BrainStorm Announces Scientific Presentation of NurOwn® Exosome Preclinical ARDS Data at ISCT 2021 New Orleans VIRTUAL Meeting

Superior clinical and biomarker outcomes demonstrated with NurOwn exosomes compared to MSC exosomes in Preclinical ARDS Model

NEW YORK, May 25, 2021 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of cellular therapies for neurodegenerative diseases, announced the presentation today of a poster titled, "Molecular Mechanisms Underlying MSC-NTF (NurOwn®) Exosome Benefits in a Mouse LPS-induced ARDS Model" at the ISCT 2021 New Orleans VIRTUAL Meeting, being held from May 25-28, 2021. The poster will be presented during Virtual Poster Hall Session 2: May 25, 20:00-21:30 EDT.

POSTER HIGHLIGHTS:

- One of the most severe complications of the current COVID-19 pandemic is acute respiratory distress syndrome (ARDS). ARDS is caused by increased amounts of pro-inflammatory cytokines, leading to severe lung damage and loss of lung function.
- Results from a study in a mouse model of lipopolysaccharide (LPS)-induced ARDS showed that intratracheal administration of NurOwn (MSC-NTF cells)-derived exosomes resulted in a statistically significant improvement in multiple lung parameters and superior results compared to MSC exosomes. These included functional lung recovery, reduction in pro-inflammatory cytokines (IFN-γ, IL-6, RANTES, and TNF-α) and attenuation of lung damage (fibrin deposition) and coagulation biomarkers (tissue factor and thrombin–antithrombin complex).
- Analysis of the respective protein cargo demonstrated higher levels of key regulatory molecules in MSC-NTF exosomes compared to MSC exosomes that may attenuate lung inflammation and promote lung repair, including leukemia inhibitory factor (LIF); amphiregulin (AREG); hepatocyte growth factor (HGF); and tumor necrosis factor stimulated gene-6 (TSG-6).
- These positive preclinical results suggest that intratracheal-delivered may be suitable as a therapy for COVID-19 induced ARDS. The higher effectiveness of MSC-NTF exosomes on ARDS physiological, pathological, and biochemical parameters, compared to exosomes isolated from non-induced MSCs, may be related to their enhanced protein cargo.

"Our strategy at Brainstorm is to explore the full potential of our proprietary platform cell technology and we have identifying ARDS as a serious unmet medical need where our exosome technology can potentially benefit patients," said Chaim Lebovits, CEO of Brainstorm. "At the same time we remain fully committed to advancing our cellular therapeutic pipeline in ALS and progressive MS."

Revital Aricha, Ph.D., VP, Research & Development of BrainStorm added, "The International Society for Cell and Gene Therapy (ISCT) is a globally recognized organization focused on translational aspects of developing cell-based therapeutics. We are pleased to present our exciting preclinical data at this conference."

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 are designed to 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 designation status 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 completed under an investigational new drug application a Phase 2 open-label multicenter trial (NCT03799718) of autologous MSC-NTF cells in progressive multiple sclerosis (MS).

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 NurOwn® manufacturing and clinical development plans, 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, the prospects for regulatory approval of BrainStorm's NurOwn® treatment candidate, the initiation, completion, and 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, or to use third parties 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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