Minerva Neurosciences Establishes Scientific Advisory Board to Advance Development of Roluperidone and Future Pipeline Programs

June 1, 2026

Distinguished panel of experts in psychiatry and neuroscience appointed to guide Phase 3 confirmatory trial of roluperidone and broader R&D strategy

BURLINGTON, Mass., June 01, 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 the formation of its Scientific Advisory Board (SAB), fulfilling a commitment made in connection with the Company's PIPE financing announced on October 21, 2025. The SAB brings together distinguished researchers and clinicians with proven track records of advancing meaningful treatments in psychiatry and neuroscience.

"The formation of this Scientific Advisory Board reflects our commitment to bringing the highest level of scientific rigor and clinical expertise to the development of roluperidone and to building a robust pipeline for patients with serious psychiatric conditions," said Remy Luthringer, Ph.D., Chief Executive Officer of Minerva Neurosciences. "Each member of our SAB brings deep expertise and a track record of advancing meaningful treatments in psychiatry and neuroscience. We are grateful for their commitment and look forward to their counsel as we work to bring roluperidone to patients."

The SAB will advise on the Company's research and development activities, including the ongoing Phase 3 confirmatory clinical trial (NCT07565428; MIN-101C19) of roluperidone for the treatment of negative symptoms of schizophrenia, an area of profound unmet need for which no therapy is currently approved in the United States, as well as Minerva's broader pipeline for patients with serious psychiatric conditions.

Scientific Advisory Board Members

Michael Davidson, M.D.
Chief Medical Officer, Minerva Neurosciences

Philip Harvey, Ph.D.
Professor of Psychiatry and Behavioral Sciences
University of Miami

Oliver Howes, M.D., Ph.D.
Professor of Molecular Psychiatry, King's College London

Inder Kaul, M.D.
Chief Medical Officer, Draig Therapeutics
Member, Minerva Neurosciences Board of Directors

Brian Kirkpatrick, M.D.
Professor of Psychiatry
University of Arkansas for Medical Sciences

Remy Luthringer, Ph.D.
Chief Executive Officer, Minerva Neurosciences

Avi Reichenberg, Ph.D.
Professor of Psychiatry and Preventive Medicine
Icahn School of Medicine at Mount Sinai

Greg Strauss, Ph.D.
Franklin Professor of Psychology and Neuroscience
University of Georgia

About Roluperidone
Roluperidone is an investigational drug being evaluated as monotherapy for the treatment of the negative symptoms of schizophrenia, an area of profound unmet need for which there are currently no FDA-approved treatments. 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. While still investigational at this time, Roluperidone is the only monotherapy treatment, to date, to demonstrate significant meaningful improvements on the primary negative symptoms of schizophrenia, building on consistent positive results across two prior pivotal trials. Roluperidone was designed to avoid a direct blockade of dopaminergic receptors (the key pharmacological target for first- and second-generation antipsychotics), while maintaining blockade of a specific subtype of serotonin receptor called 5-HT2A (an additional key target of second-generation antipsychotics) as well as additional pharmacological targets (sigma2 and adrenergic-α1A).

Phase 3 Confirmatory Trial of Roluperidone for Negative Symptoms of Schizophrenia
NCT07565428; MIN-101C19
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 52 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.

Phase A is a 12-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). The sole key secondary endpoint is the change from baseline in the Personal and Social Performance (PSP) total score.

Phase B extends the trial for 52 weeks using a double-dummy, active-controlled, randomized design comparing continued roluperidone with three commonly prescribed antipsychotic medications (risperidone, aripiprazole, or olanzapine), designed to compare relapse rates.

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; the expected timeline, design, and conduct of Minerva's Phase 3 trial of roluperidone; and Minerva's ability to develop a broader pipeline of treatments for patients with serious psychiatric conditions. 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, 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 Minerva to use cash more quickly than expected or to change or curtail some of Minerva's plans or both; 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; 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 (the "SEC") on March 11, 2026, as supplemented by Minerva's Form 10-Q for the quarter ended March 31, 2026, filed with the SEC on May 5, 2026. 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 Minerva as of the date hereof, and Minerva disclaims any obligation to update any forward-looking statements, except as required by law.

Contacts:

Investor inquiries:

Frederick Ahlholm
Chief Financial Officer
Minerva Neurosciences, Inc.
info@minervaneurosciences.com

Corey Davis, Ph.D.
LifeSci Advisors, LLC
212-915-2577
cdavis@lifesciadvisors.com