Minerva Neurosciences Announces Update for Three Clinical Trials

October 1, 2019

Company to host conference call at 8:30 a.m. today (dial-in information below)

WALTHAM, Mass., Oct. 01, 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 an update on three clinical-stage programs with roluperidone (MIN-101), seltorexant (MIN-202) and MIN-117. The Company will hold a conference call at 8:30 a.m. today to discuss these programs (see dial-in information below).

- **Roluperidone:** A total of 384 patients of a target total number of 501 patients have been enrolled into the ongoing Phase 3 trial with roluperidone to treat negative symptoms in schizophrenia, and there are currently 33 patients in screening. Due to a cyber-attack on one of the Company's external contractors that resulted in a disruption to patient recruitment in the study, the Company now expects to complete enrollment at approximately year-end and anticipates top-line results from the 12-week, double-blind portion of the study to be available in the first half of 2020.

  This trial is a multicenter, randomized, double-blind, parallel group, placebo-controlled, 12-week study to evaluate the efficacy and safety of 32 mg and 64 mg doses of roluperidone as measured by the Positive and Negative Syndrome Scale (PANSS) Marder negative symptoms factor score. The core 12-week study is followed by a 40-week, open-label extension period during which patients on the drug continue receiving their original dose and patients on placebo receive one of the two doses of roluperidone.

- **MIN-117:** Patient screening has been completed in the Phase 2b trial of MIN-117 in moderate to severe major depressive disorder (MDD). Top-line results are expected in the fourth quarter of 2019.

- **Seltorexant (MDD2002 Phase 2 trial)**: In this clinical trial, long-term (24-week/6-month), flexibly dosed seltorexant (20 mg or 40 mg) was compared to flexibly dosed quetiapine XR (150 mg or 300 mg) for adjunctive treatment of patients suffering from Major Depressive Disorder (MDD). 102 patients with MDD not responding adequately to SSRIs and SNRIs were enrolled. The primary endpoint was discontinuation of therapy, due to all causes, over 6 months. Mood improvement, measured using the Montgomery Asberg Depression Rating Scale (MADRS), and safety and tolerability were also evaluated. This exploratory trial was intended primarily to generate data to assist with the planning of Phase 3 studies and was not powered to detect statistical significance. Quetiapine XR was used as a comparator, because it is the only medication approved for the adjunctive treatment of MDD in both the U.S. and Europe.

  Seltorexant showed a quantitative advantage in the number of discontinuations due to all causes, with 41% discontinuation in the seltorexant arm versus 47% in the quetiapine XR arm. As expected, there was not a statistical separation between the two treatment arms.

  Mood improvement as measured by MADRS total score showed patients treated with seltorexant 20 mg dose experienced a greater improvement at week 24 (-22.7 points), compared to those treated with seltorexant 40 mg dose (-7.9 points), quetiapine 150 mg dose (-17.0 points) and quetiapine 300 mg dose (-14.8 points). As was shown in previous trials of seltorexant in MDD, a greater improvement in MADRS total score was observed in patients with sleep disturbance (Insomnia Severity Index ≥15) who received the 20 mg seltorexant dose. In these patients with insomnia, the improvements observed were -26.5 for the 20 mg seltorexant dose, -7.0 for the 40 mg seltorexant dose, -18.2 for the 150 mg quetiapine dose and -13.8 for the 300 mg quetiapine dose.

  The overall safety profile of the seltorexant groups was favorable compared to quetiapine, consistent with prior seltorexant studies, and extended to longer-term exposure over 6 months. Patients receiving seltorexant also experienced fewer

potentially treatment-related discontinuations than did patients receiving quetiapine (29.4% vs 47.1%).

The results of this study, taken with the results of the two previous studies (MDD2001 in MDD patients and ISM2005 in patients with insomnia), will help to define a Phase 3 clinical development program for seltorexant that potentially will encompass both MDD and insomnia.

Conference Call Information:

Minerva Neurosciences will hold a conference call and live audio webcast on October 1, 2019 at 8:30 a.m. Eastern Time to discuss the results of this trial. To participate, please dial (877) 312-5845 (domestic) or (765) 507-2618 (international) and refer to conference ID 7235727 To access the webcast, please go to https://edge.media-server.com/mmc/p/xazdqtav..

The live webcast can also be accessed under "Events and Presentations" in the Investors and Media section of Minerva's website at ir.minervaneurosciences.com. The archived webcast will be available on the website beginning approximately two hours after the event for 90 days.

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; seltorexant (MIN-202 or JNJ-42847922), in clinical development for insomnia and Major Depressive Disorder (MDD); MIN-117, in clinical development for 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 http://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 and MIN-117; 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 and MIN-117 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed with the Securities and Exchange Commission on August 5, 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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