

BrainStorm Appoints Pharmaceutical Veteran Anthony Waclawski as Executive Vice President, Global Head of Regulatory Affairs

Company plans to further strengthen its regulatory expertise and capabilities as ALS phase 3 clinical trial nears completion in Q4

NEW YORK, September 2, 2020 – BrainStorm Cell Therapeutics Inc. ([NASDAQ: BCLI](#)), a leading developer of adult stem cell therapies for neurodegenerative diseases, announced today the appointment of Anthony P. Waclawski, Ph.D. as Executive Vice President, Global Head of Regulatory Affairs. Dr. Waclawski is an industry veteran and a recognized leader in regulatory affairs with over 35 years of multinational experience in the FDA regulatory approval process, including Biologics License Applications (BLAs), New Drug Applications (NDAs), and FDA Advisory Committees.

"Tony's unique regulatory experience within one of the largest global pharmaceuticals, makes him exceptionally well qualified to join the BrainStorm leadership team," commented Chaim Lebovits, BrainStorm's Chief Executive Officer. "He has held leadership roles in many of the key functions of regulatory, including regulatory strategy and operations, establishing a track record of success for many development stage and marketed products. Dr. Waclawski will enhance our global regulatory strategy, as we work to bring better treatment options to patients afflicted with ALS and other neurodegenerative diseases. We look forward to the strategic contributions and key insights he will bring to BrainStorm."

Anthony Waclawski commented, "I'm very excited to join the team at Brainstorm and do all I can to help bring new therapies to patients with ALS and other neurodegenerative diseases. This is a challenging area for drug development and there is a critical need for effective and safe therapies".

Prior to his appointment at BrainStorm, Dr. Waclawski spent 35 years of increasing responsibility at Bristol-Myers Squibb, most recently as Vice President and Head, Regulatory and Pharmaceutical Sciences, Cardiovascular, Immunosciences, Fibrosis, and Genetically-defined diseases. In this role, he was responsible for the strategic and operational deliverables of regulatory, biostatistics, clinical pharmacology, and pharmacometrics for the development assets in these areas. Dr. Waclawski's experience spans a broad range of regulatory capabilities across multiple therapeutic areas and geographies, guiding successful FDA interactions and establishing and executing successful global regulatory strategies.

Dr. Waclawski holds a Ph.D. in Pharmaceutical Sciences, a Master of Pharmaceutical Science, and a Bachelor of Science in Pharmacy from Rutgers University.

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 status designation 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 fully enrolled a phase 3 pivotal trial in ALS (NCT03280056); this trial is investigating repeat-administration of autologous MSC-NTF cells at six U.S. sites supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989). The pivotal study is intended to support a filing for FDA approval of autologous MSC-NTF cells 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) started enrollment in March 2019.

For more information, visit the company's website at www.brainstorm-cell.com.

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, 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 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, health 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.

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