BrainStorm Cell Therapeutics Summarizes Key Messages from Its Participation as Expert Speakers in an Invited Presentation and Panel Discussion at The 2023 ALS Drug Development Summit

- *Presentation by Co-CEO Stacy Lindborg, Ph.D., held at 2023 ALS Drug Development Summit*

- *Summit Focused On Transforming Translational Tools to Accelerate Future ALS Approvals*

NEW YORK, May 19, 2023 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, joined an international audience of patient advocacy groups, physicians, research organizations, industry representatives, key thought leaders and decision makers dedicated to ALS research, at The 2023 ALS Drug Development summit, through an invited presentation and panel discussion on May 17 and 18, 2023.

Stacy Lindborg, Ph.D., Co-Chief Executive Officer BrainStorm and Antonio Trejo Diaz, Vice President, Regulatory Affairs, both participated as invited expert speakers at the summit which was focused on transforming translational tools to accelerate future ALS approvals.

Dr. Lindborg presented an invited talk entitled "Reviewing ALSFRS-R as the Established Endpoint for ALS Clinical trials".

Highlights from the presentation included:

- Describing and quantifying challenges with the ALSFRS-R endpoint in its current state, including its utility but clear limitations measuring a treatment effect in the extreme ends of the scale, rendering the ALSFRS-R unable to measure ongoing decline in participants with the most Advanced ALS.
- Providing evidence that suggests the floor effect with the ALSFRS-R exists in historical trials and in the NurOwn clinical program. The FDA has defined that a floor effect occurs when the scale of measurement is not able to capture progression at the bottom of the scale. It can occur at the item level or at the scale score level. While acknowledged by the FDA in 2018, for score endpoints in general, this was not well known prior to the NurOwn study, and not well characterized for the ALSFRS-R.
- Showcasing analysis strategies to assess a treatment impact on disease progression, by accounting for the floor effect of the ALSFRS-R within a trial.
- Identifying criteria for participants with a potential floor effect can significantly impact the study results.
- Reviewing pre-specified and post-hoc analysis can reveal a robust treatment difference in patients not impacted by the floor effect.
- Discussing recommendations for future trials, enabling access to clinical trials for a broader set of people living with ALS and implementing learnings from the ALSFRS-R floor effect to enable study goals.

Mr. Trejo Diez participated in a panel entitled "A Year in Review: Showcasing the Breakthrough Developments in ALS Drug Development". The panel reviewed the important progress made during the past year with two new therapies approved by the U.S. Food and Drug Administration (FDA) for ALS and recognized the efforts of the agency to show regulatory flexibility for the benefit of the ALS community. The panel agreed that there is an opportunity to leverage the experience in the US and start a discussion with other Health Authorities around the world.

The regulatory flexibility shown by the US FDA is a positive sign to address the unmet need for ALS therapies. BrainStorm communicated to the conference that it has been granted an FDA Advisory Committee Meeting to discuss its Biologics License Application for NurOwn, which it expects will enable the transparent sharing of information with the medical, scientific and advocacy communities dedicated to improving the lives of people living with ALS.

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).

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.

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