Fifth and Final Site Announced for BrainStorm's Progressive Multiple Sclerosis Phase 2 Clinical Trial

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NEW YORK and BOSTON, Feb. 27, 2020 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leader in developing innovative autologous cellular therapies for highly debilitating neurodegenerative diseases, today announced that Partners MS Center at Brigham and Women's Hospital , a leading research and clinical care center, has contracted with BrainStorm as a clinical study site for the Company's Phase 2 open-label, multicenter study of repeated intrathecal administration of NurOwn® (autologous MSC-NTF cells) in participants with progressive Multiple Sclerosis (MS) (NCT03799718).

"Tanuja Chitnis, MD, Director of the CLIMB Natural History Study, which is assessing the disease course and prognosis of approximately 2000 MS patients, will serve as the Principal Investigator at Brigham and Women's Hospital," said Chaim Lebovits, President and CEO of BrainStorm. He added, "The Partners MS Center at Brigham and Women's Hospital provides comprehensive patient care, innovative technology and ongoing clinical research trials. We're excited to have them join the trial, and we expect that they will soon enroll participants under the supervision of Dr. Chitnis and her highly experienced clinical team."

Ralph Kern, MD, MHSc, Chief Operating and Chief Medical Officer of BrainStorm added, "It has been less than a year since we contracted with our first progressive MS clinical site, half of the study participants have already been screened and 2 study participants have completed all study visits. We are very privileged to have Dr. Chitnis and her team advance our clinical study of NurOwn in progressive MS."

"We are excited to participate in this research study, which will allow us the opportunity to investigate potential new therapies for our patients with progressive MS," said Chitnis, who is also a professor of Neurology at Harvard Medical School and a senior neurologist at Brigham and Women's Hospital.

Tanuja Chitnis, MD, and the Partners MS Center at The Brigham and Women's Hospital team join the other top US MS centers: Cleveland Clinic, Stanford University, School of Medicine, Mount Sinai Medical Center and University of Southern California for the Company's Phase 2 open-label, multicenter study of repeated intrathecal administration of autologous MSC-NTF cells in participants with progressive Multiple Sclerosis (MS) (NCT03799718).

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 repeat-dosing autologous MSC-NTF cells (NurOwn) for the treatment of amyotrophic lateral sclerosis (ALS).

BrainStorm received U.S. FDA acceptance to initiate a Phase 2 open-label multicenter repeat-dosing trial of autologous MSC-NTF cells (NurOwn) in progressive MS and enrollment began in March 2019. Currently half of the expected trial participants are enrolled.

Top line results for both clinical trials are expected in the fourth quarter of 2020.

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 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

Safe-Harbor Statements

Statements in this announcement other than historical data and information 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, risks associated with BrainStorm's limited operating history, history of losses; minimal working capital, dependence on its license to Ramot's technology; ability to adequately protect the technology; dependence on key executives and on its scientific consultants; ability to obtain required regulatory approvals; 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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