

David Setboun Joins BrainStorm as Executive Vice President and Chief Operating Officer

International Pharmaceutical Veteran to Lead Global Business and Commercial Development Ralph Kern, MD, MHSc, Promoted to President

NEW YORK, April 01, 2020 (GLOBE NEWSWIRE) -- [BrainStorm Cell Therapeutics, Inc. \(NASDAQ: BCLI\)](#), a leading developer of cellular therapies for neurodegenerative diseases, today announced that David Setboun, Pharm.D., MBA, has been appointed Executive Vice President and Chief Operating Officer.

International pharmaceutical executive Dr. Setboun, has directed commercial development, business strategy, and product launches for 2 decades at 3 major biopharmaceutical companies. Most recently, Dr. Setboun served as VP Corporate Development, Strategy & Business at Life Biosciences. In this role, David was instrumental in the development of various critical commercial, operating and funding milestones. From June 2015 to June 2018, he served as President, Biogen, France where he launched Biogen's rare disease franchise. In addition, he supervised the launch of key neurology products and oversaw the Biosimilar business unit. Prior to his tenure at Biogen, Dr. Setboun, served as President, AstraZeneca, Portugal from 2012 to 2015, where he managed a product portfolio that grossed over \$200 million annually. Prior to this role, David led the European Sales & Marketing function as AstraZeneca's VP Europe where he directed a team of executives in marketing, commercial excellence, pricing and market access. During his tenure, he expanded AstraZeneca's Oncology, Diabetes and Cardiovascular franchises. From 2002 to 2009, Dr. Setboun directed national and international teams and projects for Eli Lilly and Company in France and the USA. Fluent in French, English, Spanish and Portuguese, Dr. Setboun received his Pharmaceutical Doctorate (Pharm.D.) from University Paris XI in 1997 and his MBA from H.E.C Paris in 2001. More recently, David graduated from Harvard Business School (AMP 194).

"BrainStorm's investigational therapy, NurOwn® is an amazing technology platform that has the potential to bring treatment to those with ALS and progressive MS and other neurodegenerative indications. With a fully enrolled Phase 3 Pivotal Trial for ALS in place, a Phase 2 Trial for progressive MS, an investigational platform in exosomes and the most ambitious biomarker program in ALS, I know I am joining a company with outstanding potential," said Dr. Setboun.

"David's experience launching products for international biopharmaceutical companies and his expertise in commercial, business development and investments, make him an outstanding new member of the BrainStorm leadership team. His extensive experience at all levels of sales and marketing, coupled with his business strategy experience comes to us at a critical time in the evolution of NurOwn® and helps us achieve our goal of bringing new treatment options to patients afflicted with neurodegenerative diseases, including ALS and progressive MS," said Chaim Lebovits, Chief Executive Officer of BrainStorm.

"Additionally, I am very pleased to announce Ralph Kern MD, MHSc, has been promoted to President of BrainStorm. Ralph joined BrainStorm in March 2017 as Chief Operating Officer and Chief Medical Officer. Directing our clinical development, Ralph has helped the Company rapidly achieve clinical milestone, after clinical milestone, while guiding the Company to expand its product pipeline to investigate additional applications and disease indications. In recognition of his ongoing, outstanding service, Ralph has been elevated to the position of President and Chief Medical Officer of BrainStorm."

[About NurOwn®](#)

NurOwn® (autologous MSC-NTF cells) represent a promising investigational 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. 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. NurOwn® is currently being evaluated in a Phase 3 ALS randomized placebo-controlled trial and in a Phase 2 open-label multicenter trial in Progressive MS.

[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® Cellular Therapeutic Technology Platform used to produce autologous MSC-NTF cells through an exclusive, worldwide licensing agreement as well as through its own patents, patent applications and proprietary know-how. Autologous MSC-NTF cells have received Orphan Drug status designation from the U.S. Food and Drug Administration (U.S. FDA) and the European Medicines Agency (EMA) in ALS. BrainStorm has fully enrolled the Phase 3 pivotal trial in ALS (NCT03280056), investigating repeat-administration of autologous MSC-NTF cells at six sites in the U.S., supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989). The pivotal study is intended to support a BLA filing for U.S. FDA approval of autologous MSC-NTF cells in ALS. BrainStorm received U.S. FDA clearance to initiate a Phase 2 open-label multi-center trial of repeat intrathecal dosing of MSC-NTF cells in Progressive Multiple Sclerosis (NCT03799718)

in December 2018 and has been enrolling clinical trial participants since March 2019. For more information, visit the company's [website](#).

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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Source: BrainStorm Cell Therapeutics Inc.

Additional assets available online: [Photos \(1\)](#)

<https://ir.brainstorm-cell.com/2020-04-01-David-Setboun-Joins-BrainStorm-as-Executive-Vice-President-and-Chief-Operating-Officer>