BrainStorm Granted GMP Certification for a Marketing-Level Manufacturing of NurOwn®

January 3, 2018 7:42 AM ET

HACKENSACK, N.J. and PETACH TIKVA, Israel, Jan. 3, 2018 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, today announced it has received Good Manufacturing Practice (GMP) approval from the Israel Ministry of Health (MoH) for its Israeli contract manufacturing facility. The GMP certificate confirms the company's manufacturing site compliance with Israeli GMPs which are recognized as equivalent with EU GMP. This approval paves the way for the company's application to the Israel MoH for the treatment of ALS patients in Israel for a fee, under the newly introduced Hospital Exemption regulation. The GMP certificate was granted after an inspection of BrainStorm's contract manufacturing facilities.

"BrainStorm received overwhelming demand from patients and physicians in many countries for access to NurOwn®. We are pleased to receive this important GMP approval, taking us one step closer to making our therapy available to patients who do not have the opportunity to participate in our U.S. trial," said Dr. Ralph Kern, M.D., Chief Operating Officer & Chief Medical Officer of BrainStorm.

"ALS is a debilitating neurodegenerative disease with few treatment options available," said Chaim Lebovits, President & CEO of BrainStorm. "NurOwn® is a novel advanced stem cell therapy now being studied in a multi-site Phase 3 pivotal trial at leading ALS centers, and we look forward to making it available to patients through innovative regulatory pathways."

About NurOwn®
NurOwn® utilizes a patient's own cells which have been engineered outside the body, to produce and secrete factors known to promote neuronal survival. NurOwn® has the potential to be the first ALS treatment to improve patient functioning as a regenerative medicine. Regenerative medicine solutions are desperately needed in the field of neurodegenerative diseases as current therapies have limited efficacy, only slow progression and do not maintain or restore function. NurOwn® is currently being tested in a multi-site Phase 3 clinical trial in the U.S. and, if successful, the results from this trial will submitted to the FDA and other regulatory authorities around the world with the goal of obtaining marketing approval. BrainStorm has completed two single arm clinical trials which established the safety profile of NurOwn® and provided indications of a treatment benefit. Additionally, the company has completed a double-blind, placebo-controlled Phase 2 study at three prestigious academic medical centers in the US. In this study, clinically meaningful changes in functioning were observed in patients receiving NurOwn®.

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 a higher response to NurOwn® compared with placebo. 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. 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.

Contacts

Corporate:
Uri Yablonka
Chief Business Officer
BrainStorm Cell Therapeutics Inc.
Phone: 646-666-3188
uri@brainstorm-cell.com

Investors:
Michael Rice
LifeSci Advisors LLC
Phone: 646-597-6979
mrice@lifesciadvisors.com

Media:
Matt Middleman, M.D.
LifeSci Public Relations, LLC
Phone: 646-627-8384
matt@lifescipublicrelations.com

View original content with multimedia:http://www.prnewswire.com/news-releases/brainstorm-granted-gmp-certification-for-a-marketing-level-manufacturing-of-nurown-300576968.html

SOURCE BrainStorm Cell Therapeutics Inc.