

BrainStorm to Present ALS Phase 3 Biomarker Analyses at Annual NEALS Meeting October 6th, 2021

NEW YORK, Oct. 6, 2021 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of cellular therapies for neurodegenerative diseases, announced today that a scientific abstract titled "CSF biomarker correlations with primary outcome in NurOwn Phase 3 clinical trial" will be presented as a scientific poster at the fully digital [2021 Northeast Amyotrophic Lateral Sclerosis Consortium® \(NEALS\)](#) conference. The presentation will be delivered by James Berry, M.D. MPH, Winthrop Family Scholar in ALS Sciences, Director of the Massachusetts General Hospital (MGH) multidisciplinary ALS clinic and Chief of the Division of ALS and Motor Neuron Diseases, Boston MA. The Phase 3 trial (NCT03280056) evaluated three repeated intrathecal administrations of NurOwn® (MSC-NTF cells), each given two months apart, as a treatment for amyotrophic lateral sclerosis (ALS). The presentation will highlight CSF biomarkers that demonstrate high accuracy in predicting the primary clinical outcome using an unbiased stepwise logistic regression analysis.

Presentation details:

Session Date: October 6th 2021

Presenting Time: 4:00pm – 5:00pm ET

"We are fully committed to advance our proprietary cell therapy NurOwn® in ALS" said Chaim Lebovits, Chief Executive Officer of BrainStorm. "We believe that making tangible progress in ALS science and clarifying the molecular signature of NurOwn's mechanism of action in ALS will be an important next step in bringing a much needed therapy to patients with ALS who have a terminal disease and have limited treatment options."

Stacy Lindborg, EVP and Head of Global Clinical Research at Brainstorm commented, "We are excited to show the significant changes of NurOwn across a range of biomarkers spanning important domains such as neurodegeneration, neuroinflammation and neuroprotection. Furthermore, by using biomarker response and an innovative statistical model, we can predict treatment outcomes in the study with great accuracy. These objective biomarker endpoints provide more confidence as we continue researching and developing NurOwn."

The poster will be available on the [Publications](#) page of Brainstorm's corporate website, following the presentation at the NEALS conference.

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 are designed to 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 designation status 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 a Phase 3 pivotal trial in ALS (NCT03280056); this trial investigated the safety and efficacy of repeat-administration of autologous MSC-NTF cells and was supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989). BrainStorm completed under an investigational new drug application a Phase 2 open-label multicenter trial (NCT03799718) of autologous MSC-NTF cells in progressive multiple sclerosis (MS) and was supported by a grant from the National MS Society (NMSS).

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 NurOwn® manufacturing and clinical development plans, 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, the prospects for regulatory approval of BrainStorm's NurOwn® treatment candidate, the initiation, completion, and 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, or to use third parties 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, health 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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