

# 21st Century Cures Act Passed by U.S. Congress Provides an Accelerated Approval Pathway for Regenerative Medicine Therapies

## Legislation Potentially Has Direct and Positive Implications for NurOwn®

HACKENSACK, N.J. and PETACH TIKVAH, Israel, Dec. 15, 2016 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, today announced its support for the 21st Century Cures Act. The Act, which has been passed by both houses of congress and is expected to be signed into law in the near future, has specific provisions for accelerated approval and priority review for regenerative medicine therapies.

This act allows the Food and Drug Administration (FDA) to grant accelerated approval for regenerative therapeutic products and directs the agency to consider the unique characteristics of such therapies and determine if they would address an unmet medical need. Expedited approval would require a rigorous collection of post-approval data to confirm the safety and efficacy of a drug candidate.

"We applaud the work of Congress for making sure that this important healthcare legislation remained a priority. We believe the passing of this act is timely, given the enormous advances that are currently being made in regenerative medicine," said Chaim Lebovits, BrainStorm's President and Chief Executive Officer. "Importantly, we believe this legislation may have direct and positive implications for Brainstorm's development programs, including NurOwn®, which is in late stage clinical trials for the treatment of ALS."

Earlier in 2016, Brainstorm announced positive results from its U.S. Phase 2 randomized, placebo controlled study of NurOwn in patients with ALS. The study achieved its primary objective, demonstrating that NurOwn was safe and well tolerated. NurOwn also achieved multiple secondary efficacy endpoints, showing clear evidence of a clinically meaningful benefit.

### **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 75 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](http://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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