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Neuralstem Expands Phase 1 Safety Trial of NSI-566 Neural Stem Cells in Spinal Injury

Investigating New Patient Cohort with Cervical Injury

GERMANTOWN, Md., April 12, 2017 (GLOBE NEWSWIRE) -- Neuralstem, Inc. (Nasdaq:CUR), a biopharmaceutical company focused on the development of nervous system therapies based on its neural stem cell technology, announced that a new cohort of four patients will be added to its ongoing Phase 1 human clinical trial evaluating the safety and feasibility of using NSI-566 spinal cord-derived neural stem cells to repair chronic spinal cord injury (cSCI). The amended protocol was approved by the U.S. Food and Drug Administration and the Institutional Review Board at the study site, University of California San Diego (UCSD). NSI-566 is Neuralstem's lead stem cell therapy candidate.

Under the amended protocol, updated on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01772810) (NCT01772810), four qualifying patients with AIS-A complete, quadriplegic, cervical injuries involving C5-C7 cord will be added to the study. The injury must have occurred 1-2 years prior to the time of stem cell treatment, which is a one-time surgery involving six injections of NSI-566 into the affected area of the cord. The study has begun active recruitment of patients.

About 250,000 Americans are living with cSCI, and approximately 11,000 new injuries are reported each year¹. Roughly 52% of these individuals will be considered paraplegic and 47% will be considered quadriplegic¹. cSCI is a permanent and disabling condition with few to no treatments. Its devastating effect can be measured from social, healthcare, and economic perspectives.

"This expansion of the study to cervical injuries builds on the results demonstrating that the implantation of NSI-566 stem cells in the first four patients with AIS-A complete thoracic cSCI was safe and feasible with no serious adverse events," said Karl Johe, Ph.D., Chief Scientific Officer, Neuralstem. "There is a tremendous unmet need in the treatment of cSCI and we are privileged to have the experts at UCSD School of Medicine and the Sanford Stem Cell Clinical Center at UC San Diego Health conducting the research. We look forward to further evaluating NSI-566 neural stem cells in chronic complete cervical injuries."

Long-term safety data from the first cohort of chronic complete thoracic injuries is currently being analyzed by the study team at UCSD School of Medicine.

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 also enables the discovery of small molecule compounds by systematic screening chemical compounds against its proprietary human hippocampal stem cell line. 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.

¹ <http://www.sci-info-pages.com/facts.html>

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