BrainStorm Cell Therapeutics Announces Submission of IND for NurOwn® in Progressive Multiple Sclerosis

NEW YORK, Nov. 19, 2018 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of innovative autologous adult stem cell therapeutics for debilitating neurodegenerative diseases, today announced that it has submitted an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) to initiate a Phase 2 study of NurOwn® in patients with progressive multiple sclerosis (MS).

"This important step toward the development of NurOwn® in progressive MS confirms our commitment to bring to the market innovative cellular therapies for neurodegenerative disease," said Chaim Lebovits, president and CEO of BrainStorm. "This builds upon the important progress made in advancing NurOwn® in the ongoing pivotal study in ALS."

"We plan to quickly initiate the Phase 2 clinical study of NurOwn® in progressive MS to address the significant unmet need for MS patients," said Ralph Kern, M.D., MHSc, Chief Operating Officer and Chief Medical Officer of BrainStorm. "We believe the demonstrated safety and efficacy experience of NurOwn® in our ALS clinical program and the development of neurotrophic factors and other efficacy biomarkers will allow us to confidently expand our cellular therapy pipeline."

MS affects approximately 1 million individuals in the U.S. and 2.3 million individuals worldwide. Approximately half of affected individuals will eventually develop progressive disease, which may lead to increasing levels of motor, visual, and cognitive functional impairment and disability.

About BrainStorm Cell Therapeutics Inc.

BrainStorm Cell Therapeutics Inc. is a leading developer of innovative autologous adult stem cell therapeutics for debilitating neurodegenerative diseases. The Company holds the rights to clinical development and commercialization of the NurOwn® technology platform through an exclusive, worldwide licensing agreement. NurOwn® has received Fast Track designation from the U.S. Food and Drug Administration (U.S. FDA) in ALS and orphan status by the U.S. FDA and the European Medicines Agency (EMA). BrainStorm is currently enrolling a Phase 3 pivotal trial in ALS (NCT03280056), investigating repeat-administration of NurOwn® at six sites in the U.S., supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989). The pivotal study is intended to support a filing for U.S. FDA approval of NurOwn® in ALS. For more information, visit BrainStorm's website at www.brainstorm-cell.com.

Safe-Harbor Statements

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

Media:
Joseph Petroziello
BrainStorm Cell Therapeutics
Phone: +1.215.485.6797

Email: JP@brainstorm-cell.com

Investors:
Marcy Beth Nanus
Solebury Trout
Phone: +1.646.378.2927
Email: MNanus@troutgroup.com

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