# BrainStorm's NurOwn® Phase 3 ALS Clinical Trial Now Fully Enrolled

NEW YORK, Oct. 11, 2019 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics, Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapies for neurodegenerative diseases, announced today that it has fully enrolled the 200-patient Phase 3 clinical trial evaluating repeat intrathecal administration of NurOwn® Cellular Therapeutic (autologous MSC-NTF cells) in ALS (Amyotrophic Lateral Sclerosis). BrainStorm's Phase 3 clinical trial is being conducted at the University of California, Irvine; Cedars-Sinai Medical Center; California Pacific Medical Center; Massachusetts General Hospital; University of Massachusetts Medical School; and the Mayo Clinic.

"The BrainStorm team is very excited to reach this important milestone in the development and potential commercialization of NurOwn in ALS. We have been fully dedicated to this journey since we began clinical trial enrollment in October 2017. To date, a significant percentage of the 200 enrolled patients have received three treatments and we expect that all trial participants will complete planned study visits and assessments by October 2020." commented Chaim Lebovits, President and CEO of BrainStorm.

"Having reached this turning point in our Company's history, I would like to publicly acknowledge the professionalism and commitment of the clinical investigators, but, most of all, I want to express my sincere gratitude to the many patients and their families, who by participating in this trial have confirmed their belief in the potential of NurOwn. The entire BrainStorm team is grateful for your contribution in advancing the development of NurOwn and our understanding of ALS."

Maria Millan, MD, President and CEO of the California Institute for Regenerative Medicine (CIRM) said, "CIRM's mission is to accelerate stem cell treatments to patients with unmet medical needs. ALS is a debilitating and fatal neurodegenerative condition for which there is no effective treatment. Based on BrainStorm Cell Therapeutics' scientific and early phase clinical trial data, CIRM awarded them $15.9 million to advance their investigational therapy NurOwn into a Phase 3 trial. Our support helped bring this program to three leading California medical centers. We congratulate Brainstorm Cell Therapeutics in completing enrollment, an important milestone toward developing a much-needed treatment for ALS."

Ralph Kern, MD, MHSc, Chief Operating Officer and Chief Medical Officer of BrainStorm stated, "We are very pleased to have fully enrolled our Phase 3 randomized placebo-controlled clinical trial in ALS and look forward to reporting top-line results before the end of next year. This clinical milestone is a key inflection point in the development of NurOwn. We are deeply thankful to many who have made an important contribution to this effort and look forward to quickly completing all clinical and biomarker analyses in support of the filing of a biological license application with the goal of bringing an innovative and much needed treatment option to ALS patients."

## About NurOwn®

NurOwn® (autologous MSC-NTF cells) represent a promising investigational 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. NurOwn® is currently being evaluated in a Phase 3 ALS randomized placebo-controlled trial and in a Phase 2 open-label multicenter trial in Progressive MS.

## 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® Cellular Therapeutic 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 the 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 BLA filing for U.S. FDA approval of autologous MSC-NTF cells in ALS. BrainStorm received U.S. FDA clearance to initiate a Phase 2 open-label multi-center trial of repeat intrathecal dosing of MSC-NTF cells in Progressive Multiple Sclerosis (NCT03799718) in December 2018 and has been enrolling clinical trial participants since March 2019. For more information, visit the company's website.

Safe-Harbor Statements
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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