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# Minerva Neurosciences Provides Update on MIN-202, Selective Orexin-2 Receptor Antagonist

## Data in Insomnia Presented by Janssen at SLEEP 2015

#### IND Now in Effect to Expand Clinical Testing into Adjunctive Major Depressive Disorder

WALTHAM, Mass., June 16, 2015 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (Nasdaq:NERV), a clinical-stage biopharmaceutical company focused on the development of innovative therapies to treat central nervous system (CNS) disorders, today provided an update on MIN-202 (JNJ-42847922), a selective orexin-2 receptor antagonist under joint development with Janssen Pharmaceutica NV.

Preclinical and single ascending dose clinical data with respect to this compound were presented by Janssen at the 29<sup>th</sup> Annual Meeting of the Associated Professional Sleep Societies (SLEEP 2015), June 6-10, 2015 (Abstract 0009, Characterization of JNJ-42847922, a selective orexin-2 receptor antagonist, as a clinical candidate for the treatment of insomnia).

"Based on data from a Phase 1b single-dose study in patients with Major Depressive Disorder (MDD), MIN-202 has a potential favorable pharmacokinetic and safety profile, as well as the pharmacodynamic profile for an insomnia treatment," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "Of particular interest, polysomnography data obtained in the Phase 1b study in major depressive patients showed that the selective blockade of orexin-2 by this compound not only accelerated sleep induction and prolonged sleep duration but more importantly also preserved physiologic or restorative sleep. The compound is quickly absorbed to facilitate rapid sleep onset and has an appropriately short half-life, which may avoid daytime sedation. Importantly, in addition to the objective measurements of sleep reported above, there was a statistically significant improvement in quality of sleep as measured by the Stanford Sleepiness Scale in MDD patients suffering from comorbid insomnia."

An Investigational New Drug Application (IND) is now in effect to enable the advancement of clinical testing with MIN-202 into Adjunctive MDD. MDD is the most prominent sub-type of depression, and the link with sleep disorder is well established.

"Insomnia is often a key contributor to MDD, and we want to investigate whether treatment of individuals with MDD using an orexin-2 receptor antagonist may forestall or limit frank depressive episodes, not only by improving sleep, but also through the other actions expected from this mechanism," said Dr. Luthringer. "We believe that the MIN-202 IND for adjunctive MDD is an important achievement that will facilitate future IND filings and clinical development, thus allowing us to explore the broader potential of this promising compound."

Minerva expects that two additional studies with MIN-202 will be initiated in the next several months. These include a Phase 2a study in patients with primary insomnia and a further Phase 1b study in patients with MDD with co-morbid insomnia.

### **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 development for the treatment of schizophrenia; MIN-202 (JNJ-42847922), in development for the treatment of insomnia; MIN-117 in development for the treatment of major depressive disorder; and MIN-301 in development for the treatment of Parkinson's disease. Minerva's common stock is listed on the NASDAQ Global Market under the symbol "NERV." For more information, please visit <a href="https://www.minervaneurosciences.com">www.minervaneurosciences.com</a>.

# 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 regarding MIN-202; the timing of future clinical trials and results of clinical trials regarding MIN-202; the clinical and therapeutic potential of MIN-202; our ability to successfully develop and commercialize MIN-202; 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 only predictions and may differ materially from actual results due to a variety of factors including, without limitation, whether MIN-202 will advance further in the clinical trials process and whether and when, if at all, it will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether MIN-202 will be successfully marketed if approved; whether our therapeutic product discovery and development efforts will be successful for MIN-202; 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 March 31, 2015, filed with the Securities and Exchange Commission on May 7, 2015. Copies of reports filed with the SEC are posted on our website at <a href="https://www.minervaneurosciences.com">www.minervaneurosciences.com</a>. 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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