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Minerva Neurosciences Announces Completion of FDA Review of Investigational New Drug Application for MIN-202 and Plans for First U.S.-Based Clinical Trial

Bioavailability Study in U.S. for Investigational Therapy in Development for Treatment of Insomnia to be Initiated

CAMBRIDGE, Mass., Sept. 22, 2014 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (Nasdaq:NERV), a leader in the development of new therapies to treat neuropsychiatric diseases and disorders, today announced that the U.S. Food and Drug Administration has completed its review of the Investigational New Drug Application for MIN-202, the Company's selective antagonist for the orexin-2 receptor in development for the treatment of insomnia. A bioavailability study to advance development of MIN-202, which is being developed by Minerva Neurosciences in collaboration with Janssen Pharmaceutica N.V. and Janssen Research & Development, LLC, is being initiated by Janssen. The bioavailability study will be the first clinical trial initiated for MIN-202 in the United States.

"We are very pleased that FDA has indicated that the bioavailability study may proceed following their review of the IND for MIN-202, and that we are now in position to initiate the first U.S.-based clinical trial for this promising compound," said Rogerio Vivaldi, MD, MBA, Minerva Neurosciences' president and chief executive officer. "With the recent FDA approval of a dual orexin antagonist for the treatment of insomnia, we are especially encouraged by research indicating that our selective orexin antagonist may be positioned to offer improved specificity and a more adequate pharmacokinetics/pharmacodynamics profile."

The bioavailability study will be a randomized, open-label, 3-way crossover study in healthy male subjects to evaluate the bioavailability, food effect, safety and tolerability of solid dosage formulation of MIN-202. In addition to this study, Janssen is conducting two other phase 1 studies with MIN-202, including a Phase 1b study in patients suffering from secondary insomnia and major depressive disorder and a randomized, double-blind, placebo-controlled multiple ascending dose (MAD) study in healthy male and female subjects. The primary objective of the MAD study is to investigate pharmacokinetics data for several doses of MIN-202 after repeated administration and to explore the safety and tolerability of MIN-202 versus placebo during 10 days of consecutive dose administration.

"With the initiation of the bioavailability trial in the U.S., our development program for MIN-202 will include three separate trials, representing significant progress in advancing this promising compound," said Remy Luthringer, PhD, executive vice president and head of R&D at Minerva Neurosciences.

About Minerva

Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of product candidates to treat neuropsychiatric diseases. The company was incorporated under the name Cyrenaic Pharmaceuticals, Inc. on April 23, 2007. In November 2013, it merged with Sonkei Pharmaceuticals, Inc. and the combined company was renamed Minerva Neurosciences, Inc.

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 clinical and therapeutic potential of MIN-202 and our ability to successfully develop and commercialize MIN-202. 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 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; 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 June 30, 2014, filed with the Securities and Exchange Commission on August 7, 2014. Copies of reports filed with the SEC are posted on our website. 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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