

## BrainStorm Cell Therapeutics' Phase 3 Trial of NurOwn® in ALS Now Open to Canadian Patients

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### Canada-Based ALS Patients Can Be Enrolled at The University of Massachusetts

NEW YORK and PETACH TIKVAH, Israel, March 28, 2018 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today announces that it has amended the protocol of its Phase 3 clinical trial of NurOwn® for the treatment of amyotrophic lateral sclerosis (ALS). Per the protocol amendment, Canada-based ALS patients may now enroll in the ongoing Phase 3 NurOwn clinical trial.



"We are pleased to open enrollment to Canada-based ALS patients," said Chaim Lebovits, president and chief executive officer of BrainStorm Cell Therapeutics. "Although there are thousands of patients worldwide with ALS, we initially designed the Phase 3 trial to enroll U.S.-based patients only, primarily to make it easier for patient follow-up visits at the six U.S. clinical sites. However, due to an outpouring of inquiry and support from Canadian patients wanting to enroll in the trial, we filed an amendment with the FDA to allow Canada-based ALS patients to participate. The amendment was approved and we are pleased to announce today that Canada-based patients may now enroll in our study at the University of Massachusetts (UMass)."

The trial is designed to enroll 200 patients with ALS, and is being conducted at six leading ALS clinical sites in the U.S. The primary outcome measure is the ALSFR-S score responder analysis. The patient population is being optimized to include the pre-specified subgroups who demonstrated superior outcomes in the NurOwn Phase 2 ALS clinical trial. Top-line data are expected in 2019. For more information, refer to [www.clinicaltrials.gov](http://www.clinicaltrials.gov), using the NCT identifier [NCT03280056](https://www.clinicaltrials.gov/ct2/show/study/NCT03280056).

#### 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 be 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](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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