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Neuralstem Announces First Surgery Completed in Cervical Cohort of Phase 1 Clinical Trial in Patients with Chronic Spinal Cord Injury

GERMANTOWN, Md., April 10, 2018 (GLOBE NEWSWIRE) -- Neuralstem, Inc. (Nasdaq:CUR), a biopharmaceutical company focused on the development of nervous system therapies based on its neural stem cell technology, today announced that it completed the first surgery in the second, cervical injury cohort of a Phase 1 clinical trial in patients with chronic spinal cord injury (cSCI). NSI-566 is Neuralstem's lead stem cell therapy candidate.

"This study involves complete injury patients with no motor or sensory function below injury. The first four paraplegic cases with thoracic injury went exceptionally well. We are excited to move forward with the next four quadriplegic cases with cervical injury," said Karl Johe, Ph.D., the Chief Scientific Officer of Neuralstem.

Neuralstem is conducting a Phase 1 human clinical trial evaluating the safety and feasibility of using NSI-566 spinal cord-derived neural stem cells to repair cSCI. The clinical trial is being conducted at the University of California San Diego, Division of Neurosurgery. In April 2017, the clinical trial was expanded to include a new cohort of four qualifying patients with AIS-A complete, quadriplegic, cervical injuries involving C5-C7 of their spinal cord, after promising results were observed with the first cohort. The clinical trial is evaluating the safety and feasibility of using NSI-566 spinal cord-derived neural stem cells to repair 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) and can be found on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01772810) (NCT01772810). The first surgery for the second cohort was completed on March 28.

According to the National Spinal Cord Injury Statistical Center at UAB, as of 2015, about 250,000 Americans are living with cSCI, and approximately 11,000 new injuries are reported each year. Approximately, 52% of these individuals will be considered paraplegic and 47% will be considered quadriplegic. cSCI is a permanent and disabling condition with few to no treatments. Its devastating effect can be measured from social, healthcare, and economic perspectives.

About Neuralstem

Neuralstem is a clinical-stage biopharmaceutical company developing novel treatments for nervous system diseases of high unmet medical need. The Company has two lead development candidates:

- NSI-189, is a small molecule in clinical development for major depressive disorder and in preclinical development for Angelman syndrome, irradiation-induced cognitive impairment, Type 1 and Type 2 diabetes, and stroke.
- NSI-566 is a stem cell therapy being tested for treatment of paralysis in stroke, Amyotrophic Lateral Sclerosis (ALS) and chronic spinal cord injury (cSCI).

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, 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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