BrainStorm Cell Therapeutics Announces Support for FDA Guidelines on ALS Drug Development

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BrainStorm Holds a Roundtable Discussion with ALS Advocacy Group Leaders

NEW YORK, Sept. 27, 2019 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leader in the development of innovative autologous cellular therapies for highly debilitating neurodegenerative diseases supports the US FDA's publication on September 24, 2019 of "Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment Guidance for Industry." This document outlines ALS drug development guidelines and potential opportunities to advance novel ALS therapies through innovative clinical trial design and validated clinical outcome measures.

In addition, Brainstorm's President & CEO Chaim Lebovits, COO & CMO Ralph Kern MD MHSc, and Mary Kay Turner, VP Government Affairs and Patient Advocacy, convened a roundtable discussion with ALS advocacy group leaders in Washington, DC, on September 25, 2019. Members of The US Congress and their Staff, including the Staff of the Co-Chairs of the ALS Caucus, attended to listen to the voice of the ALS Community. Members of the ALS Community included: ALS Association, ALS One, Compassionate Care ALS, NoMoreExcuses, ALS Therapy Development Institute, Paralyzed Veterans of America, IamALS, and Project ALS. The Roundtable was convened for the ALS Community to learn more about Brainstorm's NurOwn® phase 3 clinical development program in ALS and to ensure the patient voice was an ongoing, integral part of the discussion.

Chaim Lebovits, President and CEO of BrainStorm stated, "The updated guidelines recognize the serious and life-threatening nature of ALS and enormous unmet need. We are encouraged that the FDA has updated the ALS guidance document and we commend the advocacy community for keeping the patient voice at the center of this dialogue." Mr. Lebovits added, "The guidance document proposes regulatory flexibility, the importance of establishing clinical benefit based on functional endpoints, and practicable study size and duration. We believe that these new guidelines are essential in order to develop critically needed drugs for those suffering from ALS."

Mary Kay Turner, Vice President of Government Affairs and Patient Advocacy of BrainStorm stated, "Now is such a hopeful time for the ALS Community - the Community is active, informed and engaged in powerful ways. The roundtable discussion was organized as a forum where representatives of the ALS Advocacy Community, Members of the US Congress and their Staff, and the BrainStorm team exchanged many meaningful ideas. Over the course of several hours, challenges and hopes were expressed, and the incredible ALS community shared their visions for a future where ALS is no more. Having Members of Congress and their Staff join the meeting underscores the ALS patient voice is being heard in a powerful and very meaningful way."

About NurOwn®

NurOwn® (autologous MSC-NTF) cells represent 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. 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. BrainStorm is currently conducting a Phase 3 pivotal trial of autologous MSC-NTF cells for the treatment of amyotrophic lateral sclerosis (ALS). BrainStorm also recently received U.S. FDA acceptance to initiate a Phase 2 open-label multicenter trial in progressive MS and enrollment began in March 2019.

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 (U.S. FDA) and the European Medicines Agency (EMA) in ALS. BrainStorm is currently enrolling a 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 filing for U.S. FDA approval of autologous MSC-NTF cells in ALS. BrainStorm also recently received U.S. FDA clearance to initiate a Phase 2 open-label multicenter trial in progressive Multiple Sclerosis. 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 Statements

Statements in this announcement other than historical data and information 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, risks associated with BrainStorm's limited operating history, history of losses; minimal working capital, dependence on its license to Ramot's technology; ability to adequately protect the technology; dependence on key executives and on its scientific consultants; ability to obtain required regulatory approvals; 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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