BrainStorm Cell Therapeutics to Meet with US FDA to Discuss Development Plan for NurOwn as a Treatment of ALS

- *Path forward for ALS is a registrational Phase 3b U.S. clinical trial* -

- *Biologics License Application to be withdrawn without prejudice* -

- *Conference call and webcast at 8:30am ET today* -

NEW YORK, Oct. 18, 2023 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today announced that the US Food and Drug Administration (FDA) has invited the Company to request an expedited face-to-face meeting to discuss the path forward for NurOwn® as a treatment for amyotrophic lateral sclerosis (ALS). BrainStorm remains committed to the ALS Community and is actively exploring the next steps in support of NurOwn, including publication of emerging clinical data and development of a protocol for an additional clinical study.

"We are confident in the data supporting the value of NurOwn as an addition to the options for treating ALS, and we have every desire to bring it to the ALS community," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. "We look forward to working with the FDA to define the path forward. We understand that an additional pivotal trial will be necessary, and we are doing everything in our power to execute on this as quickly as possible."

Brainstorm is withdrawing the Biologics License Application (BLA) for NurOwn. The decision to withdraw the BLA was coordinated with FDA and is viewed by FDA as a withdrawal without prejudice.

Conference call and webcast

Toll Free: 888-506-0062
International: 973-528-0011
Participant Access Code: 610368

Webcast : https://www.webcaster4.com/Webcast/Page/2354/49296

Those interested in listening to the conference call live via the internet may do so by using the webcast link above or by visiting the "Investors & Media" page of BrainStorm's website here and clicking on the conference call link.

A replay will be available, those that wish to listen to the replay of the conference call can do so via the webcast link or by dialing the numbers below.

Toll Free: 877-481-4010
International: 919-882-2331
Replay Passcode: 49296

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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