FDA Grants Fast Track Designation to NurOwn™ for the Treatment of ALS

NEW YORK and PETACH TIKVAH, Israel, Oct. 7, 2014 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, announced today that the United States Food and Drug Administration (FDA) has designated NurOwn™ as a Fast Track product for the treatment of amyotrophic lateral sclerosis (ALS, or Lou Gehrig's Disease). NurOwn™ consists of autologous mesenchymal stem cells that have been induced to secrete neurotrophic factors, and is currently being studied in a randomized, double-blind, placebo-controlled phase 2 clinical trial in ALS patients.

"We are pleased that the FDA has granted Fast Track status for NurOwn™ as this will allow us greater and more frequent dialogue with the Agency as we continue the development of this ground-breaking cell therapy for the treatment of ALS," said Tony Fiorino, MD, PhD, Chief Executive Officer of BrainStorm. "We expect Fast Track designation, which recognizes the potential of NurOwn™ as to address an unmet medical need in ALS, to help speed and improve our development program."

The FDA's Fast Track program is designed to facilitate the development and expedite the review of drugs and biologics intended to treat serious conditions and demonstrate the potential to address unmet medical needs. Under the FDA Modernization Act of 1997, the Fast Track program provides for increased meetings with and written communications from the FDA, and allows for the submission of an NDA on a rolling basis. For more information, see http://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm.

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 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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