BrainStorm Announces Presentations at June 2022 Scientific Conferences

Analyses accounting for ALSFRS-R floor effect in ALS yields new results to be presented at the ENCALS meeting in Edinburgh, Scotland

Clinical, biomarker and preclinical data from NurOwn® Phase 2 clinical trial in MS to be presented at CMSC meeting in National Harbor, MD, USA

NEW YORK, May 31, 2022 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of cellular therapies for neurodegenerative diseases, today announces presentations at forthcoming ALS and MS scientific conferences in June 2022. Insights into the ALS Phase 3 primary endpoint leveraging ENCALS model patient prognosis trajectories will be presented as a scientific poster at the European Network to Cure ALS (ENCALS) meeting in Edinburgh, Scotland June 1-3, 2022. At the Consortium of Multiple Sclerosis Centers (CMSC) meeting in National Harbor, Maryland, June 1-4, 2022, Brainstorm will present three scientific posters describing NurOwn's effect on visual outcomes, and inflammatory CSF biomarkers from a Phase 2 trial, as well as data from an in vitro preclinical study evaluating the impact of concomitant use of Siponimod, an approved treatment for secondary progressive multiple sclerosis, on NurOwn neuroprotection.

ENCALS Meeting, Edinburgh Scotland:

Presentation Details: **ALS Phase 3 NurOwn Trial: Insight into the primary outcome through ENCALS modeled trajectories**
Presenter: Jonathan Katz MD, California Pacific Medical Center, San Francisco, CA USA
Date/Time: Thurs June 2, 17.00-18.30 BST
Conference Link: ENCALS

NurOwn's Phase 3 trial (BCT-002-US) included participants with advanced and rapidly declining ALS, making this trial subject to floor effects and reduced sensitivity of the clinical endpoint, the Revised ALS Functional Rating scale (ALSFRS-R). This presentation will summarize the clinical response on the primary endpoint this trial after applying two methods, ENCALS model and ALSFRS-R baseline value, to identify and minimize the impact of participant data most impacted by floor effects of the ALSFRS-R scale . Key findings:

- In participants predicted by the ENCALS model to have intermediate to very long survival, a treatment effect was observed.
- ENCALS model categories intermediate, long and very long, were less likely to be influenced by ALSFRS-R scale floor effect challenges.
- Clinical response on the primary endpoint in participants with either a high rate of decline (ALSFRS-R slope) and low baseline ALSFRS-R values, and with ENCALS model categories very short and short survival, may have been a misclassification due to the ALSFRS-R scale floor effect, which favored the placebo group in BCT-002.

In summary, the results confirm the importance of accounting for the floor effect in more advanced and rapidly declining ALS participants to potentially avoid misclassifying treatment responses.

CMSC 2022 Meeting, National Harbor MD, USA:

Presentation Details: **NurOwn (MSC-NTF Cells) Phase 2 Clinical Trial in Progressive MS: Effects on Monocular and Binocular Low Contrast Letter Acuity (LCLA) Outcomes**
Presenter: Ralph Kern MD, MHSc, President and Chief Medical Officer, Brainstorm Cell Therapeutics.
Date/Time: Thursday June 2, 2022, 17:00- 19:00 ET
Conference Link: CMSC

This presentation evaluated the impact of NurOwn therapy on visual outcomes (monocular and binocular LCLA) in progressive MS study participants in an open-label Phase 2 clinical trial in progressive MS (NCT 03799718). The key findings were:

- We observed improvements in monocular and binocular LCLA (1.25% and 2.5% thresholds) at week 28 that were consistent with corresponding pre-specified responder outcomes (≥8 letter improvement)
- Matched patients from the long term CLIMB study and participants from the placebo arm of the SPRINT

study showed worsening in LCLA over a similar time period
- Numerically larger LCLA improvements were seen at 1.25% threshold vs. 2.5% threshold and in monocular LCLA compared to binocular LCLA

In summary, this Phase 2 study of NurOwn therapy in progressive MS demonstrated encouraging results in monocular and binocular LCLA that should be further evaluated in a placebo-controlled clinical trial. This poster was nominated for an award at the CMSC meeting.

Presentation Details: **NurOwn (MSC-NTF) Phase 2 Clinical Trial in Progressive MS: Effects on CSF Inflammatory Biomarkers**
Presenter: Christopher Lock, MD PhD, Stanford School of Medicine.
Date/Time: Thursday June 2, 2022, 17:00- 19:00 ET
Conference Link: CMSC

In this scientific presentation, the effect of NurOwn treatment on CSF biomarkers in the Phase 2 clinical trial in progressive MS (NCT 03799718) is described. The key findings were:

- NurOwn treatment resulted in consistent reductions in CSF inflammatory biomarkers (OPN, sCD27, MCP-1and SDF-1a) that may be relevant to disease progression and treatment response in progressive MS.
- Associated with these positive inflammatory biomarker effects of NurOwn were improvements in a variety of functional outcomes.

In summary, these observations may guide future efforts to optimize this innovative autologous mesenchymal cellular therapy in progressive MS. This poster was nominated for an award at the CMSC meeting.

Presentation Details: **NurOwn (MSC-NTF) Cells Maintain Neurotrophic and Immunomodulatory Effects with S1P Modulator Siponimod**
Presenter: Sidney Spector MD PhD, Senior Vice President, Medical Affairs and Global Strategy, Brainstorm cell Therapeutics
Date/Time: Thursday June 2, 2022, 17:00- 19:00 ET
Conference Link: CMSC

This presentation describes the results of an invitro preclinical experiment evaluating the interaction of the S1P modulator Siponimod with MSC-NTF cell-induced neurite outgrowth in a human neuroblastoma cell line, and on the immunomodulatory effect on human activated peripheral blood mononuclear cells (PBMC).

MSC-NTF cells were able to induce neurite extension and inhibit inflammatory cytokine secretion, a finding that was not modified by co-culture with Siponimod, an S1P modulator recently approved for the treatment of secondary progressive MS (SPMS).

In summary, this suggests that co-administration of Siponimod does not interfere with known measures of MSC-NTF cell neuroprotection and immunomodulation and may guide future efforts to optimize this innovative autologous mesenchymal cellular therapy in progressive MS.

CMSC abstracts are available on-line: abstracts

"We are very privileged to share scientific insights at these meetings with world experts in ALS and MS," said Ralph Kern MD MHSc, President and Chief Medical Officer at Brainstorm. "Importantly, these very insightful analyses help us identify where NurOwn may provide better benefits for ALS and MS patients. This work underscores our commitment to advancing our cellular therapy technology to address the unmet medical need in these two patient populations, while continuing to contribute to the scientific community."

Chaim Lebovits, CEO Brainstorm Cell Therapeutics commented, "Brainstorm is very proud of the continued efforts of our dedicated teams in advancing scientific understanding in ALS and progressive MS. We remain committed to addressing patient unmet needs and at the same time creating shareholder value".

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).

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, prospects for future 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 products and 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; the impacts of the COVID-19 pandemic on our clinical trials, supply chain, and operations; 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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