BrainStorm Announces Completion of All Dosing in NurOwn® Phase 2 MS Study

Topline clinical trial results expected by the end of the first quarter 2021

NEW YORK, Dec. 18, 2020 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapies for neurodegenerative diseases, announced today that all dosing has been completed in the ongoing Phase 2 trial evaluating NurOwn® (MSC-NTF cells) as a treatment for progressive MS. The Phase 2 open-label clinical trial of repeat-dosing CSF-delivered autologous MSC-NTF cells (NurOwnâ) is being conducted at five clinical trial sites in the United States.

"Completed dosing of the Phase 2 progressive MS clinical trial is a major milestone for BrainStorm as we advance our goal to develop the NurOwn platform technology in neurodegenerative diseases," said Chaim Lebovits BrainStorm CEO. "We are very thankful for the dedicated efforts of the investigators and their teams and to the patients who participated in this important clinical trial. Through their combined efforts, we hope to bring a promising therapeutic option to those affected by progressive MS."

Ralph Kern MD, MHSc BrainStorm President and Chief Medical Officer commented, "Now that all dosing of the NurOwn Phase 2 progressive MS clinical trial is complete, we will shift our focus to completing all remaining patient clinical trial assessments and biomarker analyses. We look forward to generating clinical trial top line results by the end of the first quarter 2021 and to advancing this promising treatment option based on a thorough analysis of the clinical trial outcomes."

Stacy Lindborg PhD, EVP and Head of Global Clinical Research at BrainStorm added, "Detailed analyses of the full study data set at the conclusion of the trial will add to our understanding of the potential of NurOwn technology in progressive MS and to the growing body of evidence for NurOwn in neurodegenerative disease. The data and scientific insights we will share with the MS scientific community at upcoming conferences and in subsequent publications will help advance understanding of progressive MS and the potential benefits of NurOwn as a treatment."

MS is a chronic neuroinflammatory and neurodegenerative disorder that affects the brain and spinal cord. MS affects approximately 1 million individuals in the U.S. and 2.5 million individuals worldwide. Approximately half of affected individuals will eventually develop a progressive form of the disease, which may lead to increasing levels of motor, visual, and cognitive functional impairment, and disability.

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 can 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 status designation 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 fully enrolled a phase 3 pivotal trial in ALS (NCT03280056); this trial is investigating repeat-administration of autologous MSC-NTF cells at six U.S. sites supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989). The pivotal study is intended to support a filing for FDA approval of autologous MSC-NTF cells in ALS. BrainStorm is also conducting an FDA-approved phase 2 open-label multicenter trial in progressive multiple sclerosis (MS). The phase 2 study of autologous MSC-NTF cells in patients with progressive MS (NCT03799718) started enrollment in March 2019.

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

Safe-Harbor Statement

Statements in this announcement other than historical data and information, including statements regarding future clinical trial enrollment and data, 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, regulatory approval of BrainStorm's NurOwn® treatment candidate, the 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 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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