Catalent and Minerva Neurosciences Enter Commercial Supply Agreement for Schizophrenia Drug Roluperidone

September 24, 2019

WALTHAM, Mass. and SOMERSET, N.Y., Sept. 24, 2019 (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, and Catalent, the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, gene therapies, and consumer health products, today announced that they have entered into a long-term commercial supply agreement for Roluperidone (MIN-101), an investigational compound under development by Minerva for the treatment of negative symptoms of schizophrenia. Under the terms of the agreement, Catalent will manufacture and package the finished dose form of the drug at its facility in Schorndorf, Germany.

Negative symptoms can persist chronically throughout the lifetime of patients with schizophrenia and contribute to poor quality of life and functional outcomes. No treatment is approved to treat these symptoms in the United States. Minerva is currently conducting a pivotal Phase 3 clinical trial with roluperidone at sites in Europe and the U.S. and could potentially be the first to market.

“Launching any new drug with a partner marks the culmination of many years of hard work and having to overcome challenges, and is a milestone for a project,” commented Aris Gennadios, Ph.D., President, Catalent Softgel & Oral Technologies. He added, “Catalent has a proven track record in developing new treatments and bringing them to market quickly, efficiently, and in the most patient-friendly dose form; and we are pleased to partner with Minerva on this important potential therapy.”

“We are pleased to be working closely with our partner, Catalent, under a long-term supply agreement for a compound with the potential to treat negative symptoms, one of the leading unmet needs in schizophrenia,” said Rick Russell, President of Minerva Neurosciences.

To date, Catalent has worked with Minerva to undertake the tech transfer from pilot to commercial-scale production. This included analytical methods transfer and validation, process optimization, stability studies, and registration batch manufacturing; as well as packaging studies, and assessing the influence of formulation factors on the product’s critical quality attributes as required by Quality by Design (QbD) process.

About Catalent

Catalent is the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, gene therapies, and consumer health products. With over 85 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable global clinical and commercial product supply. Catalent employs nearly 13,000 people, including approximately 2,400 scientists, at more than 35 facilities across five continents, and in fiscal year 2019 generated over $2.5 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit www.catalent.com. **More products. Better treatments. Reliably supplied.™**

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 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; the clinical and therapeutic potential of this compound; 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 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 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.

Contact:

William B. Boni
VP, Investor Relations/

Corp. Communications
Minerva Neurosciences, Inc.
(617) 600-7376

For Catalent:

Chris Halling
+44 (0) 7580 041073
Chris.halling@catalent.com

Richard Kerns
+44 (0) 161 728 5880
richard@nepr.agency

Source: Minerva Neurosciences, Inc