BrainStorm Receives FDA Clearance to Initiate Phase 3b Trial of NurOwn® for ALS

Investor call and webcast scheduled for today at8:30 a.m. ET

NEW YORK, May 19, 2025 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapies for neurodegenerative diseases, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company to initiate its Phase 3b clinical trial of NurOwn® (autologous MSC-NTF cells) for the treatment of amyotrophic lateral sclerosis (ALS).

The trial design was previously agreed upon with the FDA under a Special Protocol Assessment (SPA), confirming the study's endpoints and statistical methodology are appropriate to support a future Biologics License Application (BLA) submission. This clearance allows the company to proceed with patient enrollment.

"This FDA clearance is a defining milestone for BrainStorm and the ALS community," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. "We are now positioned to swiftly activate clinical sites in a phased manner, diligently preparing to enroll the first patient in the Phase 3b trial. At the same time, we are actively working to secure funding through multiple avenues, including non-dilutive grants, to ensure the timely and successful launch of this critical study."

The Phase 3b trial will enroll approximately 200 participants at leading academic medical centers and will consist of a 24-week randomized, double-blind, placebo-controlled phase followed by a 24-week open-label extension where all participants will receive NurOwn®. The primary endpoint is the change from baseline to week 24 in the ALS Functional Rating Scale-Revised (ALSFRS-R). For more details on the trial, refer to ClinicalTrials.gov ID NCT06973629.

BrainStorm management will discuss this important development on its corporate update conference call and webcast, taking place today, May 19 at 8.30am ET. To access the call, refer to the events page on the company's website here. The company will provide further ongoing updates as the trial progresses and key milestones are achieved.

About BrainStorm Cell Therapeutics Inc.

BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI) is a leading developer of autologous adult stem cell therapies for debilitating neurodegenerative diseases. The company's proprietary NurOwn® platform uses autologous mesenchymal stem cells (MSCs) to produce neurotrophic factor-secreting cells (MSC-NTF cells), designed to deliver targeted biological signals that modulate neuroinflammation and promote neuroprotection.

NurOwn® is BrainStorm's lead investigational therapy for amyotrophic lateral sclerosis (ALS) and has received Orphan Drug designation from both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). A Phase 3 trial in ALS (NCT03280056) has been completed, and a second Phase 3b trial is set to launch under a Special Protocol Assessment (SPA) agreement with the FDA. The NurOwn clinical program has generated valuable insights into ALS disease biology, including pharmacogenomic response associated with the UNC13A genotype, biomarker data collected at seven longitudinal time points, and a comprehensive analysis of the "Floor Effect" — a critical challenge in measuring clinical outcomes in advanced ALS. BrainStorm has published its findings in multiple peer-reviewed journals. In addition to ALS, BrainStorm has completed a Phase 2 open-label multicenter trial (NCT03799718) of MSC-NTF cells in progressive multiple sclerosis (MS), supported by a grant from the National MS Society. BrainStorm is also advancing a proprietary, allogeneic exosome-based platform designed to deliver therapeutic proteins and nucleic acids. The company recently received a Notice of Allowance from the U.S. Patent and Trademark Office for a foundational patent covering its exosome technology, further strengthening BrainStorm's growing IP portfolio in this emerging area of regenerative medicine. To learn more, visit www.brainstorm-cell.com.

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), 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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