BrainStorm Cell Therapeutics Announces Management Changes as Company Plans Registrational Phase 3b Trial of NurOwn

Bob Dagher, MD, Promoted to Chief Medical Officer

Dr. Stacy Lindborg Stepping Down as Co-CEO and Transitioning to Board of Directors

NEW YORK, April 16, 2024 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today announced the promotion of Dr. Bob Dagher to Executive Vice President and Chief Medical Officer. In addition, after four years of maintaining top executive roles, Dr. Stacy Lindborg stepping down from the role of Co-CEO and will remain with BrainStorm as a member of its Board of Directors. These strategic management changes are being made as the Company prepares to embark on a registrational Phase 3b trial for NurOwn®, its investigational cell therapy treatment for amyotrophic lateral sclerosis (ALS).

Dr. Dagher has served as our Chief Development Officer since July 2023. In his new role as Executive Vice President and Chief Medical Officer, Dr. Dagher's responsibilities will include overseeing the planned Phase 3b registration trial of NurOwn. The Company recently announced that it has reached agreement with the U.S. Food & Drug Administration (FDA) for a Special Protocol Assessment (SPA) for this trial.

"With Bob's promotion as CMO and Stacy's addition to our Board, BrainStorm is well positioned for a smooth transition into a pivotal phase for the company and continued commitment to ALS," said Chaim Lebovits, President and CEO of Brainstorm. "Bob's capabilities, which include expertise in neurology, psychiatry, and rare diseases, make him exceptionally qualified as we launch the Phase 3b trial of NurOwn and prepare for success. We are fortunate to have someone of his caliber at the helm of our clinical efforts."

Dr. Dagher commented, "I am honored to step into the role of Chief Medical Officer at such an important moment for BrainStorm. The opportunity to lead our talented clinical team through the upcoming Phase 3b trial is incredibly exciting. I am deeply committed to our mission and look forward to contributing to our success in bringing new treatments to patients and families affected by ALS."

Dr. Dagher has over 20 years' of experience in clinical research and development, with a proven track record of leading successful clinical trials and fostering innovation in drug development. Prior to joining Brainstorm he was Chief Medical Officer at Enveric Biosciences where he was responsible for defining the portfolio strategy and advancement of development plans toward regulatory approvals. He began his career in biopharmaceuticals as a medical scientist at GSK, and has served in leadership positions of science and medicine at companies such as Sanofi/Genzyme, and LabCorp/Covance. Dr. Dagher earned his medical degree at Bordeaux University and St. Joseph University School of Medicine, serving residencies in psychiatry and internal medicine at Boston University Medical Center. A past Diplomat of the American Board of Neurology and Psychiatry, he is licensed to practice medicine in Massachusetts.

"I strongly believe in the company's mission and commitment to ALS and I have great faith in the potential of debamestrocel to make life better for those living with ALS and their families," said Stacy Lindborg, co-Chief Executive Officer. "I have great confidence in Bob as the leader of the Phase 3b program, and in the entire leadership teams' dedication to move this product forward. I'm pleased to continue working with all my Brainstorm colleagues in my new capacity on Brainstorm's Board of Directors."

Mr. Lebovits concluded, "I would like to thank Stacy for her outstanding commitment and achievements at BrainStorm She excelled as a leader and talented scientist dedicated to patients. We are very pleased that she will continue to be involved in Brainstorm as a member of our Board of Directors and look forward to her contributions and strategic insights in this new role."

About BrainStorm Cell Therapeutics Inc.
BrainStorm Cell Therapeutics Inc. is a leading developer of innovative autologous adult stem cell therapeutics for debilitating neurodegenerative diseases. BrainStorm 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 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), and another grant from the ALS Association and I AM ALS. 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).

Notice Regarding Forward-Looking Statements
This press release contains "forward-looking statements" that are subject to substantial risks and uncertainties, including statements regarding meetings with the U.S. Food and Drug Administration (FDA), Special Protocol Assessment (SPA), ADCOM meeting related to NurOwn, the timing of a PDUFA action date for the BLA for NurOwn, the clinical development of NurOwn as a therapy for the treatment of ALS, the future availability of NurOwn to patients, and the future success of BrainStorm. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will" "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on BrainStorm's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. These 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, 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.

CONTACTS

Media:
Lisa Guiterman
Phone: +1 202-330-3431
lisa.guiterman@gmail.com

IR:
Michael Wood
Phone: +1 646-597-6983
mwood@lifesciadvisors.com

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

SOURCE BrainStorm Cell Therapeutics Inc.

Additional assets available online: Photos (1)

https://ir.brainstorm-cell.com/2024-04-16-BrainStorm-Cell-Therapeutics-Announces-Management-Changes-as-Company-Plans-Registrational-Phase-3b-Trial-of-NurOwn