January 21, 2015

# Minerva Neurosciences Reports Positive Phase 1 Data With MIN-202, Selective Orexin-2 Antagonist for Treatment of Sleep Disorders Including Primary and Comorbid Insomnia

*Preliminary results provide additional support for progression of MIN-202 into next stage of clinical development. Minerva developing MIN-202 in collaboration with Janssen.*

WALTHAM, Mass., Jan. 21, 2015 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (Nasdaq:NERV) today announced that preliminary results from a Phase 1 clinical study showed that treatment with MIN-202, a selective orexin-2 antagonist, resulted in significant improvements in sleep onset and sleep duration in patients with comorbid insomnia related to major depressive disorder (MDD). Preliminary results from two additional Phase 1 studies also suggest that MIN-202 is well tolerated and possesses advantageous pharmacokinetic and pharmacodynamic features. The three Phase 1 studies were conducted by Janssen Research & Development, LLC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, as part of a collaboration to develop MIN-202 with Minerva that was facilitated by Johnson & Johnson Innovation Ltd in London.

"Treatment of sleep disorders remains a significant challenge in patients with both primary insomnia and many CNS diseases. These positive data indicate that MIN-202 could be an effective treatment able to both induce and maintain sleep," said Remy Luthringer, PhD, president and CEO of Minerva, adding "With these findings we have identified a dose range to advance this compound."

In patients with mood disorders, sleep disturbances (both insomnia and hypersomnia) have been associated with a suboptimal response to antidepressant drug (AD) therapy, an increased risk for relapse (in AD-responsive patients), and prodromal depression. Recent studies have shown that orexin-2 receptor antagonism might have a beneficial effect on overall arousal and stress level.

"We are especially encouraged by findings that support the use of MIN-202 in the treatment of both primary insomnia as well as sleep disorders associated with MDD," Dr. Luthringer added.

MIN-202 Phase 1b Study in MDD Patients

This was a double-blind, placebo-controlled, randomized, four-way crossover, single dose study in 20 male and female patients with MDD and insomnia. The primary endpoint was the effect of MIN-202 (dosed PM) on latency to persistent sleep (LPS). Some additional endpoints were evaluated by PSG (polysomnography). Preliminary results demonstrated a statistically significant effect on LPS in all three doses tested (10, 20, and 40 mg). Treatment with MIN-202 also resulted in prolonged total sleep duration by approximately 45 minutes.

MIN-202 Phase 1 Multiple Ascending Dose (MAD) Study in Healthy Volunteers

This was a double-blind, placebo-controlled, randomized MAD study in sequential cohorts of healthy males and females. MIN-202 was administered in the morning at dose levels ranging from 5mg to 60mg for 10 days. A dose level as low as 5mg was shown to elicit sedation while dose levels ≥ 20mg induced (daytime) somnolence. MIN-202 plasma exposure was dose proportional from 5mg to 20mg. At higher doses, the exposure was less than dose proportional.

MIN-202 Phase 1 Bio-Availability (BA) Study

The two studies described above were carried out using a suspension formulation of MIN-202. This third study evaluated treatment with a solid dose formulation of MIN-202 to potentially support additional clinical studies. In this study, similar pharmacokinetic profiles were observed for both formulations, qualifying the solid dose to support further clinical studies.

In these Phase 1 studies, MIN-202 was found to be generally well tolerated.

**About MIN-202**

MIN-202 is an orexin-2 (OX) antagonist being developed by Minerva Neurosciences in collaboration with Janssen Pharmaceutica NV, for the treatment of sleep disorders. The most commonly available medications to treat insomnia are GABA-mimetics (e.g., Ambien), which activate sleep-promoting neurons. During the last decade, the critical role of the orexin system in maintaining wakefulness in humans has been confirmed. Promoting sleep by inhibiting the OX-2 receptor may hold the

promise of improved safety (decreased interactions with other CNS functions), better restoration of natural sleep architecture (structure and pattern of sleep), and improved continuity (amount and distribution of sleep versus wakefulness), potentially leading to improvements in sleep quality and next day functioning.

**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 its lead program MIN-101 in Phase IIb development for the treatment of schizophrenia, MIN-202 in Phase I development for primary and comorbid insomnia, MIN-301, which is in preclinical development for the treatment of Parkinson's disease, and MIN-117 targeting major depressive disorder. 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 the timing and results of future clinical milestones; the timing of future clinical trials and results of clinical trials regarding MIN-202; clinical and therapeutic potential of MIN-202; our ability to successfully develop and commercialize MIN-202; 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 final results of the three MIN-202 Phase 1 studies will differ materially from the preliminary results; whether MIN-202 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-202 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.*

CONTACT: Media Contact:

Bill Berry

Berry & Company Public Relations

Tel: 212-253-8881

bberry@berrypr.com

Investor Contact:

Renee Leck

Stern Investor Relations

Tel: 212-362-1200

renee@sternir.com

Source: Minerva Neurosciences, Inc

News Provided by Acquire Media