BrainStorm Announces that Pivotal Phase 3 Trial Remains on Track for Topline Data in Q4-2020

June 2, 2020

The fully enrolled placebo-controlled Phase 3 trial is evaluating NurOwn® investigational treatment in ALS patients

All patients have received at least 2 doses of NurOwn®

Completion of all dosing is expected by July 2020

NEW YORK, June 2, 2020 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapies for neurodegenerative diseases, announced today an update on the Company's Phase 3 pivotal trial investigating NurOwn® in ALS. The Company continues to expect that top-line data from the trial will be announced by Q4-2020, despite the ongoing COVID-19 pandemic that has delayed hundreds of other clinical trials around the world.

Due to the importance of the clinical trial and the recognized high unmet need in ALS, Brainstorm and the 6 prestigious U.S. clinical sites have been able to continue treatment visits throughout the COVID-19 pandemic with only occasional scheduling changes to treatments. The decision to continue the trial is also shared by the ALS community and the FDA. The clinical trial sites are at University of California, Irvine; Cedars-Sinai Medical Center; California Pacific Medical Center; Massachusetts General Hospital; University of Massachusetts Medical School and Mayo Clinic. Importantly, the trial's primary outcome measurement (the ALSFRS-R rating scale) is fully validated for telephonic administration, which allowed non-treatment visits to be conducted remotely and to be aligned with protocol assessment timelines. This allows for ongoing high-quality data collection while prioritizing safety of patients and clinical trial site staff.

"Despite the challenges presented by COVID-19, patient dosing remains on track with all participants having received at least 2 treatments of NurOwn®," said Dr. Merit Cudkowicz, 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. "Moving forward, only 20 patients are still to be dosed for the third and final time, and these final treatments remain on schedule."

Chaim Lebovits, CEO of BrainStorm stated, "BrainStorm made the decision to continue our Phase 3 trial and we have been strongly supported by our partners in the clinical community. Quick planning and coordination across our clinical sites and the support and direction of the U.S. FDA enabled our Phase 3 investigational trial for NurOwn to advance, with final dosing by July 2020. While numerous clinical trials in the U.S. have been interrupted or completely shut down by the COVID-19 pandemic, trial participants, their families, and the investigational teams remain committed to the trial's advancement. I am extremely proud and grateful for the outstanding work and commitment of so many, and particularly by these trial participants and their caregivers. We hope to soon reward their commitment by bringing forward a much-needed treatment for ALS."

Ralph Kern, MD, MHSc, BrainStorm's President and Chief Medical Officer said, "We are very fortunate to have developed an outstanding team of partners who are committed to BrainStorm's investigational therapy NurOwn and share its promise in ALS research. Our primary concerns will always be the overall health and safety of trial participants and the scientific integrity of the trial. Fortunately, ALSFRS-R, the primary outcome measurement of the Phase 3 trial, is validated by phone and allows for the collection of quality data with minimal risk of COVID-19 exposure. This, along with the collective efforts of so many of our employees, partners, and patients, has enabled us to remain on track for study completion as planned in the fourth quarter of this year."

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 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 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 recently 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 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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