BrainStorm Cell Therapeutics and Catalent Announce Completion of Technology Transfer for NurOwn® Manufacturing

NEW YORK and SOMERSET, N.J., Dec. 7, 2021 /PRNewswire/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of cellular therapies for neurodegenerative diseases, and Catalent (NYSE: CTLT), a global leader in enabling biopharma, cell, gene and consumer health partners to optimize development, launch, and supply of better patient treatments across multiple modalities, today announced that the technology transfer for NurOwn® manufacturing at Catalent's facility has been finalized. NurOwn is BrainStorm's autologous cellular therapy being developed for the treatment of amyotrophic lateral sclerosis (ALS), progressive multiple sclerosis (PMS) and other neurodegenerative diseases.

Catalent entered into a partnership with Brainstorm in 2020 to provide CGMP clinical supply of NurOwn, in anticipation of the product candidate's potential regulatory approval. NurOwn will be manufactured at Catalent's world-class 32,000 square-foot cell therapy manufacturing facility in Houston, Texas.

"The successful completion of this technology transfer with Catalent is an important step in establishing manufacturing preparedness for NurOwn," said Chaim Lebovits, Chief Executive Officer, Brainstorm Cell Therapeutics. "The manufacturing of cellular therapies such as NurOwn is complex, and requires careful planning and very specific expertise. We are very pleased with the progress we have made with our partner Catalent, which has industry-leading capabilities in this area."

Manja Boerman, Ph.D., President, Catalent Cell & Gene Therapy, said, "Our extensive experience in cell therapy development and scale-up was key to the completion of this technology transfer to our state-of-the-art cell therapy facility in Houston, Texas. We look forward to continuing our partnership with BrainStorm and are committed to enabling the advancement of their autologous stem cell therapy product candidate toward a potential future commercial launch."

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 Catalent

Catalent is the global leader in enabling pharma, biotech, and consumer health partners to optimize product development, launch, and full life-cycle supply for patients around the world.

With broad and deep scale and expertise in development sciences, delivery technologies, and multi-modality manufacturing, Catalent is a preferred industry partner for personalized medicines, consumer health brand extensions, and blockbuster drugs. Catalent helps accelerate over 1,000 partner programs and launch over 150 new products every year. Its flexible manufacturing platforms at over 50 global sites supply over 70 billion doses of more than 7,000 products to over 1,000 customers annually.

Catalent's expert workforce exceeds 17,000, including more than 2,500 scientists and technicians. Headquartered in Somerset, New Jersey, the company generated $4 billion in revenue in its 2021 fiscal year. For more information, visit www.catalent.com.

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) and was supported by a grant from the National MS Society (NMSS).

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, heath 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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