

BrainStorm Cell Therapeutics Announces Research Grant Award From the National Multiple Sclerosis Society

NEW YORK, Nov. 14, 2019 (GLOBE NEWSWIRE) -- [BrainStorm Cell Therapeutics, Inc. \(NASDAQ:BCLI\)](#), a leading developer of adult stem cell therapies for neurodegenerative diseases, announced today that the Company has received a \$495,330 grant from the National Multiple Sclerosis Society, through its Fast Forward program, to advance BrainStorm's Phase 2 open-label, multicenter clinical trial of repeated intrathecal administration of NurOwn® (autologous MSC-NTF cells) in participants with progressive Multiple Sclerosis ([NCT03799718](#)).

Chaim Lebovits, President and CEO of BrainStorm stated, "We are very pleased to receive this generous grant from the National MS Society. Currently, we are conducting our Phase 2 study in three leading US medical centers: The Keck School of Medicine of USC, The Stanford School of Medicine, and Cleveland Clinic. This research funding will help advance our investigational therapy NurOwn as a potential unmet need for patients with progressive MS. MS continues to devastate the lives of patients and their families and we thank the National MS Society for helping us advance our innovative research program."

"Currently, progressive MS treatment options are limited and NurOwn is a promising new autologous cellular treatment modality that has the potential to directly address MS disease pathways," said Ralph Kern MD MHSc, COO and CMO of BrainStorm. He added, "This funding from the National MS Society will help us explore key neuroinflammation and neural repair biomarkers in progressive MS to confirm NurOwn's unique mechanism of action and guide the design of future clinical trials to address this important unmet patient need."

"Leveraging resources in this Phase 2 clinical study of a cell-based therapy for progressive MS exemplifies our work to accelerate research to improve clinical care for people living with MS," said Mark Allegretta, PhD, Vice President of Research at the National MS Society. "We're pleased to work with BrainStorm to test a broad panel of biomarkers of neuroinflammation and repair as correlates of the effect of treatment with NurOwn®".

[About Multiple Sclerosis](#)

Multiple sclerosis is an unpredictable, often disabling disease of the central nervous system. There is currently no cure for MS. Symptoms vary from person to person and range from numbness and tingling, to mobility challenges, blindness and paralysis. An estimated 1 million people live with MS in the United States. Most people are diagnosed between the ages of 20 and 50 and it affects women three times more than men.

About The National Multiple Sclerosis Society:

The National MS Society, founded in 1946, funds cutting-edge research, drives change through advocacy, and provides programs and services to help people affected by MS live their best lives. Connect to learn more and get involved: [nationalMSSociety.org](#), [Facebook](#), [Twitter](#), [Instagram](#), [YouTube](#) or 1-800-344-4867.

[About NurOwn®](#)

NurOwn® (autologous MSC-NTF) cells represent a promising investigational therapeutic approach to targeting disease pathways important in neurodegenerative disorders. MSC-NTF cells are produced from autologous, bone marrow-derived mesenchymal stem cells (MSCs) that have been expanded and differentiated ex vivo. MSCs are converted into MSC-NTF cells by growing them under patented conditions that induce the cells to secrete high levels of neurotrophic factors. Autologous MSC-NTF cells can effectively deliver multiple NTFs and immunomodulatory cytokines directly to the site of damage to elicit a desired biological effect and ultimately slow or stabilize disease progression. BrainStorm has fully enrolled a Phase 3 pivotal trial of autologous MSC-NTF cells for the treatment of amyotrophic lateral sclerosis (ALS). BrainStorm also recently received U.S. FDA acceptance to initiate a Phase 2 open-label multicenter trial in progressive MS and enrollment began in March 2019.

[About BrainStorm Cell Therapeutics Inc.](#)

BrainStorm Cell Therapeutics Inc. is a leading developer of innovative autologous adult stem cell therapeutics for debilitating neurodegenerative diseases. The Company holds the rights to clinical development and commercialization of the NurOwn® technology platform used to produce autologous MSC-NTF cells through an exclusive, worldwide licensing agreement. Autologous MSC-NTF cells have received Orphan Drug status designation from the U.S. Food and Drug Administration (U.S. FDA) and the European Medicines Agency (EMA) in ALS. BrainStorm has fully enrolled a Phase 3 pivotal trial in ALS (NCT03280056), investigating repeat-administration of autologous MSC-NTF cells at six U.S. sites supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989). The pivotal study is intended to support a filing for U.S. FDA approval of autologous MSC-NTF cells in ALS. BrainStorm also recently received U.S. FDA clearance to initiate a Phase 2 open-label multicenter trial in progressive Multiple Sclerosis. The Phase 2 study of autologous MSC-NTF cells in patients with progressive MS (NCT03799718) started enrollment in March 2019. For more information, visit the company's website at [www.brainstorm-cell.com](#).

Statements in this announcement other than historical data and information, including statements regarding future clinical trial enrollment and data, constitute "forward-looking statements" and involve risks and uncertainties that could cause BrainStorm Cell Therapeutics Inc.'s actual results to differ materially from those stated or implied by such forward-looking statements. Terms and phrases such as "may", "should", "would", "could", "will", "expect", "likely", "believe", "plan", "estimate", "predict", "potential", and similar terms and phrases are intended to identify these forward-looking statements. The potential risks and uncertainties include, without limitation, BrainStorm's need to raise additional capital, BrainStorm's ability to continue as a going concern, regulatory approval of BrainStorm's NurOwn® treatment candidate, the success of BrainStorm's product development programs and research, regulatory and personnel issues, development of a global market for our services, the ability to secure and maintain research institutions to conduct our clinical trials, the ability to generate significant revenue, the ability of BrainStorm's NurOwn® treatment candidate to achieve broad acceptance as a treatment option for ALS or other neurodegenerative diseases, BrainStorm's ability to manufacture and commercialize the NurOwn® treatment candidate, obtaining patents that provide meaningful protection, competition and market developments, BrainStorm's ability to protect our intellectual property from infringement by third parties, health reform legislation, demand for our services, currency exchange rates and product liability claims and litigation,; and other factors detailed in BrainStorm's annual report on Form 10-K and quarterly reports on Form 10-Q available at <http://www.sec.gov>. These factors should be considered carefully, and readers should not place undue reliance on BrainStorm's forward-looking statements. The forward-looking statements contained in this press release are based on the beliefs, expectations and opinions of management as of the date of this press release. We do not assume any obligation to update forward-looking statements to reflect actual results or assumptions if circumstances or management's beliefs, expectations or opinions should change, unless otherwise required by law. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

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