Brainstorm Reports on Successful End of Phase 2 Meeting with FDA, Upcoming Phase 3 Trial and Planned Application for Hospital Exemption for NurOwn®

Conference Call @ 8:30am Eastern Time Today to Provide Corporate Update and Discuss Plans for 2017

HACKENSACK, N.J. and PETACH TIKVAH, Israel, Dec. 19, 2016 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (Nasdaq: BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, today provided a corporate update and announced its clinical development objectives for 2017.

2017 Goals and Objectives

- Commence an international Phase 3 trial with NurOwn® in ALS
- Submission of Application for Hospital Exemption for NurOwn® in Israel

Successful End of Phase 2 Meeting

Brainstorm recently completed a successful End-of-Phase 2 Meeting with the United States Food and Drug Administration (FDA). Brainstorm has reached general agreement with the FDA to proceed to a Phase 3 trial. Importantly, the FDA has accepted the key elements of the Phase 3 program to support a Biologic License Application (BLA) for NurOwn® in ALS. The planned Phase 3 clinical trial will be a randomized, double-blind, placebo-controlled multi-dose trial that will be conducted at multiple sites in the U.S. and in Israel. The trial is expected to begin enrolling patients in the second quarter of 2017.

"We are very pleased with the outcome of the End-of-Phase 2 meeting with the FDA, and we look forward to initiating our Phase 3 clinical trial for NurOwn® in ALS," said Chaim Lebovits, BrainStorm's President and Chief Executive Officer. "Together with our clinical investigators in the U.S. and Israel, we have worked diligently with the FDA to advance NurOwn® through to late-stage development. Building off NurOwn's safety and clinical efficacy observed to date, we are developing a Phase 3 program that, if successful, will position us to bring to the market an innovative, disease modifying treatment for patients suffering from ALS."

BrainStorm to Apply for Hospital Exemption for NurOwn ® in Israel

Brainstorm plans to submit an application in Israel that will allow patient access to NurOwn® as a treatment that has been granted Hospital Exemption. This recently approved pathway would permit Brainstorm to partner with a medical center in Israel and be allowed to treat patients with NurOwn® for a fee.

Hospital Exemption allows for advanced therapy medicinal products to be made available to a group of patients to be agreed upon by the Israeli Ministry of Health. It is intended to provide patients with the possibility to benefit from a custom-made, innovative, individual treatment where there is a critical unmet need and an absence of valid therapeutic alternatives. The treatment is usually a custom-made product, such as NurOwn®, manufactured using a patient's own cells that are prepared on a non-routine basis. In order to qualify for a Hospital Exemption, a number of important criteria must be met including preparation according to specific quality standards (equivalent to those for a licensed product), use in a hospital and use under the exclusive responsibility of a medical practitioner.

"Our planned application for Hospital Exemption is our first step toward providing ALS patients with access to NurOwn," said Mr. Lebovits. "Our decision to proceed with this application is based on a strong interest voiced by ALS patients via a questionnaire. We foresee possible treatments under this pathway as early as the second half of 2017."

Conference Call and Webcast Details

Brainstorm will host a conference call and live webcast, today, Monday December 19 th, at 8.30am Eastern Time. The call will be conducted in English. Callers may participate in the conference call by dialing:

USA:	888-389-5987
Canada:	719-325-2425
Israel:	1 80 924 5905

Conference ID:	3566333
Webcast:	http://public.viavid.com/index.php?id=122186

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. Brainstorm 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 Brainstorm'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. 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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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/brainstorm-reports-on-successful-end-of-phase-2-meeting-with-fda-upcoming-phase-3-trial-and-planned-application-for-hospital-exemption-for-nurown-300380878.html

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