NeuroGenesis Receives FDA Clearance for Phase IIb Study

Focused on Secondary Progressive Multiple Sclerosis, in Partnership with URMC

ROCHESTER, NY, UNITED STATES, April 24, 2023 /EINPresswire.com/ -- On the heels of Multiple Sclerosis (MS) Awareness Month, NeuroGenesis officially announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) to enroll patients in the U.S. for its Phase IIb study for its cell therapy platform, NG-01, in the treatment of Secondary Progressive Multiple Sclerosis (SPMS). Dr. Andrew Goodman of the University of Rochester Medical Center (URMC), will be the lead investigator for the trial, further assessing the effect of NG-01 autologous proprietary subpopulation of remyelinating “biofactory cells” on patients with progressive MS.

The results of a previous double blind, randomized, placebo-controlled trial which were published in Brain (Oxford University) (https://academic.oup.com/brain/article/143/12/3574/6012789), a prestigious peer-reviewed journal, and selected as the “Editor’s Choice”, showed that:

- No serious, treatment-related safety issues were detected;
- Significantly fewer patients experienced treatment failure (disease progression) in the intrathecal (IT) and intravenous (IV) NG-01 treatment groups compared with those in the placebo group (6.7%, 9.7%, and 41.9%, respectively, P = 0.0003 and P = 0.0008);
- 58% of the patients treated intrathecally with NG-01 did not show Any Evidence of Disease Activity (NEDA) during the entire treatment period (vs. 97% in the placebo treated group) (P<0.0001)
- NG-01 treatment groups demonstrated a significant improvement in walking ability as measured by 25-foot walking time (P = 0.0017)
- Intrathecal administration of NG-01 was more efficacious than intravenous in several key parameters of the disease: relapse rate (89% decrease in the relapse rate), functional MRI (improvement of motor networks), monthly changes of the MRI T2 lesion load and the 9-hole peg test, as compared to the control (placebo-treated) group.

“We are looking forward to testing the reproducibility of the encouraging results from the last trial, in the search for better treatments for such a progressive and debilitating neurodegenerative disease. To be able to make a positive impact for the better is the centerpiece of the University’s health research, teaching and patient care missions,” said Dr. Andrew Goodman, Professor of Neurology, Chief of the Neuroimmunology Division, and Director of the Multiple Sclerosis Center .

“When we were looking to bring our revolutionary studies to the US, we wanted to be sure and connect with the right medical research partners to bring our solution to life. Making Rochester our US headquarters was serendipitous given the proximity to both URMC and its scientific research powers, and the Upstate NY region, with its history of higher prevalence of MS compared to the remainder of the US. ” said Tal Gilat, Founder & CEO of NeuroGenesis. “We look forward to proliferating this new approach that may not only slow down the progression but provide improvement for those with progressive MS.”

NeuroGenesis’ technology entails collecting bone marrow from the patient. Then by utilizing a proprietary process, a unique subpopulation of bone marrow cells is identified, cultured, and enhanced towards remyelinating “biofactory” cells (NG-01) that also possess neurotrophic, immunomodulatory and neuroprotective properties. The NG-01 cell population is injected directly into the central nervous system (through the cerebrospinal fluid), where the cells hone-in on the damaged area and produce significant amounts of neurotrophic factors.

“Progressive MS is a chronic, debilitating disease with no satisfactory treatment to improve or reverse established disability,” said Gilat. “We are pleased to witness the significant positive effect of our NG-01 cells and continuing advanced studies in additional indications such as amyotrophic lateral sclerosis (ALS).”

About the NG-01 Phase IIb Trial
The Phase IIb NG-01 trial is a multi-center, placebo-controlled, randomized, double-blind trial designed to evaluate the safety and efficacy of repeat doses of NG-01 in secondary progressive multiple sclerosis (SPMS) patients.

About Multiple Sclerosis
Multiple sclerosis (MS) is an immune-mediated disease that causes damage in the myelin and the nerve cells of the central nervous system (brain, optic nerves, and spinal cord), resulting in cumulative neurological disability. The destruction of the myelin (the covering that protects nerves and promotes the efficient transmission of nerve impulses) causes secondary damage to the nerve cells and progressive atrophy. MS often causes sensory disturbances in the limbs, including a prickling or tingling sensation (paresthesia), numbness, and pain. Motor problems are common in people with MS. Affected individuals may have tremors, muscle stiffness (spasticity), exaggerated reflexes (hyperreflexia), weakness or paralysis of the muscles of the limbs, difficulty in walking, and poor sphincter control. The condition is also associated with visual problems, such as blurred or double vision. There is no known cure for MS.

About NeuroGenesis
NeuroGenesis is a clinical-stage cellular therapy company focused on developing novel and effective treatments for neurodegenerative diseases. The company has established NG-01 as a proprietary method to transform a unique subpopulation of marrow-derived stem cells into bio-factories for sustained delivery of regenerative and neuroprotective proteins. By promoting myelin and neuronal regeneration, the NG-01 technology is optimized to treat neurodegenerative diseases such as progressive multiple sclerosis (MS) and amyotrophic lateral sclerosis (ALS). To date, more than 160 progressive MS and ALS patients from around the world have been treated with this breakthrough therapeutic modality. Headquartered in Upstate NY, NeuroGenesis is steadily moving forward with a global, FDA-approved multi-site Phase 2b trial for secondary progressive multiple sclerosis, in partnership with major medical research centers in the United States and abroad.

About URMC
One of the nation’s leading academic medical centers, URMC – comprised of Strong Memorial Hospital, Eastman Institute for Oral Health, the University of Rochester School of Medicine and Dentistry and its faculty practice, and the University of Rochester School of Nursing – forms the centerpiece of the University of Rochester’s health research, teaching and patient care missions. Under the UR Medicine clinical brand, URMC serves as upstate New York’s premier health care delivery network, anchored by Strong Memorial, an 886-bed, University-owned teaching hospital designated by the New York State Department of Health as a Level One Regional Trauma & Burn Center.

Sarah Heximer
NeuroGenesis
media@neurogenesis-cell.com
