

BrainStorm Announces Scientific Presentation of NurOwn® Exosome Preclinical ARDS Data at NYSCF 2021 VIRTUAL Meeting

Superior clinical and biomarker outcomes demonstrated with NurOwn exosomes compared to MSC exosomes in preclinical ARDS models

NEW YORK, Oct. 18, 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, "Therapeutic Benefits of MSC-NTF (NurOwn®) Exosomes in Acute Lung Injury Models" at the [NYSCF 2021 VIRTUAL Meeting](#), being held on October 19-20, 2021. The poster will be presented tomorrow, October 19, at 3:45 – 5:00pm Eastern Time.

POSTER HIGHLIGHTS:

- Lung diseases are one of the leading global causes of acute and chronic morbidity and mortality across all ages and are in need of innovative therapeutic solutions.
- Using two different acute lung injury models, lipopolysaccharide (LPS) and Bleomycin, we compared the effect of two types of small extracellular vesicles (sEVs): sEVs isolated from naïve MSC (Exo MSC) or sEVs isolated from MSCs which were induced to secrete increased levels of regenerative and immunoregulatory factors (Exo MSC-NTF), based on the NurOwn technology platform.
- Results in both models showed that the beneficial effects of intratracheal administration of Exo MSC-NTF were superior to Exo MSC in multiple parameters, including increase in blood oxygen saturation and reduction in lung pathology, inflammatory infiltration and levels of proinflammatory cytokines in bronchoalveolar lavage fluid (BALF), in addition to reduction of lung fibrosis in Bleomycin model.
- 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).

The observed positive preclinical results suggest that intratracheal administration of Exo MSC-NTF may have clinical potential as a therapy for acute lung related pathologies and may be more effective at modifying physiological, pathological, and biochemical outcomes than sEVs isolated from naïve MSCs.

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) and was supported by a grant from the National MS Society (NMSS).

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, health 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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