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NEURALSTEM INC.

Neuralstem Investigator Provides Phase II Update on ALS Cell Therapy at American Neurological Association Annual Meeting

GERMANTOWN, Md., Sept. 29, 2015 /PRNewswire/ -- Neuralstem, Inc. (Nasdaq: CUR), a biopharmaceutical company using neural stem cell technology to develop small molecule and cell therapy treatments for central nervous system diseases, announced that nine-month Phase II and combined Phase I and Phase II data on the NSI-566 trial in amyotrophic lateral sclerosis (ALS) was presented at the American Neurological Association Annual Meeting by principal investigator, Eva Feldman, MD, PhD, Director of the A. Alfred Taubman Medical Research Institute and Director of Research of the ALS Clinic at the University of Michigan Health. The data showed that the intraspinal transplantation of the cells was safe and well-tolerated throughout the escalating doses, reaching a maximum tolerated dose of 16 million cells via 20 bilateral injections. There appeared to be no acceleration in disease progression due to the therapeutic intervention.

Researchers calculated a 95% confidence limit around the slopes of decline of ALSFRSr scores, forced vital capacity (FVC) and grip strength of the ProAct historical database subjects, and evaluated if trial subjects fell within or outside those limits. 73% of Phase II patients, and 79% of combined Phase I and II patients, fell above the upper confidence limit of the ALSFRSr score. 50% of Phase I and II combined, and 40% of Phase II patients' forced vital capacity percent predicted fell above the upper confidence limit, compared to the ProAct database. ALSFRSr scores correlated most strongly with FVC preservation, which was the target of the cervical injections. For grip strength control, researchers used the Ceftriaxone (CEF) study database, since grip strength data was not available in the ProAct database. 67% of Phase I and II combined, and 60% of Phase II patients, all at nine months post-intervention, fell above the 95% upper confidence limit.

The most common adverse event (AE) was transient post-operative pain due to surgery. One serious adverse event due to the surgical procedure was observed, but was not attributed to the cells themselves. The patient's motor function was initially weakened and then recovered to the patient's ALS baseline.

"Based on this encouraging safety and clinical effect, we look forward to moving to a registration-directed trial in 2016," said Karl Johe, PhD, Chief Scientific Officer.

About the Trial

The Phase II open-label, dose-escalating trial of NSI-566 evaluated 15 ambulatory patients with ALS, averaging a mean duration of disease of 15.5 months. Participants were divided into five dosing cohorts with three patients in each, who received increasing quantities of cells in the cervical region of the spinal cord via bilateral intraspinal injections

ranging from two million to eight million cells. The fifth cohort received an additional eight million cells in the lumbar region. There was no control or placebo group included in the trial. The primary endpoint of the study was the safety of the maximum tolerated dose of stem cell transplantation. Secondary efficacy endpoints included stabilization of ALS Functional Rating Scale-revised (ALSFRSr) scores, and assessment of respiratory functioning, grip strength and muscle strength. 9 of the 15 participants in Phase I and all 15 participants in Phase II were included in the 9-month data. Dr. Eva Feldman, principal investigator, is an unpaid consultant to Neuralstem.

About Amyotrophic Lateral Sclerosis (ALS)

ALS is a progressive disease that affects nerve cells, or neurons, in the brain and the spinal cord, leading to degeneration and eventual atrophy of the surrounding muscles. As the condition worsens, motor neurons die, and the brain can no longer control the affected muscles. In time, this causes the loss of patients' ability to speak, eat, move and breathe, eventually resulting in death. It is estimated that more than 5,600 people in the U.S. are diagnosed with ALS each year, amounting to 15 new cases per day, totaling approximately 30,000 Americans living with the disease at any given time. There is currently no cure or treatment that that halts or reverses the progression of the disease.[1]

About Neuralstem

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

Neuralstem's ability to generate human neural stem cell lines for chemical screening has led to the discovery and patenting of compounds that Neuralstem believes may stimulate the brain's capacity to generate neurons, potentially reversing pathologies associated with certain central nervous system (CNS) conditions. The company has completed Phase Ia and Ib trials evaluating NSI-189, its first neurogenic small molecule product candidate, for the treatment of major depressive disorder (MDD), and is expecting to initiate a Phase II study for MDD and a Phase Ib study for cognitive deficit in schizophrenia in 2015.

Neuralstem's first stem cell product candidate, NSI-566, a spinal cord-derived neural stem cell line, is under development for treatment of amyotrophic lateral sclerosis (ALS). Neuralstem has completed two clinical studies, in a total of thirty patients, which met primary safety endpoints. In addition to ALS, NSI-566 is also in a Phase I trial in chronic spinal cord injury at UC San Diego School of Medicine, as well as in clinical development to treat ischemic stroke.

Neuralstem's next generation stem cell product, NSI-532.IGF, consists of human cortex-derived neural stem cells that have been engineered to secrete human insulin-like growth factor 1 (IGF-1). In animal data presented at the Congress of Neurological Surgeons 2014 Annual Meeting, the cells rescued spatial learning and memory deficits in an animal model of Alzheimer's disease.

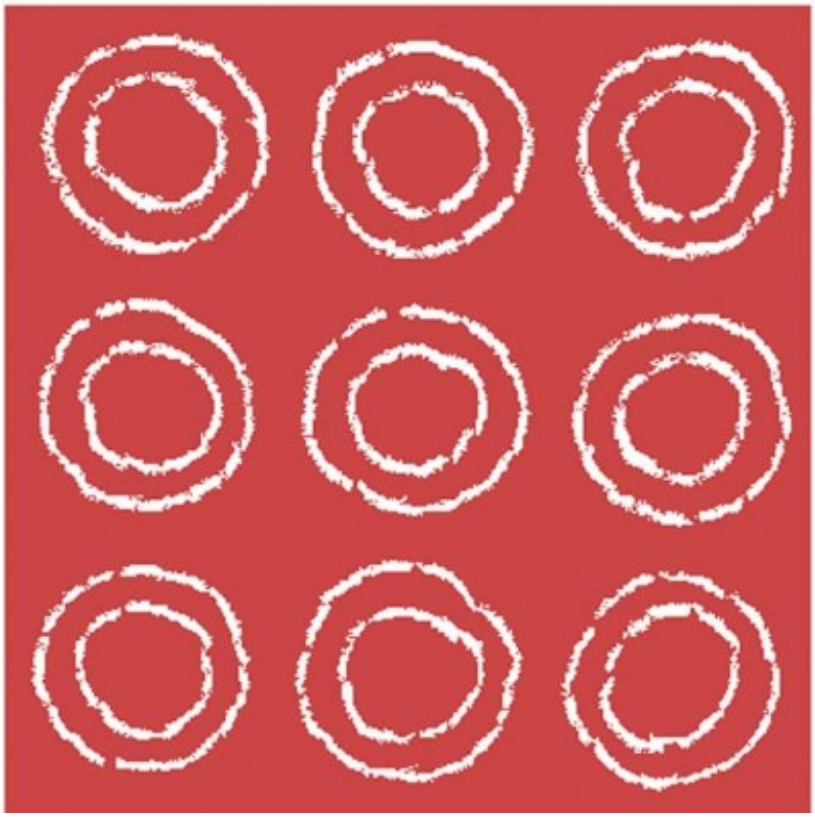
For more information, please visit www.neuralstem.com or connect with us on Twitter, Facebook and LinkedIn.

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, 2014, and Form 10-Q for the three and six months ended June 30, 2015, filed with the Securities and Exchange Commission (SEC), and in other reports filed with the SEC.

References:

1. ALS Association. About ALS. Available at: http://www.alsa.org/about-als/. September 28, 2015.



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