BrainStorm Cell Therapeutics Announces Presentations on NurOwn® at 2024 Annual NEALS Meeting

NEW YORK, Sept. 24, 2024 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of cellular therapies for neurodegenerative diseases, today announced the acceptance of two abstracts featuring NurOwn® (MSC-NTF or Debamestrocel) at the 2024 Annual Northeastern Amyotrophic Lateral Sclerosis Consortium (NEALS) Meeting, to take place October 21 - 24, in-person in Clearwater, Florida and virtually.

"We look forward to sharing the latest update on NurOwn at this year's NEALS meeting. The insights and feedback that we gather from the ALS community are invaluable in advancing our mission to address the unmet needs of patients with this devastating disease," said Chaim Lebovits, President and CEO of BrainStorm. "Our top priority continues to be the initiation of a Phase 3b clinical trial, in order to confirm NurOwn's efficacy and conclusively demonstrate its efficacy in early stage ALS patients. Our team is energized by the progress to date and is working diligently to ensure the execution and success of this important study. As we make preparations, we anticipate multiple key milestones in the coming months that we believe will have potential to drive value. We remain committed to advancing our novel treatment option for ALS patients and achieving regulatory approval as quickly as possible."

Presentation details

Title:	Debamestrocel Long-Term Benefits on Survival and Neurodegeneration in ALS Expanded Access Program
Lead Author:	Bob Dagher, MD
Session:	Poster Session 1
Date and time:	4.30 –6.30pm ET, Tuesday, Oct 22
Location:	Sea Salon & Sand Salon, Opal Sands Resort, FL

Title:	An Overview of The Phase 3b Clinical Trial of Debamestrocel in ALS
Lead author:	Bob Dagher MD
Session:	Poster Session 2
Date and time:	4.00 –6.00pm ET, Wednesday, Oct 23
Location:	Sea Salon & Sand Salon, Opal Sands Resort, FL

Copies of the posters will be available on the BrainStorm corporate website, at the conclusion of the NEALS meeting.

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 harvested from each person with ALS and are manufactured using an innovative and proprietary process, to secrete neurotrophic factors to target specific neurodegenerative diseases. The lead program for NurOwn is for the treatment of ALS. BrainStorm's long-term commitment to ALS is demonstrated in preclinical research and a series of clinical studies, all of which have been published in peer-reviewed journals.

The NurOwn clinical program has generated valuable insights into the pathology of ALS, as well as disease progression and treatment. Since the initial Phase 3 readout, BrainStorm has shared the full dataset through rigorous peer-reviewed analysis, including: quantification of Floor Effect, which had been noted, but never before explored in depth; evaluation of multiple pre-specified biomarkers, collected at seven different points across 20 weeks during the trial, allowing a longitudinal view; and analysis of genetic data, which represents one of the first ALS trials to prospectively invoke pharmacogenomic analysis of clinical outcome, offering great promise for the development of future treatments for ALS.

About BrainStorm Cell Therapeutics Inc.
BrainStorm Cell Therapeutics Inc. is a leading developer of innovative autologous adult stem cell therapeutics for debilitating neurodegenerative diseases. BrainStorm 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 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), and another grant from the ALS Association and I AM ALS. 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).

Notice Regarding Forward-Looking Statements

This press release contains "forward-looking statements" that are subject to substantial risks and uncertainties, including statements regarding meetings with the U.S. Food and Drug Administration (FDA), Special Protocol Assessment (SPA), ADCOM meeting related to NurOwn, the timing of a PDUFA action date for the BLA for NurOwn, the clinical development of NurOwn as a therapy for the treatment of ALS, the future availability of NurOwn to patients, and the future success of BrainStorm. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will" "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on BrainStorm's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. These 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, 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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