BrainStorm's NurOwn® for the Treatment of ALS Published in JAMA Neurology

Clinical Data Suggest that NurOwn Can Slow Disease Progression in ALS
First Human Experience With Stem Cells Induced Under Culture to Produce Neurotrophic Factors (NTFs)
Conference Call Today at 10:45am ET / 7:45am PT

HACKENSACK, N.J. and PETACH TIKVAH, Israel, Jan. 11, 2016 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (Nasdaq: BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, announced the publication of a paper in the January 2016 edition of *JAMA Neurology* discussing the outcome of the first in man Phase 1/2 study and Phase 2 dose escalation study with NurOwn® in ALS. The data provide indication of clinically meaningful benefit as reflected by a slower rate of disease progression in the period post treatment. There was also a positive trend on two novel biomarkers, rate of decline of muscle volume and of compound motor axon potential (CMAPs). These are the first published clinical data with stem cells that have been induced under culture conditions to produce NTFs, with the potential to achieve a neuroprotective effect in ALS and modify the course of disease.

The lead author on the paper, entitled *Safety and Clinical Effects of Mesenchymal Stem Cells Secreting Neurotrophic Factor Transplantation in Patients with Amyotrophic Lateral Sclerosis,* was Professor Dimitrios Karussis, MD, PhD, of Hadassah Medical Center in Jerusalem who had served as Principal Investigator in the ALS studies conducted in Israel. The topline results from these two clinical trials were previously announced by Brainstorm on January 5 th, 2015 and presented in a poster at the American Academy of Neurology annual meeting in April 2015.

"We are pleased to have these clinical data selected for publication in *JAMA Neurology*," stated Chaim Lebovits, CEO of Brainstorm. "The data from the studies described in this paper confirm the excellent safety profile of NurOwn® in ALS and the observed improvements in the rate of disease progression, as measured by two well established endpoints, suggest a clinically meaning effect. The results have informed the design of our ongoing placebo-controlled multicenter Phase 2 clinical trial as well as our planned multidose trial, which we hope will provide further and more substantive evidence on the benefits of NurOwn."

HMO Principal Investigator Dr. Karussis commented on the JAMA study findings: "The results were impressive with close to 90% of patients who were injected intrathecally through the spinal cord fluid being responders to the treatment (by at least 25%) either in terms of their respiratory function or motor disability. Almost all of the patients injected in this way showed slower progression or improvement in their respiratory or motor function. The ongoing Phase 2 double blind trial in the U.S. is using an identical treatment protocol."

"Although this treatment does not represent a cure for ALS at this stage, our data provide strong indications of clinically meaningful beneficial effects," continued Dr. Karussis. "I am confident that in the near future we may provide a treatment to ALS patients that can stop the progression and induce some kind of recovery. I see this treatment as having the potential to become one of the major clinical tools to treat degenerative diseases of the brain and spinal cord, in general."

NurOwn was found to be safe and well tolerated over the study follow up period in the twenty six patients treated across the two clinical trials. Most of the adverse events were mild and transient and there were no treatment related adverse events.

The efficacy results demonstrated indications of clinically meaningful benefits in those patients that received intrathecal (IT) treatment with NurOwn. In the subgroup of patients treated IT or IT plus intramuscular (IM) injections, the investigators also conducted a post hoc comparison that looked at the progression rate of the ALS Functional Rating Scale-Revised (ALS-FRS-R) score and of respiratory function as measured by Forced Vital Capacity (FVC) in the pretreatment versus post treatment periods. This analysis showed a statistically significant improvement in the progression of FVC and a trend (very close to statistical significance) in the improvement in the rate of ALS-FRS-R progression. The rate of progression of FVC was reduced from -5.1% to -1.2% per month during the six month follow up period versus the pretreatment period ($p<0.036$). The rate of progression on the ALS-FRS-R score was reduced from -1.2 to 0.6 points per month during the same period ($p=0.52$).

In the same subgroup of patients (IT or IT+IM), in those with 3 months follow up (n=18), 78% (n=14) were considered responders to therapy. Response was defined as a post treatment improvement in the slope of at least 25% to either ALS-FRS-R score or FVC. In those with 6 months follow up (n=15), 87% (n=13) were considered responders. At six months, 80% of patients (n=12) had improved by more than 35% and 67% of patients (n= 10) improved by more than 50%.

The investigators also looked at changes in muscle mass (estimated by 3 dimensional MRI) and in compound motor axon potential (CMAP) during the six month post treatment period compared with those in the run-in period. The MRI analysis revealed a reduced rate of decline in muscle mass in the right arm, the site of NurOwn administration as compared to the left arm. Electromyography demonstrated a similar favorable effect in the decline of CMAP in the right arm.

About the Phase 1/2 and Phase 2a Trials

The trials were open label proof of concept studies that enrolled ALS patients between June 2011 and October 2014 at the Hadassah Medical Center in Jerusalem. All patients were followed for up to three months prior to transplantation with NurOwn and six months after transplantation. In the Phase 1/2 part, six patients with ALS and moderate disability (ALS FRS score >30) received NurOwn intramuscularly (IM) and six patients with more advanced disease were dosed intrathecally (IT). In the Phase 2a dose escalating study, fourteen patients with ALS and moderate disability received a combined IM and IT dose of NurOwn. The primary endpoint of the studies were safety and tolerability of NurOwn. Secondary endpoints included the effects of the treatment on various clinical measurements, such as the ALS Functional Rating Scale-Revised (ALS-FRS-R) score and respiratory function as measured by Forced Vital Capacity (FVC).

To access the full paper, go to http://archneur.jamanetwork.com/journal.aspx.

Conference Call, Monday, January 11, 2016 at 10:45am ET/7:45amPT

Brainstorm is hosting a conference call today, during which Mr. Chaim Lebovits will provide an update to shareholders and discuss important company developments. Prof. Dimitrios Karussis will discuss the highlights of the *JAMA Neurology* paper and will be available to answer questions. Details of the call are as follows:

Dial in (U.S.)	888-417-8516
Dial in (international)	719-325-2329
Passcode:	4554467
Webcast:	http://public.viavid.com/player/index.php?id=117574

Replays, Available through January 25, 2016	
Dial in (U.S.)	877-870-5176
Dial in (international)	858-384-5517

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 over 30 patients with ALS in clinical trials conducted in Israel, and is currently being studied in a randomized, double-blind, placebo-controlled clinical trial in the United States. For more information, visit the company's website at 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. These forward-looking statements 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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