BrainStorm Cell Therapeutics Announces Positive DSMB Review in Phase 2 Trial of NurOwn® in ALS

HACKENSACK, N.J. and PETACH TIKVAH, Israel, Nov. 9, 2015 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, announced today that the Data and Safety Monitoring Board (DSMB) conducted its second pre-planned safety review of the randomized, double-blind, placebo-controlled phase 2 clinical trial of NurOwn® in amyotrophic lateral sclerosis (ALS) that BrainStorm is conducting at three major academic medical centers in the U.S. The DSMB recommended that the study should continue as planned and identified no safety concerns. The DSMB reviewed safety data collected through a cutoff date in October 2015, which included 47 of the 48 patients enrolled in the study and, importantly, no treatment-related serious adverse events (SAEs) were reported. Beyond this, the DSMB did not identify any adverse events, lab abnormalities or significant protocol deviations that would be cause for concern.

Dr. Carlayne Jackson, Professor of Neurology at the University of Texas Health Science Center San Antonio and Chair of the DSMB, stated "based on the laboratory data and reported adverse events to date, we are recommending continuation of the existing protocol and have no concerns about the safety or tolerability of both the intrathecal and intramuscular injections."

BrainStorm's CEO, Chaim Lebovits, commented "We are pleased that the DSMB has again identified no concerns following their review of the safety data accumulated for the NurOwn® study, consistent with the initial review. We completed enrollment in this trial in August of this year, and currently expect top-line data to be available prior to the end of the second quarter of 2016."

"The successful completion of the DSMB's second review represents another important milestone in the clinical development of NurOwn," said Dr. Tony Fiorino, Chief Medical Advisor of BrainStorm. "The safety and tolerability of intrathecal and intramuscular injections appears to be excellent, and we hope to see a similar profile as we begin giving multiple doses of NurOwn in our next planned study."

The DSMB is an independent group of experts who review the accumulated safety data in ongoing clinical trials in order to safeguard the safety and interests of participating patients. This was the second of three planned DSMB reviews of this clinical trial. The third is expected to occur after all patients in the study have completed their scheduled follow-up visits.

About BrainStorm Cell Therapeutics Inc.

BrainStorm Cell Therapeutics Inc. is a 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 develop and commercialize its NurOwn® technology through an exclusive, worldwide licensing agreement with Ramot, the technology transfer company of Tel Aviv University. NurOwn® has been administered to over 60 patients with ALS in clinical trials conducted in Israel and the United States, and is currently being studied in a randomized, double-blind, placebo-controlled clinical trial at three major clinical centers in the United States. 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 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. These forward-looking statements 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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