

BrainStorm Expands Manufacturing of NurOwn® for Phase 2 Progressive MS Trial

BrainStorm has contracted with the Connell and O'Reilly Families Cell Manipulation Core Facility at Dana-Farber Cancer Institute, currently supporting the Phase 3 ALS Trial, to Produce NurOwn®

NEW YORK and BOSTON, Dec. 26, 2018 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, announced today that it has expanded its autologous cell manufacturing capacity to produce NurOwn® to support clinical trials in additional indications, including a Phase 2 progressive Multiple Sclerosis (MS) study, to begin in first quarter of 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 a progressive disease, which may lead to increasing levels of motor, visual, and cognitive functional impairment and disability.

"We are excited to rapidly advance our investigational stem cell therapy for progressive MS patients and sincerely thank the Connell and O'Reilly Families Cell Manipulation Core Team for allocating resources and dedicated manufacturing space to allow us to initiate our Phase 2 progressive MS study in early 2019," said Chaim Lebovits, president and CEO of BrainStorm.

BrainStorm expanded the existing manufacturing contract with the Connell and O'Reilly Families Cell Manipulation Core Facility (CMCF) at Dana-Farber Cancer Institute (Dana-Farber), to also produce NurOwn® for the new Phase 2 progressive MS trial in addition to supporting ongoing production for the Phase 3 pivotal ALS trial.

The CMCF Team at Dana-Farber is collaborating with clinical researchers in advancing novel cell-based therapies in trials for cancer and other diseases (like ALS and progressive MS) to evaluate the potential of adoptive cell therapy (for investigational cell product candidates like CAR-T cells and NurOwn®).

"Cellular therapies represent an exciting new therapeutic modality that can potentially benefit patients who do not have other effective treatment options. We are very glad to support BrainStorm's plan to evaluate the potential role of NurOwn® in the treatment of other debilitating neurologic diseases such as progressive Multiple Sclerosis," said Jerome Ritz, MD, Executive Director of the Connell and O'Reilly Families Cell Manipulation Core Facility at Dana-Farber.

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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Additional assets available online: [Photos \(1\)](#)

<https://ir.brainstorm-cell.com/2018-12-26-BrainStorm-Expands-Manufacturing-of-NurOwn-R-for-Phase-2-Progressive-MS-Trial>