

Brainstorm Announces Expansion of NurOwn® IP Portfolio with Grant and Allowance of Multiple Patents and Applications in Major Markets

NEW YORK, June 15, 2021 /PRNewswire/ -- Brainstorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today announced the grant and/or allowance of a series of patents and patent applications. These patents and patent applications, which were granted/allowed in 2020 and 2021, are expected to provide broad protection for Brainstorm's proprietary NurOwn® (MSC-NTF cells) technology in territories including the U.S., E.U., Canada, Israel and Hong Kong.

"We continue to see success developing a comprehensive global patent portfolio for NurOwn and these latest patents further strengthen our overall IP position in major markets," said Chaim Lebovits, Chief Executive Officer of Brainstorm Cell Therapeutics. "The claims of these patents are the result of Brainstorm's world class expertise in applying cell therapy to treat neurodegenerative disorders. They underscore the potential value of NurOwn as a novel treatment for diseases such as ALS and MS, which represent major unmet needs."

Title: **Methods of generating mesenchymal stem cells which secrete neurotrophic factors**

Patent #: EU Patent No. 2880151

Grant Date: 3 June 2020

Patent #: Hong-Kong patent No. HK1209453

Grant date: 19 February 2021

Details: Claims cover a method of manufacturing MSC-NTF cells (NurOwn®)

Title: **Methods of qualifying cells**

Patent #: Israel Patent Application No 246943

Issue date: 1 September 2020

Details: Allowed claims include a cell population that secretes neurotrophic factors which is qualified as useful as a therapeutic for treating ALS and a method for qualifying said population

Title: **Pharmaceutical composition comprising bone-marrow derived mesenchymal stem cells**

Patent #: Canadian patent application No. 2,937,305

Grant date: 15 December 2020

Details: Allowed claims cover a pharmaceutical composition comprising NurOwn® (MSC-NTF cells, mesenchymal stem cells secreting neurotrophic factors)

Title: **Isolated cells and populations comprising same for the treatment of CNS diseases**

Patent #: US patent No. 10,869,899

Grant date: 22 December 2020

Details: Allowed claims cover a cell population secreting GDNF, a pharmaceutical composition comprising the isolated cells, and a device comprising the pharmaceutical composition, including a device that is adapted for administration of the isolated cell population into the spinal cord

Title: **Mesenchymal stem cells for the treatment of CNS diseases**

Allowance date: 1 June 2021

US Patent Application No.: 16/047,129

Details: Allowed claims cover a method of treating a disease selected from the group consisting of Parkinson's, amyotrophic lateral sclerosis (ALS), Alzheimer's disease, stroke and Huntington's disease using MSC-NTF cells (NurOwn)

About NurOwn®

The NurOwn® technology platform (autologous MSC-NTF cells) represents 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 (NTFs). Autologous MSC-NTF cells are designed to 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.

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 designation status from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of amyotrophic lateral sclerosis (ALS). BrainStorm has completed a Phase 3 pivotal trial in ALS (NCT03280056); this trial investigated the safety and efficacy of repeat-administration of autologous MSC-NTF cells and was supported by a grant from the California Institute for Regenerative Medicine (CIRM CLIN2-0989). BrainStorm completed under an investigational new drug application a Phase 2 open-label multicenter trial (NCT03799718) of autologous MSC-NTF cells in progressive multiple sclerosis (MS).

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, including statements regarding future NurOwn® manufacturing and clinical development plans, 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, the prospects for regulatory approval of BrainStorm's NurOwn® treatment candidate, the initiation, completion, and 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, or to use third parties 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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Additional assets available online:  [Photos \(1\)](#)

<https://ir.brainstorm-cell.com/2021-06-15-Brainstorm-Announces-Expansion-of-NurOwn-R-IP-Portfolio-with-Grant-and-Allowance-of-Multiple-Patents-and-Applications-in-Major-Markets>