BrainStorm Cell Therapeutics to Present NurOwn® Phase 2 Biomarker Data at North East Amyotrophic Lateral Sclerosis (NEALS) 18th Annual Meeting

NEW YORK, Oct. 02, 2019 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leader in the development of innovative autologous cellular therapies for highly debilitating neurodegenerative diseases announced today, Chief Operating Officer and Chief Medical Officer, Ralph Kern, MD, MHSc, will present NurOwn® Phase 2 biomarker data at the 18th Annual NEALS Meeting held October 2-4, 2019 in Clearwater, Florida. In addition, Dr. Kern will represent BrainStorm at the NEALS member/industry partner roundtable that will discuss the evolving landscape of ALS clinical trials and potential surrogate and functional endpoints for regulatory approval.

Chaim Lebovits, President and CEO of BrainStorm, said, “BrainStorm is pleased that Dr. Kern will be presenting our innovative CSF surrogate biomarker data at NEALS. On September 23rd, the FDA issued a new ALS therapy development guidance document emphasizing the importance of biomarkers for the advancement of ALS investigational therapies. We are pleased to have the opportunity to present our ongoing research to clinical leaders who are at the forefront of ALS investigation and scientific discovery.”

Meeting and Presentation Details:

NEALS Poster Presentation:

Title:	CSF MCP-1, a surrogate biomarker for ALS (Poster 73)
Presenter:	Ralph Kern, MD, MHSc, BrainStorm Cell Therapeutics, NY, NY.
Date:	Thursday October 3, 2019
Time:	4-5 pm

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 is currently conducting 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

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. BrainStorm also recently received U.S. FDA clearance to initiate a Phase 2 open-label multicenter trial in progressive Multiple Sclerosis. 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, 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.

CONTACTS

Corporate:
Uri Yablonka
Chief Business Officer
BrainStorm Cell Therapeutics Inc.
Phone: 646-666-3188
uri@brainstorm-cell.com

Media:
Sean Leous
Westwicke/ICR PR
Phone: +1.646.677.1839
sean.leous@icrinc.com

Source: BrainStorm Cell Therapeutics Inc.

Additional assets available online: Photos (1)

https://ir.brainstorm-cell.com/2019-10-02-BrainStorm-Cell-Therapeutics-to-Present-NurOwn-R-Phase-2-Biomarker-Data-at-North-East-Amyotrophic-Lateral-Sclerosis-NEALS-18th-Annual-Meeting