

BrainStorm Strengthens Exosome Patent Portfolio: Receives Notice of Allowance for U.S. Patent Covering Its Platform Technology

NEW YORK, Dec. 3, 2024 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, announced today that it has received Notice of Allowance from the U.S. Patent & Trademark Office (USPTO) for patent application 16/981,757 which covers its proprietary exosome technology.

The patent describes the composition and method of BrainStorm's unique exosomes that are isolated from the secretome of MSC-NTF (mesenchymal stem cells that secrete neurotrophic factors). MSC-NTF -derived exosomes are produced in bioreactors and contain cargo (i.e. active biological molecules) that includes at least one of the following neurotrophic factors (LIF, VEGFA, GDF-15), and may contain additional proteins or microRNA molecules. The exosomes express characteristic exosomal and MSC markers and are isolated in a unique process developed by BrainStorm and comprise a proprietary product. This patent enhances BrainStorm's exosome intellectual property portfolio, further strengthening the company's position as a leader in developing cutting-edge cellular and exosome-based therapies. It is expected to provide protection until April 10, 2039, subject to standard term adjustments.

"This patent strengthens BrainStorm's intellectual property portfolio and highlights our commitment to advancing novel technologies for respiratory and neurodegenerative diseases," said Chaim Lebovits, BrainStorm's President and Chief Executive Officer. "Our primary focus continues to be development of NurOwn for ALS as we prepare to initiate a Phase 3b registrational trial. We are seeking additional ways to unlock value from our assets and are pursuing strategic collaborations for the exosome platform."

About BrainStorm's Exosome Technology

Exosomes are nano-sized (typically 30–120 nm), cell-derived extracellular vesicles, naturally released by cells, that play a role in intercellular communication and the transport of biological materials. Exosomal cargo provides important regulatory functions for many cell processes, including immunomodulation and neuroprotection. BrainStorm's proprietary exosomes are developed from MSC-NTF cells. They can serve as nano-carriers to effectively deliver bio-active molecules to target tissues and cells in a non-invasive manner. They have significant therapeutic potential in different therapeutic areas, including respiratory and neurodegenerative diseases, based on their unique biological characteristics, customizable cargo, intrinsic immunomodulatory properties and ability to target specific CNS pathways.

About BrainStorm Cell Therapeutics Inc.

BrainStorm Cell Therapeutics Inc. is a leading developer of innovative therapies for debilitating neurodegenerative diseases, leveraging both autologous and allogeneic platforms. The Company holds exclusive worldwide licensing rights for the NurOwn® technology platform, which produces autologous MSC-NTF cells. These cells have received Orphan Drug designation from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for amyotrophic lateral sclerosis (ALS). BrainStorm is currently planning the launch of a confirmatory Phase 3b trial in ALS with NurOwn to further evaluate its safety and efficacy. BrainStorm's exosome technology, derived from MSC-NTF cells, represents an allogeneic therapeutic platform, providing customizable, nano-carrier-based solutions for targeted delivery of bioactive molecules. These exosomes exhibit unique immunomodulatory properties and are designed to address critical pathways in neurodegenerative and respiratory diseases. The Company has completed a Phase 3 trial assessing NurOwn in ALS and advanced clinical studies of NurOwn in progressive multiple sclerosis (MS), supported by grants from the California Institute for Regenerative Medicine (CIRM) and the National MS Society (NMSS).

Notice Regarding Forward-Looking Statements

This press release contains "forward-looking statements" that are subject to substantial risks and uncertainties, including statements regarding the expectation of continued listing of BrainStorm's common stock on The Nasdaq Capital Market. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will" "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on BrainStorm's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. These potential risks and uncertainties include, without limitation, the 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.

This press release contains "forward-looking statements" that are subject to substantial risks and uncertainties, including the clinical development of NurOwn as a therapy for the treatment of ALS, the future availability of NurOwn to patients, and the future success of BrainStorm Cell Therapeutics. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will," "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on BrainStorm Cell Therapeutic's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. These potential risks and uncertainties include, without limitation, management's ability to successfully achieve its goals, BrainStorm's ability to raise additional capital, BrainStorm Cell Therapeutic's ability to continue as a going concern, prospects for future regulatory approval of NurOwn, whether BrainStorm Cell Therapeutic's future interactions with the FDA will have productive outcomes, and other factors detailed in BrainStorm Cell Therapeutic'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 Cell Therapeutic'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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