this trial were reported in May 2016, and data from the 24-week open-label extension period of this trial were reported in October 2016.

"Cognitive impairment is a core feature of schizophrenia, affects up to 75 percent of the patient population and is a predictor of poor quality of life and functional status in patients with this disease," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "We have recently completed additional analyses from our Phase IIb trial with MIN-101 that show significant improvements in several sub-tests of cognitive functioning, including motor tests and verbal fluency in patients with schizophrenia. Deficits in these capabilities are associated with poor interpersonal and real-world functioning for these patients. We believe these latest findings hold promise for further clinical research in the improvement of cognitive function and drug development in schizophrenia."

Cognitive function in this trial was evaluated using the Brief Assessment of Cognition in Schizophrenia (BACS) scale. This scale was developed specifically to assess cognitive impairment in patients with schizophrenia. Key data findings include the following:

	P-value		**Effect size**	
	32mg	64mg	32mg	64mg
- Motor Function: Token Motor Task	0.0306	0.0493	0.42	0.38
- Motor Function: Symbol Coding Task	0.6310	0.0781	0.09	0.33
- Verbal Fluency: Semantic Fluency	0.0299	0.1838	0.42	0.25
- Verbal Fluency: Letter Fluency	0.0328	0.0878	0.41	0.32
- Total Verbal Fluency	0.0076	0.0554	0.51	0.36
- Verbal Memory	0.1544	0.3158	0.27	0.19
- Executive Function: Tower of London	0.3988	0.1952	0.16	0.25
BACS cognition assessment (Composite T Score)	0.2737	0.8253	0.21	-0.04

Top line results previously announced from the double-blind, placebo-controlled 12-week core phase of the Phase IIb trial with MIN-101 showed that it met its primary endpoint of statistically significant improvement in negative symptoms as measured by the PANSS pentagonal structure model (PSM) and also showed statistically significant benefit in multiple secondary endpoints that included general psychopathology. Data from the extension phase of this trial showed continuous improvement in negative symptoms over a nine month period.

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.

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[1]. In 2015 approximately 3.2 million people suffered from schizophrenia in the U.S., Japan and the five major European markets. 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[2]. They persist chronically throughout an individual patient's lifetime and increase with severity over time. Similar to negative symptoms, cognitive symptoms may be difficult to recognize and often are detected only when specific testing is performed. Cognitive symptoms include: poor "executive functioning," or the ability to understand information and use it to make decisions; trouble focusing or paying attention; problems with "working memory," or the ability to use information immediately after learning it. Poor cognition is related to worse employment and social outcomes for patients with schizophrenia.

[1] https://www.nimh.nih.gov/health/publications/schizophrenia-booklet-12-2015/index.shtml

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

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; the clinical and therapeutic potential of MIN-101; our ability to successfully develop and commercialize MIN-101; 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, they 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 our therapeutic product discovery and development efforts with MIN-101 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, 2016, filed with the Securities and Exchange Commission on November 3, 2016. 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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Source: Minerva Neurosciences, Inc. via Globenewswire