# BrainStorm Cell Therapeutics Announces Strategic Realignment Prioritizing NurOwn® for the Treatment of ALS

- *Resource consumption will be reduced by 50% to accelerate ALS development*

- *Plans underway for registrational Phase 3b U.S. clinical trial for NurOwn in ALS*

NEW YORK, Oct. 24, 2023 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today announced a strategic realignment to enable accelerated development of NurOwn® for the treatment of amyotrophic lateral sclerosis (ALS). This realignment is designed to 1) support the company plans to conduct a double-blind, placebo-controlled Phase 3b U.S. clinical trial for NurOwn in ALS with an open-label extension and 2) continue to publish data from NurOwn's Phase 3 clinical trial on: biomarkers, long-term safety and survival, and the Expanded Access Program, providing transparency around NurOwn data and progressing ALS drug development. In preparation for the trial design and subsequent meeting with FDA, BrainStorm is consulting with the NurOwn Principal Investigators, who are most familiar with NurOwn, an additional panel of independent ALS experts, and a patient advisory group.

"While the Phase 3 trial was confounded by the ALSFRS-R scale's inability to measure disease progression in participants with advanced ALS, the trial did demonstrate a clinically meaningful response in a pre-specified subgroup of patients with less advanced disease. This finding was further supported by biomarker data," said Stacy Lindborg PhD, co-Chief Executive Officer of BrainStorm. "Based on learnings from the Phase 3 trial, we believe in the utility of NurOwn in mild to moderate ALS and that the ALS community deserves every effort we can give to definitively demonstrate its clinical value."

To fund the Phase 3b study and ALS priorities, BrainStorm is actively exploring various options to raise capital including non-dilutive grants and capitalizing on its exosome technology. At the same time, the company will reduce and refocus resources by streamlining clean room operations and undertaking a targeted reduction in headcount of approximately 30 percent. Positions most critical to the implementation of the Phase 3b trial and regulatory submission and review will be retained. The strategic realignment will cut total resource consumption by approximately half.

As part of this strategic realignment, Dr. Kirk Taylor, EVP and Chief Medical Officer, will be stepping down from his post, which largely focused on leading global medical affairs and broader launch activities. Certain other positions that are outside the current prioritized scope will be eliminated.

"We are extremely grateful for the dedication and contributions of our impacted colleagues, particularly Dr. Taylor who added tremendous value during his time with BrainStorm," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. "We remain steadfast in our goal to make NurOwn available to the ALS community as quickly as possible, and we believe that this strategic realignment offers our best chance for success. While remaining open to partnership opportunities that could accelerate growth, the steps we are taking now reflect our unwavering commitment to those battling this horrific disease and our firm belief in the potential value of NurOwn."

**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 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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