

# BrainStorm Enrolls First Patients in Phase 3 Trial of NurOwn® in ALS

**Trial supported by a \$16M non-dilutive grant from CIRM  
Top-line data are expected in 2019**

HACKENSACK, N.J. and PETACH TIKVA, Israel, Oct. 16, 2017 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI) today announced that the first patients have been enrolled in the Phase 3 clinical trial of NurOwn® for the treatment of amyotrophic lateral sclerosis (ALS) at the Massachusetts General Hospital and UC Irvine Medical Center in California.

The trial is expected to enroll approximately 200 patients and will be conducted at six leading ALS clinical sites in the U.S. The primary outcome measure will be the ALSFR-S score responder analysis. The patient population will be 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).

"NurOwn® is a highly innovative and advanced stem cell therapy now being studied in a phase 3 trial in ALS. The support of this trial by the California Institute of Regenerative Medicine (CIRM) highlights the importance of addressing ALS unmet need beyond currently available therapies, which slow disease progression but do not maintain or restore function," said Chaim Lebovits, president and CEO of Brainstorm. "BrainStorm plans to quickly advance the phase 3 trial to confirm promising phase 2 efficacy findings and bring much needed hope to ALS patients and their families."

Dr. Robert Miller, director of the Forbes Norris ALS Research Center at California Pacific Medical Center, added: "Stem cells are emerging as a potential viable candidate to treat ALS, and we are very excited to be participating in this important Phase 3 trial. The clinical data from NurOwn® have been encouraging, demonstrating clear evidence of clinical benefit and supported by analysis of inflammatory markers and neurotrophic factors in treated patients. NurOwn® cells have the important advantage of being autologous, so patients do not need to be immunosuppressed. In addition, the production process is relatively straightforward, and the harvesting and delivery of cells is much less invasive than other stem cell systems that have been tested in the clinic. We have been conducting ALS clinical trials for more than two decades at California Pacific Medical Center and this is, by far, the most exciting trial in which we have been involved to date."

Maria Millan, M.D., president and CEO of CIRM said: "CIRM's partnership with Brainstorm Therapeutics represents an international collaboration to find a treatment for ALS or 'Lou Gehrig's Disease,' a devastating neurologic and fatal condition for which there is currently no durable treatment or cure. CIRM is partnering with Brainstorm to follow up on the Company's promising phase 2 trial in patients with ALS."

Abla Creasey, Ph.D. senior director of strategic Infrastructure at CIRM added: "Brainstorm will conduct this trial at multiple sites in California, including our Alpha Clinics Network and will also manufacture its product in California using CIRM-funded infrastructure."

This trial is supported by a \$16 million non-dilutive grant from CIRM. A milestone payment of \$5.5 million, representing approximately 30% of the grant, has been received.

## 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 a higher response to NurOwn® compared with placebo. For more information, visit the company's website at [www.brainstormcell.com](http://www.brainstormcell.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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