

# BrainStorm Poster Receives Clinical Abstract Award at NEALS Conference

## Translational Insights Support NurOwn® as a Best-In-Class Strategy in ALS

NEW YORK and PETACH TIKVAH, Israel, Oct. 04, 2018 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of innovative autologous adult stem cell therapeutics for debilitating neurodegenerative diseases, announced today that their scientific abstract presented by Dr. James Berry entitled, "MicroRNA Changes in the NurOwn® Phase 2 ALS Randomized Clinical Trial: Relationship to Neuroprotection and Innate Immunity", received the clinical abstract award at this year's Annual Northeast Amyotrophic Lateral Sclerosis (NEALS) Conference. The 17th Annual NEALS Conference concludes today in Clearwater, Florida.

The NEALS Consortium is an organization focused on translating scientific advances into novel treatment options for patients with high unmet need in ALS and Motor Neuron Disease (MND). Ralph Kern M.D., MHSc, COO & CMO, said "BrainStorm is honored to participate at this year's NEALS conference and to have our ALS translation research recognized. Receiving this prestigious award acknowledges the potential significance of our early translational insights in support of NurOwn® as a best-in-class autologous cellular therapeutic approach to treat ALS."

NEALS Clinical Poster #23, entitled "MicroRNA Changes in the NurOwn® Phase 2 ALS Randomized Clinical Trial: Relationship to Neuroprotection and Innate Immunity."

- Presenter: James Berry M.D., MHSc, Massachusetts General Hospital
- Key Academic Collaborators:
  - Massachusetts General Hospital: James Berry, M.D. and Merit Cudkowicz, M.D.
  - University of Massachusetts: Robert Brown, M.D. and Margaret Ayo Owegi, D.O.
  - Mayo Clinic: Anthony Windebank, M.D. and Nathan Staff, M.D., Ph.D.
- Objective:
  - To relate CSF miRNA changes to CSF biomarkers of apoptosis and innate immune activation in pre- and 2-weeks post-intrathecal (IT) transplantation of MSC-NTF cells in a NurOwn® Phase 2 trial (NCT02017912).
- Conclusions
  - The biomarker data demonstrated increases in miRNA 132 and miRNA 146a and statistically significant decreases in MCP-1, SDF-1, CHIT-1 and Caspase-3 levels in CSF following a single MSC-NTF cell transplantation in the NurOwn® Phase 2 trial.
  - The data presented suggests that miRNA secreted by MSC-NTF cells may contribute to CSF biomarker evidence of neuroprotection and immunomodulation.
  - Additional miRNA evaluation and biomarker correlations will be examined in the ongoing NurOwn® Phase 3 pivotal trial in ALS (NCT03280056).
- For more information: <https://goo.gl/zikHA2>

### *About BrainStorm Cell Therapeutics Inc.*

BrainStorm Cell Therapeutics Inc. is a leading cellular therapy 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 clinical development and commercialization of the NurOwn® technology platform through an exclusive, worldwide licensing agreement. NurOwn® has received Fast Track designation from the U.S. Food and Drug Administration (U.S. FDA) in ALS and has additionally been granted Orphan Status by the U.S.FDA and the European Medicines Agency (EMA). For more information, visit BrainStorm's website at [www.brainstorm-cell.com](http://www.brainstorm-cell.com).

### *About NurOwn® Phase 3 Clinical Program in ALS*

BrainStorm is currently enrolling a Phase 3 pivotal trial investigating repeat-administration of NurOwn® in ALS at six clinical sites in the U.S., supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989). The study will enroll 200 ALS patients, randomized 1:1 to receive NurOwn® or placebo, and will evaluate the ALS functional rating scale (ALSFRS-R) responder analysis as a primary efficacy outcome measure (NCT03280056). On August 23, 2018, BrainStorm announced a successful pre-specified interim safety analyses by an independent Data Safety Monitoring Board (DSMB). The completion of Phase 3 enrollment is anticipated in 1H2019 and is expected to support a BLA filing for FDA approval of NurOwn® in ALS.

### *About U.S. Sites for NurOwn® Phase 3 Trial in ALS*

- University of California Irvine; Principal Investigator: Namita Goyal, M.D.
- Cedars-Sinai Medical Center; Principal Investigator: Robert Baloh, M.D.
- California Pacific Medical Center; Principal Investigator: Robert Miller, M.D.
- Massachusetts General Hospital; Principal Investigator: James Berry, M.D.
- University of Massachusetts Medical School; Principal Investigator: Robert Brown, M.D.
- Mayo Clinic; Principal Investigator: Anthony Windebank, M.D.

#### *Safe Harbor Statements*

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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