FDA Accepts BrainStorm's NurOwn® IND Application for Progressive Multiple Sclerosis

U.S. Phase 2 Study to Begin in First Quarter of 2019

NEW YORK, Dec. 17, 2018 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of innovative autologous adult stem cell therapeutics for debilitating neurodegenerative diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Investigational New Drug (IND) application to initiate a Phase 2 clinical trial of NurOwn® for the treatment of progressive multiple sclerosis (MS).

There are currently no FDA approved autologous cellular therapies addressing MS or other neurological diseases. While treatment options for patients with MS exist, there remains a significant unmet need in progressive MS. There is currently no FDA approved therapy that addresses more than one progressive form of MS.

"This is an extremely exciting moment as we expand BrainStorm's pipeline by introducing a new indication for NurOwn® in neurodegenerative disease," said Chaim Lebovits, president and CEO of BrainStorm. "Through this trial, we are advancing a novel treatment modality into clinical-stage testing for progressive MS in early 2019."

MS affects approximately 1 million individuals in the U.S. and 2.5 million individuals worldwide. Approximately half of affected individuals will eventually develop progressive disease, which may lead to increasing levels of motor, visual, and cognitive functional impairment and disability.

"We are excited about the launch of early testing of this cell-based approach to treating progressive MS, for which there are few treatment options," commented Bruce Bebo, Ph.D., Executive Vice President of Research at theNational MS Society. "We look forward to better understanding the potential benefits and safety of this and other cell-based therapies for MS."

"We are excited to participate in this Phase 2 clinical trial and hope that this innovative cell therapy approach leads to a new treatment option for patients with progressive MS," said Dr. Fred Lublin, Director of the Corinne Goldsmith Dickinson Center for Multiple Sclerosis at Mount Sinai Medical Center and Saunders Family Professor of Neurology at Mount Sinai School of Medicine in New York. "We are particularly pleased to see a scientifically rigorous approach to advance the science of stem cell therapeutics."

About NurOwn®
NurOwn® (MSC-NTF) cells represent 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. 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. BrainStorm is currently conducting a pivotal Phase 3 clinical trial of autologous MSC-NTF cells for the treatment of amyotrophic lateral sclerosis (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. 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 (U.S. FDA) and the European Medicines Agency (EMA) in ALS. BrainStorm is currently enrolling a Phase 3 pivotal trial in ALS (NCT03280056), investigating repeat-administration of autologous MSC-NTF cells at six sites in the U.S., supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989). The pivotal study is intended to support a filing for U.S. FDA approval of autologous MSC-NTF cells in ALS. For more information, visit BrainStorm's website at www.brainstorm-cell.com.

Safe-Harbor Statements
Statements in this announcement other than historical data and information 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, risks associated with BrainStorm's limited operating history, history of losses; minimal working capital, dependence on its license to Ramot's technology; ability to adequately protect the technology; dependence on key executives and on its scientific consultants; ability to obtain required regulatory approvals; 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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