BrainStorm Cell Therapeutics Partners with NEALS, The ALS Association, and I AM ALS to Provide Public Access to Biospecimens from NurOwn's Phase 3 ALS Study

Serum and cerebrospinal fluid samples from the Phase 3 study of NurOwn® in ALS to be donated to the NEALS biorepository for use by the research community

NEW YORK, Jan. 10, 2023 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today announced that BCLI will donate biospecimens from NurOwn's placebo-controlled Phase 3 ALS trial to the Northeast Amyotrophic Lateral Sclerosis Consortium (NEALS) biorepository for use by the research community. The specimens are being submitted to the biorepository in connection with a $500,000 grant previously awarded to BrainStorm by The ALS Association and I AM ALS, to support biomarker research.

The specimens submitted to the NEALS biorepository include serum and cerebrospinal fluid (CSF) samples collected from trial participants treated with placebo. Samples of both biofluids were collected in a matched fashion and longitudinally at multiple (up to seven) time points over a 20-week period, allowing for the evaluation of intra-patient biomarker changes over time as well as comparisons of biomarker levels between serum and CSF.

"Our Phase 3 trial included one of the largest longitudinal specimen collection protocols in trial participants with ALS, which has allowed us to perform extensive and unique biomarker analyses," said Stacy Lindborg PhD, Co-Chief Executive Officer of BrainStorm. "These analyses have greatly increased our understanding of both the mechanisms driving ALS progression, as well as the biological changes in participants treated with NurOwn. We are pleased to be providing the research community with access to our clinical samples, which will drive new research and can facilitate the discovery of new breakthroughs for patients with ALS."

Chaim Lebovits, Chief Executive Officer of BrainStorm, commented, "We would like to thank The ALS Association and I AM ALS for providing important funding for our biomarker analyses, as well as NEALS for housing our clinical samples for future use by the research community. The opportunity to collaborate with these three premier ALS organizations has been invaluable as BrainStorm works to advance NurOwn through the regulatory process and towards a potential approval."

"As a clinical research organization, NEALS is committed to using the NEALS Biorepository to help ALS researchers around the globe identify biomarkers and novel therapies as rapidly as possible. We are deeply appreciative of this contribution of samples, which adds to the biorepository and helps facilitate that goal," said James Berry, MD, MPH

"We are so proud to support BrainStorm's biomarker program which will help change ALS drug development. Biomarkers are critical to understanding the biology of ALS and enabling targeted new treatments. This program gives people living with ALS hope that we will see more and more approved treatments, making ALS the next cancer," said Brian Wallach, co-Founder I AM ALS.

"We are pleased to have supported the NurOwn biomarkers study with I AM ALS, and are encouraged the scientific community will now have access to these biospecimens. This will allow for independent replication and validation of the critical biomarkers data," said Kuldip Dave, Ph.D., Senior Vice President of Research for The ALS Association

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 MS and was supported by a grant from the National MS Society (NMSS).

About the Northeast ALS Consortium

The Northeast ALS Consortium (NEALS) is an international, independent, non-profit group of 147 research sites around the world who collaboratively conduct clinical research in Amyotrophic Lateral Sclerosis (ALS) and other motor neuron diseases. The mission of NEALS is to translate scientific advances into clinical research and new treatments for people with ALS and motor neuron disease.

The NEALS Biorepository contains serum, plasma, cerebrospinal fluid (CSF), whole blood, extracted DNA, and urine samples from research studies of ALS and motor neuron disease. Samples from this repository are available to researchers for the purpose of furthering the understanding of ALS or motor neuron disease and developing disease biomarkers.

Safe-Harbor Statement

Statements in this announcement other than historical data and information, including statements regarding BrainStorm's Type A meeting with the FDA and the clinical development of NurOwn® as a therapy for the treatment of ALS, 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 "intend," "should," "could," "will," "believe," "potential," and similar terms and phrases are intended to identify these forward-looking statements. The potential risks and uncertainties include, without limitation, management's ability to successfully achieve its goals, BrainStorm's ability to raise additional capital, BrainStorm's ability to continue as a going concern, prospects for future regulatory approval of NurOwn®, whether BrainStorm's future interactions with the FDA will have productive outcomes, the impacts of the COVID-19 pandemic on our clinical trials, supply chain, and operations, 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.

CONTACTS

Investor Relations:
John Mullaly
LifeSci Advisors, LLC
Phone: +1 617-429-3548
jmullaly@lifesciadvisors.com

Media:
Lisa Guiterman
lisa.guiterman@gmail.com

Logo: https://mma.prnewswire.com/media/1166536/BrainStorm_Logo.jpg

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