Minerva Neurosciences Announces First Patient Screened in Global Phase 3 Confirmatory Trial of Roluperidone for the Treatment of Negative Symptoms of Schizophrenia

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Roluperidone has been de-risked by consistent positive results in two prior pivotal trials and remains the only late-stage drug candidate for this high-need population

Efficacy topline data expected 2H 2027

BURLINGTON, Mass., March 31, 2026 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (Nasdaq: NERV), a clinical-stage biopharmaceutical company focused on the development of therapies to treat central nervous system disorders, today announced that the first patient has been screened in its global, confirmatory Phase 3 clinical trial evaluating roluperidone as monotherapy for the treatment of negative symptoms of schizophrenia. Negative symptoms, including avolition (severe lack of motivation), anhedonia (inability to experience pleasure) and social withdrawal can lead to profound personal and functional impairment and represent one of the greatest unmet needs in schizophrenia. There are currently no FDA-approved treatments with this indication.

The Phase 3 trial will enroll approximately 380 patients across roughly 40 clinical sites worldwide, including the United States (US) and multiple European countries. This confirmatory Phase 3 trial follows productive discussions with the FDA on the overall design and efficacy assessments. It builds directly on Minerva's clinical success in the prior pivotal Phase 2b and Phase 3 trials (C03 and C07), both of which demonstrated consistent improvements in negative symptoms with the 64 mg dose of roluperidone.

"Initiation of this confirmatory Phase 3 trial is an important milestone for Minerva and for patients living with persistent and impairing negative symptoms of schizophrenia," said Dr. Remy Luthringer, Executive Chairman and CEO of Minerva Neurosciences. "With no approved treatments for this indication in the US, roluperidone remains the only late-stage candidate in development for this population. The study builds directly on our prior experience showing consistent results across the two earlier trials and our execution strategy gives us confidence in our timelines."

"Patients with schizophrenia often live with persistent negative symptoms such as avolition and anhedonia - challenges that remain even when positive symptoms are controlled with current therapies," said Dr. Elan Cohen, Principal Investigator at CenExel Marlton, New Jersey and Lead Coordinating Investigator for the trial. "By evaluating roluperidone in a population with stable positive symptoms, this trial isolates its potential to improve these core drivers of disability while laying the groundwork for a broader treatment strategy. Strengthening motivation, cognition, and functioning may ultimately support more comprehensive symptom control over time, and the consistency seen in prior studies makes this confirmatory Phase 3 trial especially compelling."

About the Phase 3 MIN-101C19 Trial
The global Phase 3 MIN-101C19 trial will enroll approximately 380 adults aged 18–55 with moderate to severe negative symptoms of schizophrenia, confirmed by a Positive and Negative Syndrome Scale (PANSS) negative subscale score greater than 20 and stable positive symptoms for at least six months. The trial utilizes a two-part design. The overall objective of the study is to confirm the effect of roluperidone on primary negative symptoms at 12 weeks compared to placebo and to evaluate longer-term relapse of positive symptoms compared with commonly prescribed antipsychotic medications for an additional 40 weeks.

The trial is designed to minimize variability and maximize sensitivity to treatment effect, including standardized assessments, and comprehensive caregiver engagement. Topline data from the 12-week Phase A portion (i.e., primary efficacy endpoint) of the trial are expected in the second half of 2027. The trial's operational model includes intensive rater training, real-time monitoring of scoring data, and structured caregiver outreach to support safety tracking, functional assessments, and adherence.

Phase A is a12-week, randomized, double-blind, placebo-controlled phase during which patients will receive 64 mg of roluperidone or placebo to evaluate the primary endpoint: change from baseline in the Marder Negative Symptoms Factor Score (NSFS), which is a factor-analytic composite created from selected PANSS items. The sole key secondary endpoint is the change from baseline in the Personal and Social Performance (PSP) total score. Other secondary endpoints include a broad set of additional clinical measures, including PANSS subscales, Clinical Global Impression – Severity (CGI-S), Clinical Global Impression – Improvement (CGI-I), the Calgary Depression Scale, avolition-specific analyses, and patient and caregiver treatment-satisfaction ratings.

Phase B extends the trial for 40 weeks using a double-dummy, active-controlled, randomized design comparing continued roluperidone with three commonly prescribed antipsychotic medications (risperidone, aripiprazole, or olanzapine). This phase is designed to compare relapse rates between treatment groups. Relapses of positive symptoms will be evaluated using a rigorous, multi-component definition incorporating psychometric endpoints based on PANSS score worsening, and clinically meaningful events such as hospitalization or dangerous behavior.

About Minerva Neurosciences
Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on developing product candidates to treat CNS diseases. Minerva's goal is to transform the lives of patients with improved therapeutic options, including roluperidone for negative symptoms of schizophrenia. For more information, please visit the Company's website.

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, but are not limited to, statements herein with respect to implied or express statements regarding the anticipated clinical benefits and market opportunities associated with roluperidone, including its potential

to address clinical and regulatory challenges; and the expected timeline, design, and conduct of Minerva's Phase 3 trial of roluperidone. 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, trials and studies may be delayed and may not have satisfactory outcomes, and earlier trials and studies may not be predictive of later trials and studies; the design and rate of enrollment for clinical trials, including the current design of the confirmatory Phase 3 trial evaluating roluperidone may not enable successful completion of the trial(s); the commercial opportunity for roluperidone in negative symptoms of Schizophrenia may be smaller than anticipated; Minerva may be unable to obtain and maintain regulatory approvals; Minerva may experience uncertainties inherent in the initiation and completion of clinical trials and clinical development; Minerva's future financial performance and position may not improve, resulting in difficulties in implementing Minerva's business strategy, and plans and objectives for future operations; the expected sufficiency of Minerva's existing cash resources and runway may not be accurate resulting in the need for additional financing sooner than anticipated or unexpected liquidity constraints; the internal and external costs required for Minerva's ongoing and planned activities, and the resulting impact on expense and use of cash, may be higher than expected, which may cause the company to use cash more quickly than expected or to change or curtail some of Minerva's plans or both; the need to align with collaborators or partners may hamper or delay development and regulatory efforts or increase costs; uncertainties of patent protection and litigation; general economic conditions; and other factors that are described under the caption "Risk Factors" in Minerva's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission. Copies of reports filed with the SEC are posted on Minerva's website at http://ir.minervaneurosciences.com/. The forward-looking statements in this press release are based on information available to the Company as of the date hereof, and the Company disclaims any obligation to update any forward-looking statements, except as required by law.

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