BrainStorm Seeking Approval To Distribute NurOwn® in Canada

Signs agreement with CCRM for regulatory support of ALS treatment

TORONTO, HACKENSACK, N.J. and PETACH TIKVAH, Israel, Feb. 21, 2017 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell technologies for neurodegenerative diseases, has signed an agreement with CCRM, a Toronto-based leader in developing and commercializing regenerative medicine technologies, and cell and gene therapies, to support the market authorization request for NurOwn®. At this time, CCRM is helping Brainstorm explore the opportunity to access Health Canada's early access pathway for treatment of patients with Amyotrophic Lateral Sclerosis (ALS). If NurOwn® qualifies for Health Canada's "Notice of Compliance with Conditions" pathway, it could be authorized in Canada for distribution in early 2018.

"We are pleased to partner with CCRM as we continue our efforts to develop and make NurOwn available commercially to patients with ALS as quickly as possible," says Chaim Lebovits, president and CEO of BrainStorm. "We look forward to discussing with Health Canada staff the results of our ALS clinical program to date, which we believe shows compelling evidence of safety and efficacy and may qualify for rapid review under Canada's regulatory guidelines for drugs to treat serious or life-threatening conditions."

"Regulatory affairs is an essential part of the commercialization process which is why CCRM has developed in-house expertise to offer consulting to our academic and industry partners," explains Dr. Michael May, president and CEO, CCRM. "Patrick Bedford is working with BrainStorm to support its efforts to bring a treatment for ALS to patients in Canada."

Patrick Bedford, manager of clinical translation and regulatory affairs, CCRM adds: "Health Canada is a world-class regulator that can use special regulatory pathways to review safety data and preliminary efficacy data to authorize promising therapies, while awaiting the completion of confirmatory efficacy studies. In fact, ALS has been specifically identified by Health Canada as a serious condition with unmet clinical needs that may qualify for a special regulatory pathway. If BrainStorm's existing clinical trial data can be found sufficient, NurOwn could be distributed to Canadians by next year."

About CCRM

CCRM, a Canadian not-for-profit organization funded by the Government of Canada, the Province of Ontario, and leading academic and industry partners, supports the development of regenerative medicines and associated enabling technologies, with a specific focus on cell and gene therapy. A network of researchers, leading companies, strategic investors and entrepreneurs, CCRM aims to accelerate the translation of scientific discovery into marketable products for patients with specialized teams, funding, and infrastructure. CCRM is the commercialization partner of the Ontario Institute for Regenerative Medicine and the University of Toronto's Medicine by Design. CCRM is hosted by the University of Toronto. Visit us at ccrm.ca

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 70 patients with ALS in two open label clinical trials and in compassionate use treatments in Israel and in a Phase 2 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. 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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