BrainStorm Cell Therapeutics Issues Statement on "Right to Try" Legislation

NEW YORK and PETACH TIKVAH, Israel, May 25, 2018 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today issues a statement following Congress passing the Federal "Right-to-Try" bill. The "Right-to-Try" bill will enable terminally ill patients who do not meet clinical trial criteria to seek out experimental therapies that do not yet have approval by the US Food and Drug Administration (FDA).

Chaim Lebovits, president and chief executive officer of BrainStorm Cell Therapeutics, stated, "BrainStorm understands the serious unmet medical need and urgency of people living with ALS. We have received countless inquiries after the passing of Federal 'Right-to-Try' legislation about patient access to NurOwn®. We have been, and will continue to, be engaged and collaborate with people with ALS, their families and caregivers, and legislators and government agencies to ensure that the voices of these groups are heard in this important discussion. Brainstorm is currently assessing the legislation and its potential implications, and when signed into law, will issue a formal policy on 'Right-to-Try' in early June."

"BrainStorm remains focused and fully committed to completing the Phase 3 clinical trial of NurOwn® as quickly as possible," added Lebovits. "While we continually evaluate ways to provide access to NurOwn® outside of the current Phase 3 trial to the many patients who can't wait, the most expedient way to make NurOwn® available to all is by completing the necessary clinical trial data collection and endpoint analyses, and submitting the required marketing applications without delay to regulatory agencies, including the FDA."

About NurOwn®

NurOwn utilizes a patient's own cells which have been engineered outside the body, to produce and secrete factors known to promote neuronal survival. NurOwn has the potential to be the first ALS treatment to improve patient functioning as a regenerative medicine. Regenerative medicine solutions are desperately needed in the field of neurodegenerative diseases as current therapies have limited efficacy, only slow progression and do not maintain or restore function. NurOwn is currently being tested in a multi-site Phase 3 clinical trial in the U.S. and, if successful, the results from this trial will submitted to the FDA and other regulatory authorities around the world with the goal of obtaining marketing approval. BrainStorm has completed two single arm clinical trials which established the safety profile of NurOwn and provided indications of a treatment benefit. Additionally, the company has completed a double-blind, placebo-controlled Phase 2 study at three prestigious academic medical centers in the US. In this study, clinically meaningful changes in functioning were observed in patients receiving NurOwn.

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 70 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 U. S., 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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