

## **In-Depth Analyses Presented at International Symposium on ALS/MND Suggest Strong Biological Effect for NurOwn®; Evidence of Halting of Disease Progression**

HACKENSACK, N.J. and PETACH TIKVAH, Israel, Dec. 14, 2016 /[PRNewswire](#)/ -- BrainStorm Cell Therapeutics Inc. (BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, announced that new data from the Company's Phase 2 study of NurOwn® in ALS were presented by lead investigator Dr. James Berry at the 27<sup>th</sup> International Symposium on ALS/MND in Dublin, Ireland.

In the Phase 2 trial, levels of neurotrophic factors and inflammatory markers were measured in cerebral-spinal fluid (CSF) samples collected from patients. In the samples of those patients treated with NurOwn, a statistically significant increase in levels of neurotrophic factors VEGF, HGF and LIF was observed from pre- to post-transplantation. There was also a statistically significant reduction in inflammatory markers (MCP-1 and SDF-1) over this period, in patients treated with NurOwn® and this was not observed in the placebo group.

Dr. Berry also presented the pre-specified responder analyses from the Phase 2 trial which examined percentage improvements in post treatment of Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R) slope compared to pre-treatment slope. These analyses showed that, in the NurOwn® treated group, a greater number of patients achieved the high threshold of 100% improvement in the post-treatment vs. pre-treatment slope, compared with the placebo group. The definition of these responders is that their disease symptoms were essentially halted for the period of the treatment effect or they achieved a positive improvement on their ALSFRS-R score. Moreover, in the pre-specified subgroup that was defined in order to exclude subjects whose disease was progressing slowly, this effect was even more pronounced.

"This Phase 2 trial demonstrated clinical meaningful improvements in disease symptoms as measured by the well-established ALSFRS-R scale", stated Dr. James Berry, Unit Chief of the Mass. General ALS Multidisciplinary Clinic. "Importantly, there is evidence that NurOwn® may be halting disease progression or improving symptoms in some patients. The CSF biomarker profiles were also encouraging. The significant increases in neurotrophic factors and decrease in inflammatory markers observed in the treated group post-transplant provide a biological mechanism supporting the observed clinical effect."

The Phase 2 trial was a randomized, double-blind, placebo-controlled multi-center study designed to evaluate the safety and efficacy of NurOwn® in 48 ALS patients. It was conducted at three sites in the U.S: Massachusetts General Hospital, UMass Medical School and the Mayo Clinic. Patients were randomized to receive NurOwn cells administered via combined intramuscular and intrathecal injection (n= 36), or placebo (n=12). The primary objective of the study was safety and tolerability. The pre-specified efficacy analyses were: change in the ALSFRS-R slope, change in Slow Vital Capacity (SVC) and muscle strength, responder analysis (the percentage of subjects who improved post-treatment compared with pre-treatment), and a subgroup analysis excluding slowly progressing patients who are less likely to have a detectable benefit from NurOwn.

Dr. Berry's presentation is posted on the "Events and Presentations" page of the Brainstorm company website ([www.brainstorm-cell.com](http://www.brainstorm-cell.com)).

### ***About the International Symposium on ALS/MND***

The MND Association organizes the International Symposium on ALS/MND. This International Symposium is the largest medical and scientific conference on Motor Neuron Disease, also known as Amyotrophic Lateral Sclerosis. It is the premier event in the MND research calendar, attracting over 800 delegates, representing the energy and dynamism of the global MND research community. For more information, refer to <http://www.mndassociation.org/research/international-symposium/>

### ***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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