

Brainstorm Announces Grant of a New Japanese Patent for NurOwn®

NEW YORK, Sept. 16, 2020 /PRNewswire/ -- [Brainstorm Cell Therapeutics Inc.](#) (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today announced that the Japanese Patent Office (JPO) has granted Brainstorm's Japanese Patent, number: 6,753,887, titled: 'Methods of Generating Mesenchymal Stem Cells which Secrete Neurotrophic Factors'.

The allowed claims cover a method of generating cells which secrete neurotrophic factors from human undifferentiated mesenchymal stem cells (MSCs) derived from the bone marrow of a single donor. The said neurotrophic factors includes: brain derived neurotrophic factor (BDNF); glial derived neurotrophic factor (GDNF); hepatocyte growth factor (HGF); and vascular endothelial growth factor (VEGF).

Patent families protecting NurOwn® manufacturing have been issued in the United States, Japan, Europe, Hong-Kong and Israel.

"We are extremely pleased with the continued development of our patent portfolio protecting our technology through strategic intellectual property achievements. This new patent grant from the Japanese Patent Office is an important addition to our IP portfolio for the NurOwn® technology and is an important element of our business strategy" commented Brainstorm's CEO Chaim Lebovits.

David Setboun, PharmD MBA, EVP and Chief Operating Officer, added: "Having our cell therapy product patented in Japan will increase our ability to enter into new commercial partnerships for NurOwn® in Japan."

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 is currently conducting 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 its 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. Brainstorm also received U.S. FDA clearance to run 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. For more information, visit the company's website at www.brainstorm-cell.com

Safe-Harbor Statements

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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<https://ir.brainstorm-cell.com/2020-09-16-Brainstorm-Announces-Grant-of-a-New-Japanese-Patent-for-NurOwn-R?elqTrackId=10da2a8f48b54ada96103c81f6494686>