BrainStorm Announces Feedback from FDA Type-C Meeting on Future NurOwn® Manufacturing Plan

FDA provided guidance on introducing semi-automated manufacturing in the future for commercialization

NEW YORK, Feb. 9, 2021 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapies for neurodegenerative diseases, announced today that it recently concluded a Type C meeting with the U.S. Food and Drug Administration (FDA) to review specific aspects of the company's planned manufacturing modifications to support the development of a semi-automated commercial manufacturing process for NurOwn® (MSC-NTF cell). The meeting included a detailed review of the requirements for comparability testing to support future modifications along with geographic considerations in the sourcing of starter materials and future manufacturing production.

"We are pleased with the outcome of the type C meeting and the actionable guidance on FDA's expected requirements for a future semi-automated process," said Chaim Lebovits. "As we consider potential paths toward a regulatory submission for NurOwn, we believe it is prudent to validate and seek guidance from the FDA on our manufacturing plan. The transition from a manual manufacturing process to semi-automated manufacturing is a very important opportunity to increase capacity. It also incorporates measures that are designed to mitigate risk in the manufacturing process. This meeting was a positive milestone toward implementing a new process."

Brainstorm has generated extensive feasibility data on the semi-automated process, the design of which is now at an advanced stage. The company will incorporate feedback from the FDA meeting and its experience from Phase 3 manufacturing to finalize a robust comparability plan that enables semiautomatic manufacturing to be introduced at the appropriate time in the future. It will also finalize the remaining steps necessary to proceed with running NurOwn® conformance batches.

The FDA also provided comments on several key aspects of the current manufacturing process, which BrainStorm will use as the company continues its work to enable operations at its commercial manufacturing partner, Catalent.

"As we review our clinical data with the FDA, we will also continue communications on manufacturing to ensure our plans remain aligned with the Agency's expectations as we advance the development of NurOwn," Lebovits concluded.

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 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 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 atwww.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.

Logo - https://mma.prnewswire.com/media/1166536/BrainStorm_Logo.jpg

CONTACTS

Investor Relations:
Corey Davis, Ph.D.
LifeSci Advisors, LLC
Phone: +1-646-465-1138
cdavis@lifesciadvisors.com

Media:
Paul Tyahla
SmithSolve
Phone: +1-973-713-3768
paul.tyahla@smithsolve.com

SOURCE BrainStorm Cell Therapeutics Inc.
