BrainStorm's NurOwn® Demonstrates a Statistically Significant Effect in ALS Patients

Phase 2a Results and New Analyses Presented at American Academy of Neurology

HACKENSACK, N.J. and PETACH TIKVAH, Israel, April 21, 2015 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, is presenting results from its phase 2a study of NurOwn® in amyotrophic lateral sclerosis (ALS) at a poster session today at the American Academy of Neurology annual meeting, taking place in Washington D.C. In addition to previously disclosed topline results, further data and analyses are being presented for the first time today.

Among the new results is a piecewise linear regression analysis of all subjects who received intrathecal (IT) administration in the phase 2a study and the prior phase 1/2 study. At six months post-treatment, there was a statistically significant improvement in the estimated rate of decline in Forced Vital Capacity (FVC), from -5.1% per month pre-treatment to -1.2% per month post-treatment (two-sided p=0.036) and a nearly significant improvement in the rate of ALS Functional Rating Score-Revised (ALSFRS-R) decline, from -1.2 points per month pre-treatment to -0.6 points per month post treatment (two-sided p=0.052).

Also being reported for the first time are local positive effects of intramuscular administration. 3D volumetric analysis using MRI revealed an improvement in the rate of decline in muscle mass in the right arm, the site of NurOwn® administration, through one month post-treatment, as compared to the left arm. Electromyography demonstrated a trend of stabilization of the compound motor axon potential in the right musculocutaneous nerve as compared to deterioration observed in the left.

BrainStorm's CEO Tony Fiorino, MD, PhD, commented "These results represent further validation for our NurOwn® platform. In this study, we observed a large and clinically meaningful benefit after treatment with NurOwn®. Moreover, our analysis of subjects who received IT administration in our two completed trials showed a statistically significant improvement in the rate of FVC decline, and a nearly significant improvement in the rate of ALSFRS-R decline, at six months post-treatment, a notable achievement given the small sample size. With our US phase 2 trial now more than half-enrolled and a multi-dose study being planned, BrainStorm is well-positioned to confirm and extend these findings over the coming year."

Professor Dimitrios Karussis of Hadassah University Medical Center, the principal investigator for the study, stated "We have observed in our two studies clear indications that a single intrathecal administration of NurOwn® can induce clinically meaningful beneficial effects in ALS patients. In these studies, 88% of subjects with 3 months follow-up and 73% of those with six months follow-up responded to the cells, showing a post-treatment improvement in either ALSFRS-R or FVC, or both. We eagerly await the results of current and planned studies that will define the safety and efficacy profile of NurOwn®, and we are particularly hopeful that the administration of repeated doses will increase the magnitude or duration of benefit, or both."

For full details of the study and results, a pdf version of the poster will be available on our website at www.brainstorm-cell.com.

Presentation Details

Poster: P2.059 "Autologous Transplantation of Mesenchymal Stem Cells Secreting Neurotrophic Factors (Nurown™) in ALS: Results of a Phase 2 Clinical Trial"

Session Date/Time: Session P2, Tuesday April 21, 2015, 7:30am to 12:00pm (EST)

Location: Walter E. Washington Convention Center, Washington, DC

About the Phase 2a Study

This study enrolled 14 ALS patients in three dosing cohorts. After a three month pre-treatment run-in period, during which the baseline rate of disease progression was assessed, subjects received NurOwn® via IT and intramuscular (IM) administration, and were then followed for six more months. For further information, refer to https://clinicaltrials.gov/show/NCT01777646.

Previously Reported Results

On January 5, 2015, BrainStorm reported topline results from this study. The study met its primary objective in demonstrating that IT (up to 2 million cells/kg) and IM (up to 48 million cells to the upper arm) administration of NurOwn® cells was safe and well-tolerated. Subjects in the study experienced clinically meaningful improvements in the rate of disease progression, as assessed by both ALSFRS-R (mean baseline score of 40) and FVC (mean baseline of 93% of predicted). After administration of NurOwn®, the rate of progression improved from -1.41 points per month during the run-in period to -0.60 points per month for the six months following treatment. A similar effect was observed for percent-predicted FVC, where the pre-treatment decline of 2.60% per month improved to a decline of 0.86% per month for the six months following treatment.

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. 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, including any statements regarding future results or the release of data, 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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