BrainStorm Cell Therapeutics Announces Completion of Enrollment in Phase 2 Clinical Trial of NurOwn® in ALS

HACKENSACK, N.J. and PETACH TIKVAH, Israel, Aug. 11, 2015 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, announced today that it has completed enrollment in its ongoing randomized, double-blind placebo-controlled phase 2 clinical trial of NurOwn® in amyotrophic lateral sclerosis (ALS). The targeted enrollment of 48 subjects has been achieved.

"Completion of enrollment in this phase 2 trial is a major corporate milestone for BrainStorm," stated CEO Tony Fiorino, MD, PhD. "We continue to expect the last subject to be treated early in the fourth quarter of this year and top line results to be available shortly after the follow-up period is complete. This study has attracted much interest from both patients and physicians, and we anticipate it to give us valuable insights into the safety and efficacy of NurOwn® in ALS. Given the limited treatment options for patients with ALS, we are hopeful that this study will move NurOwn® another step closer to becoming a treatment for ALS."

Merit Cudkowicz, MD, Professor of Neurology at Harvard Medical School, Director of the ALS Clinical at Massachusetts General Hospital ALS Clinic, and a principal investigator for the trial, stated, "I want to thank the participants and their families for being part of this study and helping develop new therapies for ALS. Completion of enrollment is a very important milestone. We look forward to completing close follow-up and learning the results of this study."

This multi-center, randomized, double blind, placebo controlled study is evaluating the safety and efficacy of a single combined intramuscular and intrathecal administration of MSC-NTF cells (NurOwn®) in early-stage ALS patients. After enrolling in the study, subjects are followed for a three months run-in period, during which their bone-marrow is harvested and mesenchymal stromal cells are isolated and expanded. Subjects are then randomized to receive either NurOwn® or placebo, after which they are followed for six months. The primary endpoint of the study is safety, and secondary endpoints are efficacy measures including the ALS Functional Rating Scale (ALSFRS), slow vital capacity (SVC), and grip strength. More information can be found at https://clinicaltrials.gov/show/NCT02017912.

In February 2015, the Data Safety and Monitoring Board (DSMB) overseeing the trial completed its first safety review of the trial, and did not find any lab abnormalities, adverse events or significant protocol deviations that would be cause for concern. A second and final DSMB review is planned the fourth quarter of 2015.

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 50 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 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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