

## **BrainStorm Cell Therapeutics Announces In-Person Meeting with the FDA to Discuss Confirmatory Phase 3 Trial for NurOwn® in ALS**

**Meeting will take place on December 6; Company plans to seek Special Protocol Assessment (SPA)**

NEW YORK, Nov. 20, 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 & Drug Administration (US FDA) has granted the company a meeting to discuss the regulatory path forward for NurOwn® in amyotrophic lateral sclerosis (ALS). The meeting is scheduled to take place on December 6, 2023. Brainstorm will discuss plans for a Special Protocol Assessment (SPA) with the FDA to agree on the overall protocol design for a confirmatory Phase 3 trial in ALS.

"We are pleased that the FDA has granted this expedited in-person meeting to discuss the best path forward for NurOwn for ALS," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. "Our proposed plan is to conduct a confirmatory Phase 3b trial and it is important that we are aligned with the Agency on the expected requirements for re-submitting a Biologics License Application. We believe that reaching an agreement through a SPA on the overall protocol design and the adequacy to address the requirements for marketing approval will be a key step to position the company for success and to potentially de-risk the program. We are grateful for the FDA's support and quick response in granting this meeting as we remain committed to our goal of making NurOwn available to the ALS community."

### **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.

## **CONTACTS**

John Mullaly  
LifeSci Advisors, LLC  
Phone: +1 617-429-3548  
[jmullaly@lifesciadvisors.com](mailto:jmullaly@lifesciadvisors.com)

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