BrainStorm Cell Therapeutics Announces FDA Advisory Committee Meeting to Review Biologics License Application for NurOwn® for the Treatment of ALS

Conference call and webcast at 8:00 a.m. ET

NEW YORK, March 27, 2023 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today announced that the U.S. Food and Drug Administration (FDA) will hold an Advisory Committee Meeting ('ADCOM') to discuss the company's Biologics License Application (BLA) for NurOwn® for the treatment of amyotrophic lateral sclerosis (ALS). Given the goal to proceed to an ADCOM as expeditiously as possible, BrainStorm requested that the Center for Biologics Evaluation and Research (CBER) utilize the FDA's File Over Protest procedure and has filed an amendment to the BLA which responds to most of the outstanding questions the FDA has posed.

"The FDA provided us with more than one path to an ADCOM for NurOwn. Our goal has always been to make NurOwn available to people living with ALS as quickly as possible, therefore we chose the File Over Protest pathway since this offered the fastest path to an ADCOM and regulatory decision relative to other pathways provided by the FDA," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. "The ALS community needs additional treatment options now, and we firmly believe our data support regulatory approval of NurOwn. We are grateful to the FDA for the opportunity to have the clinical evidence supporting NurOwn reviewed."

Stacy Lindborg, Ph.D., BrainStorm's Co-Chief Executive Officer commented, "ALS is a horrific, neurodegenerative disease that moves at a terrifying speed, robbing people of their ability to move, speak, eat, and breathe. Securing an ADCOM represents an important step towards our goal of making NurOwn broadly available to individuals living with ALS who are in urgent need of new, effective therapies. The meeting will provide an open forum for BrainStorm and the FDA, together with medical experts, statisticians, and the ALS community, to thoughtfully review all available evidence supporting NurOwn. We remain confident in NurOwn and we are committed to doing everything in our power to make the product available quickly to people living with ALS. We look forward to a robust scientific discussion."

Brian Wallach, patient advocate and founder of the non-profit organization I AM ALS, added, "I want to thank the FDA and BrainStorm for having this important ADCOM. As was said in the petition submitted to the FDA and signed by over 30,000 people living with ALS, caregivers, and advocates, 'an Advisory Committee Meeting will allow for an independent review of NurOwn as well as the data on efficacy and safety. It is critical for all ALS treatments that they be given the chance to proceed to an ADCOM.' The ALS community has waited years for this ADCOM. It is time to let the science have a full, fair, and transparent hearing so that we can get this treatment to people who are living with and dying from ALS as soon as possible."

Conference Call and webcast:

Brainstorm management will host a conference call and webcast, including a Q&A session, today, March 27, 2023, at 8:00 a.m. ET. The investment community may participate in the conference call by dialing the following numbers:

Toll Free: 888-506-0062
International: 973-528-0011
Entry Code: 102674

Webcast URL: https://bit.ly/3lAfCOv

Those interested in listening to the conference call live via the internet may do so by using the webcast link above or by visiting the 'Investors & Media' page of BrainStorm's website at

https://ir.brainstorm-cell.com/events-and-presentations and clicking on the conference call link.

Those that wish to listen to the replay of the conference call can do so by dialing the numbers below. The replay will be available for 14 days.

Replay Numbers:
Toll Free: 877-481-4010

International: 919-882-2331
Replay Passcode: 47939

Teleconference Replay Expiration: Monday, April 10, 2023.

Webcast link: https://bit.ly/3lAfCOv (Webcast Replay Expiration: Wednesday, March 27, 2024)

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.

BrainStorm filed the BLA for ALS on September 9, 2022. BrainStorm received a Refusal to File letter from FDA on November 8, 2022, and requested a Type A meeting on December 9, 2022, which was held on January 11, 2023. On January 25, 2023, Brainstorm held a meeting with the Center for Biologics Evaluation and Research (CBER) as part of dispute resolution, during which FDA provided multiple options to return the BLA to active review and an FDA Advisory Committee Meeting.

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 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 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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