BrainStorm Reports Last Patient Visit in Phase 2a ALS Study

NEW YORK and PETACH TIKVAH, Israel, Oct. 6, 2014 /PRNewswire/ -- BrainStorm Cell Therapeutics (NASDAQ: BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, today announced that the last patient has completed the last visit in its phase 2a clinical trial of NurOwn™ in Amyotrophic Lateral Sclerosis (ALS), conducted at the Hadassah Medical Center in Jerusalem. The company expects to release final results of the study in the fourth quarter of 2014 upon completion of statistical analysis. Preliminary interim data from this study were presented In June 2014 at the Joint Congress of European Neurology by principal investigator Professor Dimitrios Karussis of Hadassah (see the company's June 2, 2014 press release).

"The completion of patients follow-up in this second clinical trial of NurOwn™ is an important milestone in its clinical development," stated Dr. Yael Gothelf, PhD, Vice President of Scientific and Regulatory Affairs for BrainStorm. "We are very pleased with the safety and efficacy profile observed to date in this study, and are looking forward to seeing the full set of results."

"I am pleased to bring this second study of NurOwn™ to a successful conclusion," added Professor Karussis. "I have now treated over 30 ALS patients with NurOwn™ in two clinical trials, as well as in several compassionate use treatments, and I am enthusiastic about its emerging safety and efficacy profile."

The primary endpoint of this single-arm, single-center dose-ranging study is the safety of a single administration of NurOwn[™] via intrathecal and intramuscular injection. Efficacy measures include the ALS Functional Rating Score-Revised (ALSFRS-R) and forced vital capacity (FVC). A total of 14 subjects were enrolled in this study into three dose cohorts. All subjects underwent a three month run-in period followed by NurOwn[™] administration, then six months of follow-up visits, with safety and efficacy assessments made at each visit.

NurOwn[™] is currently being studied in a randomized, double-blind, placebo-controlled phase 2 clinical trial conducted at three sites in the United States (see http://clinicaltrials.gov/show/NCT02017912 for further details). Enrollment in this study began in June 2014 and is expected to continue through mid-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 30 patients with ALS in clinical trials conducted in Israel, 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 forwardlooking 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

Media:

Tony Fiorino, MD, PhD Chief Executive Officer BrainStorm Cell Therapeutics Inc.

Phone: (646) 666-3188 info@brainstorm-cell.com

Investors:

Michael Rice LifeSci Advisors, LLC Phone: 646-597-6979 mrice@lifesciadvisors.com

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