BrainStorm Cell Therapeutics Announces Successful Interim Safety Analysis in Phase 3 Trial of NurOwn® Therapy for ALS

NEW YORK, and PETACH TIKVA, Israel, Aug. 23, 2018 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc., (NASDAQ: BCLI), a leading developer of adult stem cell therapies for neurodegenerative diseases, today announced that the independent Data Safety Monitoring Board (DSMB) has completed the pre-specified interim analysis of safety outcomes for the first 31 participants treated with NurOwn® in the Phase 3 trial in ALS (NCT03280056). The DSMB indicated there were no significant safety concerns and recommended that the trial continue, as planned.

“The DSMB appreciates the continued commitment of Brainstorm and the research teams to conducting this trial in such an exemplary manner”, said Carlayne Jackson MD, DSMB Chairperson, “We commend them on their outstanding enrollment and the quality of data collection.”

BrainStorm is conducting a repeat dose US Phase 3 trial of NurOwn® for ALS participants at 6 US sites, supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989). The study is expected to enroll 200 ALS participants, randomized 1:1 to NurOwn® or placebo, and is evaluating the ALS functional rating scale (ALSFRS-R) as the primary efficacy outcome measure, 28 weeks after the first of three NurOwn® intrathecal treatments.

To date, 82 participants have been enrolled in the trial, with 61 currently active. Many of the active participants have received two intrathecal treatments, with some completing all three. The Company anticipates that 110 participants in total will be enrolled in the trial by January 2019. Given the current pace of enrollment, we anticipate completing enrollment by mid 2019, which would then put us in a position to file a Biologics License Application for US FDA approval, once all clinical trial evaluations are completed.

“BrainStorm is focused on completing the NurOwn® ALS Phase 3 study and to bringing a much needed treatment option to ALS patients,” said Chaim Lebovits, president and CEO of BrainStorm, “We welcome the DSMB’s review which confirms the safety profile of NurOwn® following repeat dose intrathecal administration.”

Ralph Kern MD, MHSc, Chief Operating Officer and Chief Medical Officer of BrainStorm said, "We are very pleased the DSMB has found no safety concerns that would require modification to the NurOwn® ALS Phase 3 protocol. This represents an important clinical advancement for BrainStorm and for NurOwn® as a viable cellular therapy approach for ALS patients”.

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 approximately 100 patients with ALS in clinical trials conducted in the United States and Israel. In a randomized, double-blind, placebo-controlled clinical trial conducted in the US, a clinically meaningful benefit was demonstrated by higher response to NurOwn® compared with placebo. 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. 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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