BrainStorm Announces First Patient Enrolled in Phase 2 Clinical Trial of Progressive MS

Enrollment Announced During MS Awareness Week

NEW YORK and CLEVELAND, March 14, 2019 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leader in developing innovative autologous cellular therapies for highly debilitating neurodegenerative diseases, announced today that the first patient has been enrolled in its Phase 2 open-label, multicenter study of repeated intrathecal administration of autologous MSC-NTF cells in participants with progressive Multiple Sclerosis (MS).

Chaim Lebovits, president and CEO of BrainStorm stated, “Midway through MS Awareness Week: March 10-16, we are pleased to announce the first participant with progressive MS has been enrolled in our Phase 2 clinical trial. Progressive MS has deeply affected the lives of many and dramatically impacted family members, caregivers and others. Today, there is no U.S. FDA approved therapy addressing more than one progressive form of MS and we are pleased to deploy our NurOwn® technology platform in this new indication. Soon, we will announce additional sites where the clinical trials will be conducted.”

“The first participant enrolled in our Phase 2 trial represents an important milestone in our commitment to address the unmet medical need in progressive MS,” said Ralph Kern, MD MHSc, Chief Operating and Chief Medical Officer of Brainstorm. “We plan to quickly initiate enrollment across all study sites and look toward top line data by the middle of 2020.”

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 form of the disease, which may lead to increased levels of motor, visual, and cognitive functional impairment and disability.

For more information, refer to www.clinicaltrials.gov, using the NCT identifier (NCT03799718).

About NurOwn® Technology Platform

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 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 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) started enrollment in March 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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