

BrainStorm to Present at FDA and Scientific Workshops Highlighting Innovation in ALS Trial Designs and Continued Progress with NurOwn® Cellular Therapy Platform

September 12, 2018 8:50 AM ET

NEW YORK and PETACH TIKVAH, Israel, Sept. 12, 2018 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for debilitating neurodegenerative diseases, announced today that members of BrainStorm's executive team will present and participate on expert panel discussions with industry leaders in Cell & Gene therapy at upcoming FDA and scientific conference workshops.

Chaim Lebovits, President and Chief Executive Officer, and Joe Petroziello, BSc, MSc, Vice President of Scientific and Corporate Communications, will be attending the Morgan Stanley 16th Annual Global Healthcare Conference on September 12-13 in New York City, and will be available for one-on-one meetings.

FDA Rare Diseases Scientific Workshop

Special FDA Rare Disease Scientific Workshop entitled, "Continued Challenges at the FDA: Industry Examples."

Date: Thursday, September 13, 2018

Time: 1:00 pm to 2:30 pm Eastern Time (Washington, D.C.)

Location: Willard Intercontinental Hotel, Washington, D.C.

Presenter: Ralph Kern, MD, MHSc, Chief Operating Officer & Chief Medical Officer

Presentation Title: ALS Case Study: Clinical Trial Designs for Small Patient Populations

For more information: <https://goo.gl/BT7MfW>

About BrainStorm Cell Therapeutics Inc.

BrainStorm Cell Therapeutics Inc. is a leading cellular therapy biotechnology company engaged in the development of first-of-its-kind adult stem cell therapies derived from autologous bone marrow cells for the treatment of neurodegenerative diseases. The Company holds the rights to clinical development and commercialization of the NurOwn® technology platform through an exclusive, worldwide licensing agreement. NurOwn® has received Fast Track designation from the U.S. Food and Drug Administration (U.S. FDA) in ALS and has additionally been granted Orphan Status by the U.S. FDA and the European Medicines Agency (EMA). For more information, visit BrainStorm's website at www.brainstorm-cell.com.

About NurOwn® Lead Clinical Program in ALS

BrainStorm is currently enrolling a Phase 3 pivotal trial using repeat-administration of NurOwn® in ALS at leading clinical sites in the U.S., supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989). The study will enroll 200 ALS patients, randomized 1:1 to receive NurOwn® or placebo, and will evaluate the ALS functional rating scale (ALSFRS-R) responder analysis as a primary efficacy outcome measure (NCT03280056). On August 23, 2018, BrainStorm announced a successful pre-specified interim safety analyses by an independent Data Safety Monitoring Board (DSMB). The completion of Phase 3 enrollment is anticipated in 1H2019 and will enable a BLA filing in 2020 for FDA approval of NurOwn® in ALS.

About U.S. Sites for NurOwn® Phase 3 Trial in ALS

1. University of California Irvine; Principal Investigator: Namita Goyal, MD
2. Cedars-Sinai Medical Center; Principal Investigator: Robert Baloh, MD
3. California Pacific Medical Center; Principal Investigator: Robert Miller, MD
4. Massachusetts General Hospital; Principal Investigator: Merit Cudkowicz, MD; James Berry, MD
5. University of Massachusetts Medical School; Principal Investigator: Robert Brown, MD
6. Mayo Clinic; Principal Investigator: Anthony Windebank, MD

Safe-Harbor Statement

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.

CONTACTS

Corporate:

Uri Yablonka

Chief Business Officer

BrainStorm Cell Therapeutics Inc.

Phone: 646-666-3188

uri@brainstorm-cell.com

Investors:

Michael Rice

LifeSci Advisors LLC

Phone: 646-597-6979

mrice@lifesciadvisors.com

 [download.jpg](#)

BrainStorm Cell Therapeutics Inc.