FDA Authorizes Further NurOwn® Dosing Under Expanded Access Program

Three additional doses of NurOwn® will be made available to participants who completed the Expanded Access Protocol
FDA approved EAP manufacturing at the Catalent Texas site

NEW YORK, Dec. 27, 2021 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of cellular therapies for neurodegenerative diseases, today announced plans for a dosing extension of NurOwn® for participants who completed the Expanded Access Protocol (EAP). The U.S. Food and Drug Administration (FDA) recommended that BrainStorm submit an EAP protocol amendment to provide additional dosing for these participants. Under the original EAP protocol, participants who had completed the Phase 3 NurOwn trial and who met specific eligibility criteria had the opportunity to receive 3 doses of NurOwn. Under the amended EAP protocol, these eligible participants will receive up to 3 additional doses. Data collected from the original EAP treatments informed the decision to move forward with additional doses for participants who completed it.

"This dosing extension for the expanded access protocol is an appropriate next step following the new analysis and biomarkers results of the Phase 3 study. It is deeply appreciated by our ALS patients. Eligible patients now have the opportunity to receive as many as 9 doses of NurOwn in total, allowing additional data collection to better understand the potential benefits of longer-term treatment," said Robert Brown, MD DPhil, Leo P. and Theresa M. LaChance Chair in Medical Research, and Chair, Department of Neurology, University of Massachusetts Medical School and UMass Memorial Medical Center, and one of the Principal Investigators in the NurOwn® Phase 3 study.

"I applaud BrainStorm for having the conviction to continue their EAP which has brought true hope to those in it. I am also grateful that they recognize the value and importance of EAPs and are willing to invest in doing them right despite being a small company. I look forward to the day, hopefully very soon, when every person living with ALS has access to NurOwn," stated Brian Wallach, person living with ALS, and Co-Founder of I AM ALS.

Chaim Lebovits, Chief Executive Officer, Brainstorm Cell Therapeutics, commented, "We are pleased to be able to provide additional treatments to these patients. This program is an outcome of a fruitful collaboration between the FDA, Patient Advocacy groups and Brainstorm. We look forward to continuing this dialogue with the FDA for the best path forward."

The NurOwn EAP was established in 2020, following conclusion of the Phase 3 trial, and the protocol was developed in partnership with the FDA. Patients were treated at one of six clinical centers of excellence that participated in the Phase 3 trial. These six centers are: University of California, Irvine; Cedars-Sinai Medical Center; California Pacific Medical Center; Massachusetts General Hospital; University of Massachusetts Medical School; and Mayo Clinic. The FDA approved BrainStorm to manufacture NurOwn for the EAP Program at the Catalent facility in Houston, Texas.

According to the FDA, EAPs, alternatively known as "compassionate use" programs, provide a pathway for appropriate patients to receive an investigational medicine for treatment of a serious disease or condition outside of a clinical trial when no comparable or satisfactory alternative therapy options are available.

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) which was published in Muscle and Nerve; 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), in addition to a grant from I AM ALS and the ALS Association. BrainStorm completed under an investigational new drug application a Phase 2 open-label multicenter trial

(NCT03799718) of autologous MSC-NTF cells in progressive multiple sclerosis (MS) and was supported by a grant from the National MS Society (NMSS).

For more information, visit the company's website atwww.brainstorm-cell.com.

Safe-Harbor Statement

Statements in this announcement other than historical data and information, including statements regarding future clinical trials, the continued development of NurOwn® and the potential therapeutic effects and expected patient population of NurOwn®, 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 "may," "should," "would," "could," "will," "expect," "likely," "believe," "plan," "estimate," "predict," "potential," and similar terms and phrases are intended to identify these forward-looking statements. The potential risks and uncertainties include, without limitation, BrainStorm's need to raise additional capital, BrainStorm's ability to continue as a going concern, the prospects for regulatory approval of BrainStorm's NurOwn® treatment candidate, the initiation, completion, and success of BrainStorm's product development programs and research, regulatory and personnel issues, development of a global market for our services, the ability to secure and maintain research institutions to conduct our clinical trials, the ability to generate significant revenue, the ability of BrainStorm's NurOwn® treatment candidate to achieve broad acceptance as a treatment option for ALS or other neurodegenerative diseases, BrainStorm's ability to manufacture, or to use third parties to manufacture, and commercialize the NurOwn® treatment candidate, obtaining patents that provide meaningful protection, competition and market developments, BrainStorm's ability to protect our intellectual property from infringement by third parties, heath reform legislation, demand for our services, currency exchange rates and product liability claims and litigation; 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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