BrainStorm Announces Scientific Presentation at the Annual NEALS Meeting

Presentation outlines design of pivotal Phase 3 trial evaluating NurOwn® as a treatment for ALS Trial remains on track for topline data in 4Q-2020

NEW YORK, Sept. 30, 2020 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapies for neurodegenerative diseases, announced the presentation of a poster titled, "Advancing NurOwn® for ALS: Phase 3 Clinical Trial Design" at the Annual Northeast ALS (NEALS) Meeting, being held virtually. The poster, which will be presented virtually today by Stacy Lindborg, Ph.D., Executive Vice President and Head of Global Clinical Research at Brainstorm, details the design of the Company's placebo-controlled, randomized, double-blind, Phase 3 trial evaluating NurOwn® (MSC-NTF cells) as a treatment for ALS patients.

"This pivotal study has been rigorously designed and powered to detect clinically meaningful effects of NurOwn® in rapidly progressing ALS patients," said Dr. Lindborg. "Compelling Phase 2 data showed that a single NurOwn® administration slowed disease progression in this patient population, and the current Phase 3 trial aims to confirm this effect in a larger study cohort and show that its duration can be extended through repeated administrations. To test this hypothesis, we are comparing the rate of patient level decline in ALS disease as measured by the ALS Functional Rating Scale between the pre-treatment period to the rate of decline observed after the initiation of treatment. Such an analysis allows us to compare the magnitude of change in disease progression resulting from NurOwn® and placebo treatments while accounting for important variable factors known to influence disease progression. We look forward to sharing the results of this analysis later this year."

The poster will be discussed by Dr. Lindborg during a live session at NEALS. A copy of the poster will be also be available in the "Investors and Media" section of the BrainStorm website under Events and Presentations.

About the Phase 3 NurOwn® Trial

The Phase 3 NurOwn® trial is a placebo-controlled, randomized, double-blind trial being conducted at six centers of excellence: University of California, Irvine; Cedars-Sinai Medical Center; California Pacific Medical Center; Massachusetts General Hospital; University of Massachusetts Medical School and Mayo Clinic. Patient dosing in the trial is complete and topline data is expected in 4Q-2020. The primary endpoint of the trial is a responder analysis of the rate of decline in ALS Functional Rating Scale (ALSFRS-R) score over 28 weeks. Secondary endpoints include safety, the percentage of patients with disease progression halted or improved, ALSFRS-R change from baseline, combined analysis of function and survival, slow vital capacity, tracheostomy-free survival, overall survival and cerebrospinal fluid biomarker measurements. For more information on the trial, visit https://clinicaltrials.gov/ct2/show/NCT03280056.

About NEALS

The Northeast Amyotrophic Lateral Sclerosis (NEALS) Consortium is a multi-function organization that aims to translate scientific advances into new treatments for people with ALS and motor neuron disease (MND) as rapidly as possible. To achieve its goal, NEALS functions as an academic research consortium, a contracted research organization, and a resource tool for the ALS community. NEALS is committed to the principles of open scientific communication, peer review, full and open disclosure of potential conflicts of interest, and democratic governance of its organization and activities. For more information on NEALS, visit https://www.neals.org/.

About NurOwn®

The NurOwn technology platform (autologous MSC-NTF cells) represents 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 (NTFs). 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.

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 (FDA) and the European Medicines Agency (EMA) for the treatment of amyotrophic lateral sclerosis (ALS). BrainStorm has fully enrolled a phase 3 pivotal trial in ALS (NCT03280056); this trial is 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 FDA approval of autologous MSC-NTF cells in ALS. BrainStorm is also conducting an FDA-approved phase 2 open-label multicenter trial in progressive multiple sclerosis (MS). The phase 2 study of autologous MSC-NTF cells in patients with progressive MS (NCT03799718) is fully enrolled.

For more information, visit the company's website atwww.brainstorm-cell.com.

Safe-Harbor Statement

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, heath 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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