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NEURALSTEM INC.

Neuralstem Announces Top-line Phase 2 Data of NSI-189 for Major Depressive Disorder

GERMANTOWN, Md., July 25, 2017 (GLOBE NEWSWIRE) -- Neuralstem, Inc. (Nasdaq:CUR), a biopharmaceutical company developing novel treatments for nervous system diseases, today announced top-line results from its exploratory Phase 2 clinical trial examining the efficacy of NSI-189 at 40 mg once daily (QD) and 40 mg twice daily (BID) compared to placebo for the treatment of major depressive disorder (MDD). The study, which utilized the two-staged sequential parallel comparison design (SPCD), did not meet its primary efficacy endpoint of a statistically significant reduction in depression symptoms on the Montgomery-Asberg Depression Rating Scale (MADRS). However, the 40 mg QD dose was directionally positive on the MADRS.

Of two secondary efficacy endpoints analyzed so far, the patient-rated Symptoms of Depression Questionnaire (SDQ) achieved statistical significance (p=0.044) with NSI-189 40 mg QD compared to placebo in the overall SPCD analysis. Results were also directionally positive on the Hamilton Depression Rating Scale (HAM-D17) at both doses. Both the 40 mg QD and 40 mg BID doses were well-tolerated with no serious adverse events reported.

“Depression is an important and complex area of clinical development,” said Maurizio Fava, MD, Director of the Division of Clinical Research and Executive Vice Chair, Department of Psychiatry at Massachusetts General Hospital, and the principle investigator of the trial. “NSI-189 is a novel small molecule that has shown a potential signal of efficacy in this trial. We are encouraged by its emerging clinical profile, and continuing the clinical evaluation of NSI-189 to pursue its full potential is warranted.”

The 12-week randomized, double-blind, placebo controlled, SPCD study evaluated 220 subjects diagnosed with recurrent MDD and a minimum MADRS score of 20. The mean baseline MADRS score was approximately 32. The study was conducted in two sequential six weeks stages with SPCD. Placebo non-responders from Stage 1 were re-randomized to either NSI-189 (40 mg QD or 40 mg BID) or placebo in Stage 2. Subjects received treatment at the beginning of each period. The results of Stage 1 and Stage 2 were pooled for statistical endpoints.

“I would like to thank the team at Neuralstem for their seamless execution of the Phase 2 trial, and thank the investigators and patients for their participation,” said Rich Daly, chairman and CEO, Neuralstem. “The directionally positive signals across multiple depression scales are encouraging and we look forward to further evaluation of the full dataset in the coming months.”

About Neuralstem
Neuralstem is a clinical-stage biopharmaceutical company developing novel treatments for nervous system diseases of high unmet medical need. NSI-189 is the lead compound in Neuralstem's neurogenic small molecule program. NSI-566 is a stem cell therapy being tested in stroke, chronic spinal cord injury (cSCI) and Amyotrophic Lateral Sclerosis (ALS). Neuralstem's diversified portfolio of product candidates is based on its proprietary neural stem cell technology.

Cautionary Statement Regarding Forward Looking Information
This news release contains "forward-looking statements" made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements relate to future, not past, events and may often be identified by words such as "expect," "anticipate," "intend," "plan," "believe," "seek" or "will." Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Specific risks and uncertainties that could cause our actual results to differ materially from those expressed in our forward-looking statements include risks inherent in the development and commercialization of potential products, uncertainty of clinical trial results or regulatory approvals or clearances, need for future capital, dependence upon collaborators and maintenance of our intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements. Additional information on potential factors that could affect our results and other risks and uncertainties are detailed from time to time in Neuralstem's periodic reports, including the Annual Report on Form 10-K for the year ended December 31, 2016, and Form 10-Q for the three months ended March 31, 2017, filed with the Securities and Exchange Commission (SEC), and in other reports filed with the SEC. We do not assume any obligation to update any forward-looking statements.

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