



## BrainStorm Granted SME Status by the European Medicines Agency

June 15, 2020

NEW YORK, June 15, 2020 (GLOBE NEWSWIRE) -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapies for neurodegenerative diseases, today announced that it has been granted Small and Medium-Sized Enterprise (SME) status by the [European Medicines Agency's \(EMA\) Micro, Small and Medium-Sized Enterprise \(SME\) office](#).

The newly granted SME status allows BrainStorm to participate in significant financial incentives that include a 90% to 100% EMA fee reduction for scientific advice, clinical study protocol design, endpoints and statistical considerations, quality inspections of facilities as well as fee waivers for selective EMA pre and post-authorization regulatory filings, including Orphan Drug and [PRIME designations](#).

BrainStorm is also eligible to obtain EMA certification of quality and manufacturing data prior to review of clinical data. Other incentives include EMA-provided translational services of all regulatory documents required for market authorization, further reducing the financial burden of the market authorization process.

"This is an additional and timely step in our global strategy as we continue to engage with the EMEA," said David Setboun, Pharm.D, MBA, Chief Operating Officer of BrainStorm. "Our ALS investigational product received orphan drug status in Europe in July 2013 and we will benefit from the enhanced interaction and early dialogue allowing us to optimize development plans and speed up evaluation in Europe. EMA is facilitating pathways such as PRIME designation that enables critical medicines for major unmet medical need like NurOwn® to reach patients earlier."

The EMA plays a central role in facilitating the development and authorization of medicines across Europe. The SME initiative promotes innovation from smaller companies such as BrainStorm to ensure Europe continues to be a favorable environment for preclinical and clinical development of promising new therapeutic options like NurOwn.

### [About NurOwn®](#)

NurOwn® (autologous MSC-NTF) cells represent a promising investigational therapeutic approach to targeting disease pathways important in neurodegenerative disorders. MSC-NTF cells are produced from autologous, bone marrow-derived mesenchymal stem cells (MSCs) that have been expanded and differentiated ex vivo. MSCs are converted into MSC-NTF cells by growing them under patented conditions that induce the cells to secrete high levels of neurotrophic factors. Autologous MSC-NTF cells can effectively deliver multiple NTFs and immunomodulatory cytokines directly to the site of damage to elicit a desired biological effect and ultimately slow or stabilize disease progression. BrainStorm has fully enrolled a Phase 3 pivotal trial of autologous MSC-NTF cells for the treatment of amyotrophic lateral sclerosis (ALS). BrainStorm also recently received U.S. FDA acceptance to initiate a Phase 2 open-label multicenter trial in progressive MS and enrollment began in March 2019.

### [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 has fully enrolled a Phase 3 pivotal trial in ALS (NCT03280056), investigating repeat-administration of autologous MSC-NTF cells at six U.S. sites 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. BrainStorm also recently received U.S. FDA clearance to initiate a Phase 2 open-label multicenter trial in progressive Multiple Sclerosis. The Phase 2 study of autologous MSC-NTF cells in patients with progressive MS (NCT03799718) started enrollment in March 2019.

### **Safe-Harbor Statement**

Statements in this announcement other than historical data and information, including statements regarding future clinical trial enrollment and data, 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, BrainStorm's need to raise additional capital, BrainStorm's ability to continue as a going concern, regulatory approval of BrainStorm's NurOwn® treatment candidate, the success of BrainStorm's product development programs and research, regulatory and personnel issues, development of a global market for our services, the ability to secure and maintain research institutions to conduct our clinical trials, the ability to generate significant revenue, the ability of BrainStorm's NurOwn® treatment candidate to achieve broad acceptance as a treatment option for ALS or other neurodegenerative diseases, BrainStorm's ability to manufacture and commercialize the NurOwn® treatment candidate, obtaining patents that provide meaningful protection, competition and market developments, BrainStorm's ability to protect our intellectual property from infringement by third parties, health reform legislation, demand for our services, currency exchange rates and product liability claims and litigation,; 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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