BrainStorm Announces the Publication of Preclinical Data Highlighting the Potential of a NurOwn® Derived Exosome-Based Treatment for COVID-19 ARDS

Intratracheal administration of NurOwn® derived exosomes significantly improves lung function and histology in a mouse model of acute respiratory distress syndrome (ARDS)

NEW YORK, Jan. 20, 2021 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapies for neurodegenerative diseases, announced today the peer-reviewed publication of a preclinical study in the journal *Stem Cell and Research Therapy*. The study, entitled "MSC-NTF (NurOwn®) exosomes: a novel therapeutic modality in the mouse LPS-induced ARDS model," evaluated the use of NurOwn® (MSC-NTF cell) derived exosomes in a mouse model of acute respiratory distress syndrome (ARDS).

ARDS is a type of respiratory failure that is frequently associated with COVID-19 and mediated by dysregulated cytokine production. While there are currently no effective therapies to prevent or reverse ARDS, mesenchymal stem cell (MSC)-derived exosomes have been suggested as a potential novel treatment option due to their ability to penetrate deep into tissues and efficiently deliver immunomodulatory molecules.

Results from the recently published study showed that intratracheal administration of NurOwn® derived exosomes led to a statistically significant reduction in lung disease severity score ($p < 0.05$; based on criteria set forth by the American Thoracic Society Documents: Matute-Bello et al., Am J Respir Cell Mol Biol 44;725-738, 2011) and improvements in several additional clinically relevant lipopolysaccharide (LPS)-induced ARDS markers such as lung function, fibrin presence, neutrophil accumulation, cytokine expression, and blood oxygenation levels. Notably, these improvements were significantly superior to those observed following administration of naïve MSC-derived exosomes.

"These exciting preclinical data suggest that NurOwn® derived exosomes have the potential to treat COVID-19-induced ARDS or other severe respiratory complications, and that they are more effective than exosomes isolated from naïve MSCs at combatting the various symptoms of the syndrome," said Dr. Revital Aricha, Vice President of Research & Development at BrainStorm. "This publication in a highly regarded journal provides important validation for the scientific advances and significance of BrainStorm's preclinical research programs, including on our exosome-based technology platform."

Chaim Lebovits, Brainstorm's Chief Executive Officer added, "While our primary focus is on advancing NurOwn® towards regulatory approval in ALS, we continue to evaluate the potential of our exosome-based platform to address unmet medical needs. The publication of these proof-of-concept data highlights this potential, and we are now actively assessing next steps to determine how to best generate value. We are also actively discussing with possible partners several development opportunities for the exosome technology."

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 completed a phase 3 pivotal trial in ALS (NCT03280056); this trial investigated the safety and efficacy of repeat-administration of autologous MSC-NTF cells and was supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989).

BrainStorm is in active discussions with the FDA to identify regulatory pathways that may support NurOwn's approval 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) completed dosing in December 2020, and topline results are expected by the end of the first quarter 2021.

For more information, visit the company's website at www.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 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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