BrainStorm Announces First Contracted U.S. Clinical Site for Phase 2 Progressive MS Study

Phase 2 Open-Label Trial of Autologous MSC-NTF Cell Therapy (NurOwn®) in Progressive MS Patients will Begin Enrollment in Early 2019

NEW YORK and CLEVELAND, Feb. 22, 2019 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leader in developing innovative autologous cellular therapies for highly debilitating neurodegenerative diseases, announced today Cleveland Clinic as the first U.S. clinical site contracted for a planned Phase 2 open-label, multicenter study of repeated intrathecal administration of autologous MSC-NTF cells in participants with progressive Multiple Sclerosis (MS). The Phase 2 study (NCT03799718) will enroll progressive MS patients [Expanded Disability Status Scale (EDSS) 3.0-6.5] based on 2017 revised McDonald Criteria.

MS is a chronic neuroinflammatory and neurodegenerative disorder that affects the brain and spinal cord. MS affects approximately 1 million individuals in the U.S. and 2.5 million individuals worldwide. Approximately half of affected individuals will eventually develop a progressive disease, which may lead to increasing levels of motor, visual, and cognitive functional impairment and disability.

“We are very excited to announce The Mellen Center for MS Treatment and Research at Cleveland Clinic as the first contracted U.S. clinical site for this very important Phase 2 progressive MS study that we plan to initiate in early 2019,” said Chaim Lebovits, president and CEO of BrainStorm. “This is a crucial step forward toward rapidly enrolling a Phase 2 study to evaluate this innovative autologous cell therapy approach using our NurOwn® technology platform in progressive MS patients.”

“Progressive MS treatment options are limited and do not directly address unmet need”, saidRalph Kern MD MHSc, COO and CMO of BrainStorm, “This phase 2 clinical trial is an important part of our commitment to bring a new treatment modality and hope to MS patients”.

Cleveland Clinic is currently ranked as the No. 2 hospital in the country, according toU.S. News & World Report (2017-2018). The Mellen Center for Multiple Sclerosis Treatment and Research at Cleveland Clinic is one of the largest and most comprehensive programs for MS care and clinical research worldwide, managing over 8,000 patients and over 21,000 total visits annually.

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 is currently conducting 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 plans to start enrollment in early 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 is currently enrolling a Phase 3 pivotal trial in ALS (NCT03280056), investigating repeat-administration of autologous MSC-NTF cells at six sites in the U.S., 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. For more information, visit BrainStorm's website at www.brainstorm-cell.com.

About Progressive Multiple Sclerosis
MS is an inflammatory disorder in which infection-fighting white blood cells enter the nervous system and cause injury. MS is a demyelinating disorder because the myelin sheath that protects nerves is stripped off during inflammation. Progressive MS is defined by the gradual accumulation of neurological disability independent of relapses, typically with lack of or incomplete recovery. Therapies utilizing regenerative medicine and repair approaches may offer an innovative treatment option. Autologous MSC-NTF cells are bone-marrow derived mesenchymal stem cells (MSCs) propagated and differentiated in culture to secrete high levels of neurotrophic factors (MSC-NTF). In preclinical models, there is increasing recognition that NTFs delivered by

autologous MSCs have the potential for immunomodulation, remyelination, and neuroprotection in progressive MS. The Phase 2 study of autologous MSC-NTF cells in patients with progressive MS (NCT03799718) will begin enrollment in early 2019.

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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