BrainStorm Cell Therapeutics Submits Type A Meeting Request to U.S. Food and Drug Administration

Meeting expected to occur within 30 days of the FDA's receipt of the meeting request

NEW YORK, Dec. 12, 2022 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today announced that the company has submitted a Type A Meeting Request to the U.S. Food and Drug Administration (FDA) to discuss the contents of a refusal to file letter previously issued by the FDA regarding the company's New Biologics License Application (BLA) for NurOwn® for the treatment of ALS. The Type A Meeting is expected to occur within 30 days of the FDA's receipt of the meeting request.

As previously reported, the contents of the refusal to file letter focus on topics related to chemistry, manufacturing, and controls (CMC), as well as clinical data and statistics. As part of the Type A Meeting, BrainStorm intends to discuss a path to an FDA Advisory Committee Meeting.

"Participating in a Type A meeting will be an important next step towards enabling NurOwn's advancement through the regulatory process," said Chaim Lebovits, Chief Executive Officer of BrainStorm. "The extensive briefing package submitted with our request contains a comprehensive strategy to fully address the CMC matters raised in the refusal to file letter. We anticipate achieving quick alignment with the FDA on the CMC strategy and expect that its execution will be straightforward. We therefore anticipate a Type A meeting focused primarily on discussing how we can secure an Advisory Committee Meeting, which we believe will be a critical step on NurOwn's path towards approval as an ALS therapy."

About the Phase 3 Trial of NurOwn in ALS

BrainStorm previously completed a Phase 3 trial in approximately 200 participants with ALS (Cudkowicz et al., 2022 Muscle and Nerve). In an attempt to examine a real-world population, the study enrolled people with more advanced disease than other late-stage ALS trials. In fact, more than a third of these participants with advanced disease entered the trial with one or more dimensions of physical function (e.g., dressing/hygiene, cutting food, walking) starting at the lowest possible score of 0 on the ALSFRS-R; thereby preventing the measurement of further deterioration. A pre-specified subgroup of participants, with baseline ALSFRS-R ≥35, which controls for this "scale effect" showed a trend to a meaningful increase in the clinical response with NurOwn compared to placebo. The secondary endpoint, average ALSFRS-R change from baseline to 28 weeks in this subgroup, was statistically significant (p=0.050, Muscle and Nerve Supplemental File and Muscle and Nerve Erratum). In addition, post-hoc sensitivity analyses were presented in November 2022 (21st Annual NEALS Meeting 2022) which also showed a statistical trend towards a clinically meaningful treatment effect with NurOwn across subgroups, and one that is consistent with the pre-specified subgroup of participants with less advanced ALS at baseline. Finally, biomarker data in all trial participants also showed consistent patterns of NurOwn reducing markers of inflammation and neurodegeneration, and increasing neuroprotective and anti-inflammatory markers relative to placebo, further supporting the notion that trial participants taking NurOwn are indeed experiencing a positive biological effect (ALS ONE Research Symposia 2022).

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 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 BrainStorm's request for a Type A meeting with the FDA and the clinical development of NurOwn® as a therapy for the treatment of ALS, 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 "intend," "should," "could," "will," "believe," "potential," and similar terms and phrases are intended to identify these forward-looking statements. The potential risks and uncertainties include, without limitation, management's ability to successfully achieve its goals, BrainStorm's ability to raise additional capital, BrainStorm's ability to continue as a going concern, prospects for future regulatory approval of NurOwn®, whether the FDA will grant BrainStorm's request for a Type A meeting and whether BrainStorm's future interactions with the FDA will have productive outcomes, 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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