BrainStorm to present NurOwn® Phase 3 Clinical Trial Results at 31st International Symposium on ALS/MND

- Dr. Merit Cudkowicz and Dr. Ralph Kern presentation will be featured in Oral Presentation in the Clinical Trials Platform Session
- Clinical experience with outpatient NurOwn® administration will be presented in poster session

NEW YORK, Nov. 23, 2020 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapies for neurodegenerative diseases, announced today that results from the Company's placebo controlled, randomized, double-blind Phase 3 trial evaluating NurOwn® (MSC-NTF cells) as a treatment for ALS will be presented as an oral presentation at the 31st International Symposium on ALS/MND to be held as a virtual symposium Dec 9-11th, 2020. In addition, Brainstorm will present the clinical experience with NurOwn outpatient administration during the phase 3 clinical trial in the poster session.

Each year, the Symposium attracts over 1,000 delegates. It is the largest medical and scientific conference specific to MND/ALS and is a premier event in the MND research calendar for discussion on the latest advances in research and clinical management.

The platform presentation will be jointly made by Ralph Kern, MD MHSc, President and Chief Medical Officer of Brainstorm Cell Therapeutics and Merit Cudkowicz MD, one of the Principal Investigators of this trial and the Julieanne Dorn Professor of Neurology at Harvard Medical School and the Director of the Healey Center for ALS and Chair of Neurology at Mass General Hospital on **December 9th in Session 3: Clinical Trials from 1110-1130 ET**.

The poster presentation describing the clinical experience with NurOwn outpatient administration during the phase 3 clinical trial will be made by Dr. James Berry, Associate Professor of Neurology, Massachusetts General Hospital, Chief, Division of Motor Neuron Disorders, Massachusetts General Hospital at the virtual poster presentation.

"We are encouraged by the results of the phase 3 pivotal trial of NurOwn in ALS and are privileged to make these important scientific presentations to the 31st International Symposium on ALS/MND." said Chaim Lebovits, Chief Executive Officer of BrainStorm. "We believe that presentation of these important phase 3 clinical and biomarker outcomes will increase awareness of the potential of NurOwn therapy in ALS and will enable us to listen to the ALS scientific and patient advocacy community as we seek a regulatory pathway forward with our innovative ALS cellular therapy, and hopefully provide a much-needed solution to ALS patients".

"It is an honor to jointly present our clinical trial results with Dr Cudkowicz on behalf of the study's principal investigators", said Ralph Kern, President and CMO of Brainstorm. "The trial has generated an important set of biomarkers that clearly demonstrates NurOwn's mechanism of action and may help predict ALS treatment response. We believe that there are important insights from our clinical trial and that NurOwn could potentially benefit ALS patients."

"The carefully outlined & detailed analysis plan of clinical trial and biomarker data, both finalized prior to viewing the data, provides the framework for generating evidence from this trial. The Placebo response observed in the NurOwn Phase 3 clinical trial combined with the natural heterogeneity in ALS confounds analysis of clinical trials data", said Stacy Lindborg, EVP and Head of Global Clinical Research. "The process of sharing data with ALS experts, such as a meeting like MND which draws world-renowned ALS physicians and researchers, is critical to producing evidence of NurOwn's treatment effect for patients that will stand over time. We are progressing our knowledge of the Phase 3 data and look forward to the sharing our latest insights into the Phase 3 trial data with the ALS research community."

Study Design

The Phase 3 NurOwn® trial was a multi-center, placebo-controlled, randomized, double-blind trial designed to evaluate the safety and efficacy of NurOwn® in 189 ALS patients. It was conducted at six centers of excellence: University of California Irvine (Dr. Namita Goyal); Cedars-Sinai Medical Center (Dr. Matthew Burford); California Pacific Medical Center (Prof. Robert Miller); Massachusetts General Hospital (DrsMerit Cudkowicz, James Berry and Katie Nicholson); University of Massachusetts Medical School (Prof. Robert Brown) and Mayo Clinic (Prof. Anthony Windebank, Dr. Nathan Staff). Potential participants with ALS were screened during an 18-week run-in period and those who were rapid progressors (defined as patients with at least a 3

point decrease in ALSFRS-R score during the run-in period) were randomized 1:1 to receive three intrathecal injections (8 weeks between each injection) of NurOwn® or placebo. Participants were followed for 28 weeks after treatment. The primary endpoints of the trial were safety assessments and a responder analysis of the rate of decline in ALSFRS-R score over 28 weeks, where response was defined as participants with a ³ 1.25 points/month improvement in the post-treatment versus pre-treatment slope in ALSFRS-R at 28 weeks following the first treatment. Secondary endpoints included 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 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 completed the Phase 3 pivotal trial in ALS

(NCT03280056); this trial investigated 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 was intended to support a filing for FDA approval of autologous MSC-NTF cells in ALS and discussion of potential regulatory pathways for approval are planned with the U.S. FDA. BrainStorm is also conducting an FDA-cleared 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) started enrollment in March 2019.

For more information, visit the company's website at www.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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