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NEURALSTEM INC.

Neuralstem Announces Last Subject Enrolled in Phase 2 Trial with NSI-189 for Major Depressive Disorder

- Phase 2 Data Now Expected Ahead of Schedule in 3Q 2017 -

GERMANTOWN, Md., Feb. 16, 2017 (GLOBE NEWSWIRE) -- Neuralstem, Inc. (Nasdaq:CUR), a biopharmaceutical company focused on the development of central nervous system therapies based on its neural stem cell technology, today announced completion of subject enrollment in its Phase 2 clinical trial of NSI-189 for the treatment of major depressive disorder (MDD). NSI-189 is a new chemical entity and the lead compound in Neuralstem's neurogenic small molecule program. Enrollment was completed ahead of schedule and data are expected in 3Q 2017.

“Completing the last subject enrolled in the Phase 2 study with NSI-189 for the treatment of MDD earlier than expected is a significant clinical development milestone for Neuralstem,” said Rich Daly, Chairman and CEO, Neuralstem. “We now expect results from the Phase 2 study in the 3Q of 2017, and results from the subsequent, 6-month observational study to assess NSI-189’s durability effect will be available in the first half of 2018. We are thankful to the individuals and physicians who are participating in these studies and helping us to move closer to potentially bringing this new category of treatment forward.”

The double-blind, placebo-controlled Phase 2 study randomized 220 subjects to one of three oral treatment groups: placebo, 40 mg once daily (QD), 40 mg twice daily (BID). The primary efficacy endpoint is a reduction in depression symptoms as measured by the Montgomery-Asberg Depression Rating Scale (MADRS). Secondary endpoints encompass additional clinical outcomes including objective cognition improvement measures. The trial is evaluating subjects over a 12-week dosing period with an observational follow-up period of six months to assess NSI-189's potential for durability of benefits after the cessation of therapy. The trial is being conducted in 12 select MDD trial sites across the United States.

“Our goal is to improve the success rate in the treatment of major depressive disorder, and fulfill the unmet medical need for effective and well tolerated therapies that work differently from antidepressants that are currently available,” said Maurizio Fava, MD, Slater Family Professor of Psychiatry at Harvard Medical School, Massachusetts General Hospital and principal investigator. “The Phase 1 data have shown that NSI-189’s biological mechanism of action may provide an alternative for the treatment of MDD, with the potential for cognitive benefits and durability effects beyond the course of treatment.”

NSI-189 is a proprietary, new chemical entity that has shown to safely alleviate depression

in a Phase 1b study with MDD patients. In preclinical models, NSI-189 stimulated neurogenesis, synaptogenesis and increased hippocampal volume, all of which are believed to be effective in potentially reversing depression, enhancing cognition, and promoting neuroregeneration.

About the Trial

This Phase 2 double-blind, placebo-controlled study is testing NSI-189 in a study of 220 subjects with MDD in an out-patient setting. Inclusion criteria required subjects to have a MADRS score of 20 or greater at screening and baseline. For context, a total MADRS score of 20 to 34 is suggestive of moderate depression while a score of 35 or greater is suggestive of severe depression.

Subjects were randomized to three cohorts: NSI-189 40 mg twice daily (BID), NSI-189 40 mg once daily (QD), or placebo. After the initial screening period, the randomized portion of the trial will be 12 weeks in duration.

Subjects are being evaluated along several depression measurement scales, including the MADRS, Symptoms of Depression Questionnaire (SDQ) and the Hamilton Depression Rating Scale (HAM-D), among others. The study is 80% powered ($p \leq 0.05$) to show an improvement in depression symptoms, compared to placebo, with an effect size of $d=0.5$. Subjects will continue to be followed for an additional six months after the 12-week trial period.

About Neuralstem

Neuralstem's patented technology enables the commercial-scale production of multiple types of central nervous system stem cells, which are being developed as potential therapies for multiple central nervous system diseases and conditions.

Neuralstem's technology enables the generation of small molecule compounds by screening hippocampal stem cell lines with its proprietary systematic chemical screening process. The screening process has led to the discovery and patenting of molecules that Neuralstem believes may stimulate the brain's capacity to generate new neurons, potentially reversing pathophysiologies associated with certain central nervous system (CNS) conditions.

The company has completed Phase 1a and 1b trials evaluating NSI-189, a novel neurogenic small molecule product candidate, for the treatment of major depressive disorder or MDD, and is currently conducting a Phase 2 efficacy study for MDD.

Neuralstem's stem cell therapy product candidate, NSI-566, is a spinal cord-derived neural stem cell line. Neuralstem is currently evaluating NSI-566 in three indications: stroke, chronic spinal cord injury (cSCI), and Amyotrophic Lateral Sclerosis (ALS).

Neuralstem is conducting a Phase 1 safety study for the treatment of paralysis from chronic motor stroke at the BaYi Brain Hospital in Beijing, China. In addition, NSI-566 was evaluated in a Phase 1 safety study to treat paralysis due to chronic spinal cord injury as well as a Phase 1 and Phase 2a risk escalation, safety trials for ALS. Subjects from all three indications are currently in long-term observational follow-up periods to continue to monitor safety and possible therapeutic benefits.

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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