BrainStorm Cell Therapeutics to Present New Biomarker Data on NurOwn® at the International Symposium on ALS/MND

Biomarker data suggest that NurOwn drives significant changes on multiple biomarkers across ALS disease pathways which may be important in achieving clinical outcomes
Presentation on Tuesday, December 7 at 4.05pm GMT (11.05am ET).

NEW YORK, Dec. 2, 2021 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of cellular therapies for neurodegenerative diseases, today announced that biomarker data on NurOwn® will be presented at the 32nd International Symposium on ALS/MND, to be held virtually 7-10 December 2021. The presentation "NurOwn targets multiple disease pathways in ALS Phase 3 Trial" will be delivered by Robert Brown, M.D., Director of the Program in Neurotherapeutics at the University of Massachusetts Medical School, and principal investigator in the NurOwn Phase 3 clinical trial, onTuesday, December 7 at 4.05pm GMT (11.05am ET).

Brainstorm previously announced clinical results from the Phase 3 randomized, placebo control trial which evaluated the safety and efficacy of repeat administrations of NurOwn in ALS. This new analysis evaluated the treatment effects of NurOwn on cerebrospinal fluid (CSF) biomarkers and the relationship between these biomarkers and clinical outcomes. In the Phase 3 trial, CSF samples were obtained prior to the first treatment and at 6 additional time points.

Key findings

- Robust and statistically significant CSF biomarker changes from baseline were observed with NurOwn treatment compared to placebo, particularly in biomarkers related to neuroinflammation, neurodegeneration, and neurotrophic factors. These observations are consistent with earlier trials.
- Principal Component Analysis (PCA) was conducted and confirmed the conclusions across biomarkers that NurOwn increased neuroprotection as measured by neurotrophic factors and decreased neuroinflammation and neurodegeneration relative to placebo.
- Prespecified statistical modeling utilizing machine learning identified biomarkers that are predictive of the treatment response to NurOwn with high accuracy (>80%). Markers of neuroinflammation, neurodegeneration and neuroprotection were all selected in the final model, suggesting that NurOwn's biological activity across multiple disease pathways could prove important to impacting progression of ALS disease
- These results further the understanding of NurOwn's mechanism of action in ALS which targets multiple disease pathways and provides additional evidence linking the mechanism of action to NurOwn's impact on ALS progression (Phase 3 primary endpoint).

"This analysis showed how significant changes in CSF biomarkers in patients treated with NurOwn were associated with clinical response, suggesting that NurOwn has important effects on multiple important ALS disease pathways," said Robert Brown, MD, NurOwn Phase 3 Study Principal Investigator and Director of the Program in Neurotherapeutics at the University of Massachusetts Medical School. "Simultaneously targeting these multiple ALS disease pathways may be an important factor in achieving meaningful clinical outcomes."

"This is an important step in understanding the promise of NurOwn as a novel stem cell therapy for neurodegenerative diseases with tremendous unmet need, including ALS. We are keen to understand the effects that longer term treatment with NurOwn could drive in biomarkers of neuroinflammation, neurodegeneration and neuroprotection and ultimately the effect on clinical outcomes. We are poised to gain preliminary insights into longer term treatment with NurOwn through our Expanded Access Program", said Stacy R. Lindborg, EVP and Chief Development Officer. "We believe the future is bright for novel treatments like NurOwn".

A copy of the abstract can been viewed on the MND Association websitehere (SESSION 2 CLINICAL TRIALS, abstract C5).

The slides from the presentation will be available on the Publications page of Brainstorm's corporate website following the conclusion of the International Symposium on ALS/MND.

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 atwww.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, 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.

Contacts:

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

Media:
Mariesa Kemble
kemblem@mac.com

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

SOURCE Brainstorm Cell Therapeutics Inc
