BrainStorm Announces Final Analysis of Phase 2a ALS Study Showing Nearly All Subjects Experienced Clinical Benefit from NurOwn™

NEW YORK and PETACH TIKVAH, Israel, Jan. 5, 2014 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ:BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, today announced positive final results from its phase 2a clinical trial of NurOwn™ in amyotrophic lateral sclerosis (ALS) patients, which enrolled 14 subjects at Hadassah Medical Center in Jerusalem.

The study achieved its primary endpoint in demonstrating that NurOwn™ is safe and well-tolerated at doses up to 2 million cells per kilogram administered intrathecally (IT) and 48 million cells administered intramuscularly (IM).

Importantly, nearly all subjects in this study experienced clinical benefit from treatment with NurOwn™. Of the 12 subjects with three or more months of follow-up, 92% experienced an improvement in the rate disease progression for the three month period after administration of NurOwn™, as measured by ALS Functional Rating Score-Revised (ALSFRS) or forced vital capacity (FVC). Fifty percent had an improvement in the slope of the ALSFRS score, and 67% had an improvement in the slope of the percent-predicted FVC.

NurOwn™ slowed the progression of ALS in this study, as indicated by an improving slope of both the mean ALSFRS and mean FVC curves after therapy. On ALSFRS, NurOwn™ slowed the rate of progression by 45%, from 1.41 points per month during the run-in period to 0.78 points per month for the three months following treatment, and by 57% to 0.60 per month for the six months following treatment. NurOwn™ had a similarly strong effect on the progressive loss of lung function – the rate of decline in percent-predicted FVC was reduced by 73%, from an average of 2.60% per month during the run-in period to just 0.70% per month for the three months after treatment, and by 67% to 0.86% per month for the six months following treatment.

"We are gratified to have the final data from this study and are very encouraged by the results," commented BrainStorm's CEO Tony Fiorino, MD, PhD. "This study not only extends our earlier phase 1/2 findings regarding the safety of NurOwn™, but also provide a consistent and highly promising picture of NurOwn's efficacy. In particular, I would highlight that we observed not only a highly meaningful reduction in ALS progression on mean ALSFRS and FVC, but we saw subjects with prolonged stabilization and even improvements in function, and all this was achieved with just a single dose of NurOwn™. We are excited to proceed to a multi-dose study to see if these positive results can be amplified and extended by administering repeated doses."

Professor Dimitious Karussis of Hadassah Medical Center and the principal investigator of the trial, noted "This is the second study of NurOwn™ I have completed in ALS patients, and my excitement for these cells as a possible treatment for ALS continues to grow. I am impressed by the consistency of benefit of IT administration we have seen in both studies, and we saw in this study that almost every subject experienced clinical benefit, either on ALSFRS, FVC or both measures. I believe that if future studies demonstrate a similar magnitude of benefit, NurOwn™ will become an important treatment option for patients suffering from ALS."

About the Phase 2a Study

This was a single-arm, dose escalating study of NurOwn™ (also referred to as MSC-NTF cells) in ALS (see https://clinicaltrials.gov/show/NCT01777646 for more study details). The study enrolled 14 early-stage ALS patients into three ascending dose cohorts; each subject received NurOwn™ cells via IT and IM administration after a three month run-in period, and was then followed for six additional months after treatment. Subjects in this study were assessed at monthly visits by ALSFRS score and for respiratory function by FVC. The rate of decline for these measures was determined by calculating the slope of the linear regression line for the run-in period, the three month follow-up period, and the six month follow-up period.

Conference Call Information

Monday, January 5, 2015 at 8:30 AM Eastern Standard Time

US Toll Free:	888-401-4668
Israel Toll Free:	180-924-5906
Other International:	719-325-2495
Conference ID:	6267823
Webcast:	https://viavid.webcasts.com/starthere.jsp?ei=1051486

A replay will be available through January 19, 2015:

Toll Free:	877-870-5176
International:	858-384-5517
Replay PIN:	6267823

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 atwww.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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