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# Neuralstem Reports Last Subject Out in Phase 2 Trial of NSI-189 for Major Depressive Disorder

## Top Line Results Expected in 3Q 2017

GERMANTOWN, Md., May 17, 2017 (GLOBE NEWSWIRE) -- Neuralstem, Inc. (Nasdaq:CUR), a biopharmaceutical company developing next generation treatments for nervous system diseases, today announced it has completed dosing of the last subject in its multicenter Phase 2 clinical trial evaluating the efficacy of NSI-189 for the treatment of major depressive disorder (MDD). NSI-189 is an oral antidepressant with a novel mechanism of action and is the lead compound in Neuralstem's neurogenic small molecule program.

"We believe that NSI-189 is a next generation treatment for MDD as it has the potential to promote remodeling of the hippocampus and reverse hippocampal atrophy, which has been linked to MDD pathology. Our goal is to further understand NSI-189's role in MDD and believe that it may also have application in additional indications that affect cognition and/or neurodegeneration," said Rich Daly, chairman and CEO, Neuralstem. "We look forward to unblinding the study data and analyzing the results. As previously announced, we anticipate that the top line data will be available in the third quarter of this year. We appreciate the enthusiasm of our investigators and commitment by the subjects, which has allowed the study to be completed approximately four months earlier than planned."

The Phase 2 clinical trial is a randomized, double-blind, placebo-controlled study in 220 subjects with MDD. Subjects were randomized and received 12-weeks of oral treatment with NSI-189 40 mg twice daily (BID), NSI-189 40 mg once daily (QD), or placebo in an outpatient setting. The primary efficacy endpoint is a reduction in depression symptoms as measured by the Montgomery-Asberg Depression Rating Scale (MADRS). The study is 80% powered ( $p \leq 0.05$ ) to show an improvement in depression symptoms, compared to placebo, with an effect size of  $d=0.5$ .

### **NSI-189: Neuralstem's Lead Asset**

NSI-189 is a next-generation, first-in-class compound. NSI-189 is in a Phase 2, double-blind, placebo-controlled study for the treatment of major depressive disorder (MDD). The study incorporates strategies to limit placebo effect, and is designed to randomize 220 subjects in three cohorts (two active doses plus placebo) at 12 select trial sites. Dr. Maurizio Fava, Slater Family Professor of Psychiatry at Harvard Medical School, Massachusetts General Hospital, is the principal investigator. Top line results of the Phase 2 study are expected four months ahead of schedule in the third quarter of 2017.

In a Phase 1B study in subjects with MDD, NSI-189 showed strong potential for efficacy

on both depression and cognition scales. Results from the study also indicated that the compound may impart a durable effect. Data suggest that NSI-189 works by promoting synaptogenesis or neurogenesis in the hippocampus; a different mechanism of action than current marketed antidepressants. NSI-189 may have broad utility as a neuroregenerative drug.

### **About Neuralstem**

Neuralstem is a clinical-stage biopharmaceutical company developing next-generation treatments for nervous system diseases of high unmet medical need. Neuralstem's lead asset, NSI-189, is an oral antidepressant in Phase 2 clinical development for major depressive disorder (MDD). 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, 2015, and Form 10-Q for the nine months ended September 30, 2016, 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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