

BrainStorm Announces the Mount Sinai Medical Center as a Progressive MS Phase 2 Clinical Trial Site

NEW YORK, Nov. 25, 2019 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. ([NASDAQ: BCLI](#)), a leader in developing innovative autologous cellular therapies for highly debilitating neurodegenerative diseases, today announced that The [Mount Sinai](#) Medical Center, internationally acclaimed for its excellence in research, patient care, and education in multiple sclerosis and across a range of medical specialties, has contracted with BrainStorm as a clinical study site for the Company's Phase 2 open-label, multicenter study of repeated intrathecal administration of NurOwn® (autologous MSC-NTF cells) in participants with progressive Multiple Sclerosis (MS) ([NCT03799718](#)).

"Internationally recognized Multiple Sclerosis expert [Fred Lublin, MD](#), will serve as the Principal Investigator at the Mount Sinai Medical Center," said Chaim Lebovits, President and CEO of BrainStorm. He added, "[The Corinne Goldsmith Dickinson Center for Multiple Sclerosis](#) at Mount Sinai is a leading center in MS research and discovery and we are ready to enroll patients under the supervision of Dr. Lublin and his highly experienced clinical team."

"BrainStorm looks forward to partnering with and supporting Dr. Lublin and the dedicated clinical trial team at the Mount Sinai Hospital to quickly advance the phase 2 progressive MS clinical trial," said BrainStorm Chief Operating Officer and Chief Medical Officer, Ralph Kern MD MHSc.

"We are happy to be a part of this exciting study to determine if neurally-directed stem cells can be a therapeutic approach to treating MS," said Dr. Lublin.

[About NurOwn®](#)

NurOwn® (autologous 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 has fully enrolled a Phase 3 pivotal trial of autologous MSC-NTF cells for the treatment of amyotrophic lateral sclerosis (ALS). BrainStorm also recently received U.S. FDA acceptance to initiate a Phase 2 open-label multicenter trial in progressive MS and enrollment began in March 2019.

[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 has fully enrolled a Phase 3 pivotal trial in ALS (NCT03280056), 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 U.S. FDA approval of autologous MSC-NTF cells in ALS. BrainStorm also recently received U.S. FDA clearance to initiate a Phase 2 open-label multicenter trial in progressive Multiple Sclerosis. Dr. Lublin and several leading MS experts previously served as consultants to Brainstorm in the initial study conception and design. 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 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 \(1\)](#)

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