BrainStorm Announces Publication of New Preclinical Data Supporting Proposed NurOwn® Mechanism in ALS, Progressive MS and Alzheimer's Disease

NurOwn® shown to have immunomodulatory effects on T and B Regulatory Cell Function

NEW YORK, Aug. 19, 2020 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapies for neurodegenerative diseases, announced today the publication of a manuscript titled, "Effects of MSC-NTF cells on T and B regulatory cell function in ALS" in the journal Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration.

NurOwn® (MSC-NTF cells) are autologous, mesenchymal stem cells induced by a culture-based approach to secrete significant higher levels of neurotrophic factors while retaining their intrinsic immunomodulatory activity. Brainstorm has demonstrated that a single administration of NurOwn increased circulating T regulatory cells in a phase 2a open label study and reduced cerebrospinal fluid (CSF) inflammatory biomarkers in a phase 2 randomized clinical study. To explore the link between these important biomarker observations, Brainstorm conducted a series of preclinical experiments in order to evaluate the potential of NurOwn to induce T and B regulatory cells and IL-10 secretion and confirm their immunomodulatory effects. Decreased T and B regulatory function appears to impact disease progression in ALS and other neuroinflammatory diseases. T and B cell secreted IL-10 may enhance microglia and cytokine networks and have shown therapeutic potential in ALS and neuroinflammatory preclinical models.

In the preclinical experiments, a significant ($p<0.0001$) decrease of interferon-g secretion by peripheral blood mononuclear cells (PBMC) in the presence of NurOwn® was demonstrated. When co-cultured with PBMC, NurOwn® induced CD4+CD25+FoxP3+ T regulatory cells ($p < 0.001$). When cocultured with B cells, NurOwn induced $CD24^{hi}CD38^{hi}$ B regulatory cells, and increased IL-10 secretion ($p < 0.001$).

"These preclinical observations extend the understanding of immunomodulatory effects of NurOwn on CSF inflammatory biomarkers demonstrated in the US phase 2 randomized clinical trial by providing specific mechanisms by which NurOwn may exert its beneficial effects on these important cytokine pathways," said Ralph Kern MD MHSc, President and Chief Medical Officer of Brainstorm.

Chaim Lebovits, Brainstorm Chief Executive Officer added, "We continue to expand our scientific knowledge of NurOwn's mechanism of action through preclinical and clinical research. Our goal is to efficiently bring practical solutions to patients in need, through innovative science, completion of the phase 3 ALS clinical trial and advancement of clinical programs in progressive MS and Alzheimer's disease."

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 atwww.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 fo/rward-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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