BrainStorm Issues a Statement to Patients and Shareholders

February 19, 2019

NEW YORK, Feb. 19, 2019 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leader in developing innovative autologous cellular therapies for highly debilitating neurodegenerative diseases, in response to numerous requests, issues today the following statement:

We will begin by thanking the participants and their families for participating in BCT-002. BrainStorm wishes to express its sincere gratitude to all of you. Enrolling in the trial is a brave and selfless act. You're making a difference by offering a ray of hope for all people living with ALS. Without you, we could not advance the clinical development of the investigational therapy NurOwn®. You are all heroes.

The BCT-002 double-blind placebo-controlled phase 3 trial evaluating the efficacy and safety of repeated doses of the investigational therapy NurOwn® is actively recruiting eligible participants at all 6 U.S. sites. Since the trial is double-blinded, Brainstorm, the participants and the study researchers do not know who is receiving NurOwn treatment or placebo. Therefore, in order to protect the integrity of the trial and the clinical development program for the investigational therapy NurOwn®, we cannot comment on any of the social media postings by patients or the email requests we are receiving.

Please note that based on the broad experience in ALS clinical trials, one can expect that some study participants may not respond to therapy and at the same time transient improvements can be observed in some participants after receiving placebo. Therefore, individual reports of improvement or lack of improvement should be cautiously interpreted.

Brainstorm stays fully committed to advance our pivotal phase 3 ALS trial towards a BLA submission. We strongly believe that currently this is the best and most credible pathway to demonstrate that NurOwn® may be a safe and an effective treatment option for ALS patients. If the outcome of the trial is successful, we hope to be able to bring a much-needed solution to ALS patients as quickly as possible.

As stated publicly in June 2018, we have faithfully followed through on our commitment to Matt Bellina to provide treatment through the Right to Try pathway free of charge. We confirm that the treatment has been initiated, and since NurOwn® is still an “investigational therapy” we refrain from any further comment.

In conclusion, BrainStorm remains dedicated to rapidly advancing our pivotal phase 3 ALS trial and we appreciate the support and encouragement of the ALS community.

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 used to produce autologous MSC-NTF cells through an exclusive, worldwide licensing agreement. Autologous MSC-NTF cells have received Orphan Drug status designation from the U.S. Food and Drug Administration (U.S. FDA) and the European Medicines Agency (EMA) in ALS. BrainStorm is currently enrolling a Phase 3 pivotal trial in ALS (NCT03280056), investigating repeat-administration of autologous MSC-NTF cells 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 autologous MSC-NTF cells 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.

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Source: BrainStorm Cell Therapeutics Inc.