BrainStorm Cell Therapeutics and Pluri Partner to Support NurOwn® Phase 3b Trial Manufacturing

Memorandum of Understanding has been signed

NEW YORK, Nov. 11, 2024 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of cellular therapies for neurodegenerative diseases, today announced that it has entered into a Memorandum of Understanding (MOU) with Pluri Inc. (NASDAQ: PLUR) through its wholly owned subsidiary ("Pluri"), an established global leader in the development and manufacturing of cell-based therapeutics, to manufacture NurOwn® for use in BrainStorm's planned Phase 3b trial in amyotrophic lateral sclerosis (ALS). This MOU enables BrainStorm to begin transfer of its manufacturing technology and start producing NurOwn at Pluri's manufacturing facility upon finalizing the binding definitive agreement.

Under the terms of the proposed agreement, Pluri will provide GMP-compliant manufacturing of NurOwn at its facilities in Israel. This collaboration aims to fulfill essential supply requirements of NurOwn® as BrainStorm advances its Phase 3b clinical trial. Additionally, the two companies are exploring options for manufacturing to support potential future commercial distribution, pending approval of NurOwn.

"Pluri has become a recognized leader in GMP-compliant clinical manufacturing of cell-based products, known for their exceptional quality standards and strict regulatory compliance," said Haro Hartounian, PhD, Chief Operating Officer at BrainStorm. "Pluri will offer manufacturing capacity to support our Phase 3b clinical trials, in addition to our existing development and clinical manufacturing activities at The Center for Advanced Cellular Therapies (I-ACT) in Israel. We believe that having Pluri's clinical manufacturing facility near BrainStorm's manufacturing and R&D teams will strengthen communication and foster a highly productive collaboration."

Chaim Lebovits, President and CEO of Brainstorm, added, "The Phase3b clinical trial marks a critical step toward potential regulatory approval of NurOwn, "This MOU with Pluri creates a strong foundation to meet the clinical supply requirements of NurOwn®. The proposed agreement also offers the prospect of establishing an attractive supply arrangement that aligns well with our strategic priorities as we prepare for the operational and financial commitments of the Phase 3b trial."

Yaky Yanay, CEO and President of Pluri commented, "We applaud BrainStorm for their commitment to developing a novel cell therapy for ALS. We are eager to utilize our proprietary knowledge, long years of experience and manufacturing capabilities to support their mission of bringing hope to patients and families impacted by this devastating disease."

The Phase 3b trial has been designed to enroll up to approximately 200 participants with ALS. It will be conducted in two parts: In Part A, participants will receive 3 doses of NurOwn or placebo for 24 weeks. This will be followed by an open label period, during which patients from both arms will receive 3 doses NurOwn for another 24 weeks (Part B). The primary efficacy endpoint will be a comparison of change in ALSFRS-R from baseline to week-24 (i.e. at the end of Part A) for NurOwn vs. placebo. Successful completion of Part A of the double-blind Phase 3b study will position BrainStorm to submit a Biologics License Application (BLA) for regulatory approval, potentially accelerating the path to market.

BrainStorm plans to hold a conference call for investors later in Q4 2024, during which it will provide further updates on the NurOwn Phase 3 clinical program.

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 Pluri Inc.

Pluri™ is pushing the boundaries of science and engineering to create cell-based products for commercial use and is pioneering a biotech revolution that promotes global well-being and sustainability. The Company's technology platform, a

patented and validated state-of-the-art 3D cell expansion system, advances novel cell-based solutions for a range of challenges — from medicine and climate change to food scarcity, animal cruelty and beyond. PluriCDMO™ offers CDMO services to companies from early preclinical development, through late-stage clinical trials and commercialization, with a mission to deliver high-quality, essential therapies to patients. . Pluri establishes partnerships that leverage the Company's proprietary 3D cell-based technology across various industries that require effective, mass cell production. To learn more, visit us at www.pluri-biotech.com or follow Pluri on LinkedIn and X (formerly known as Twitter).

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 statements regarding meetings with the U.S. Food and Drug Administration (FDA), Special Protocol Assessment (SPA), ADCOM meeting related to NurOwn, the timing of a PDUFA action date for the BLA for NurOwn, 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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