Catalent and BrainStorm Cell Therapeutics Announce Partnership for the Manufacture of Mesenchymal Stem Cell Platform Therapy NurOwn®

SOMERSET, N.J. and New York – October 22, 2020 — Catalent (NYSE: CTLT), the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, cell and gene therapies, and consumer health products, and BrainStorm Cell Therapeutics Inc (NASDAQ: BCLI), a leading developer of cellular therapies for neurodegenerative diseases, today announced an agreement for the manufacture of NurOwn®, BrainStorm's autologous cellular therapy being investigated for the treatment of amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease or motor neuron disease.

NurOwn induces mesenchymal stem cells (MSCs) to secrete high levels of neurotrophic factors (NTFs) known to promote the survival of neurons and neuroprotection. The therapy has received Fast Track status from the U.S. FDA for ALS and has also been granted Orphan Drug Status for ALS by both the FDA and the European Medicines Agency. BrainStorm is currently completing a 200-patient, double-blind, placebo-controlled, repeat-dosing NurOwn Phase 3 study in the U.S.

As part of its commitment, Catalent will undertake the transfer of the manufacturing process to, and provide future CGMP clinical supply of NurOwn from, its new, 32,000 square-foot cell therapy manufacturing facility in Houston, Texas. On completion of the clinical trials and in anticipation of potential approval of NurOwn, the companies will look to extend the partnership to include commercial supply from the Houston facility.

"We are proud to have a partner in Catalent whose excellence in manufacturing quality therapies will support commercial supply of NurOwn," said Chaim Lebovits, Chief Executive Officer of BrainStorm Cell Therapeutics. "We know that ALS patients are in urgent need of a new treatment option. If NurOwn is successful in the current clinical trials, this agreement will be integral to ensuring rapid access for patients."

Manja Boerman, Ph.D., President, Catalent Cell & Gene Therapy, said, "Our experience in cell therapy development, and the manufacturing capabilities that our newly constructed, state-of-the-art facility in Houston offers, position us to best support BrainStorm, with its leading therapeutic candidate for ALS treatment. We look forward to partnering with BrainStorm and providing our stem cell manufacturing expertise as we work to optimize production and streamline the product's path towards commercial launch."

About Catalent Cell & Gene Therapy

With deep experience in viral vector scale-up and production, Catalent Cell & Gene Therapy is a full-service partner for adeno-associated virus (AAV) and lentiviral vectors, and CAR-T immunotherapies. When it acquired MaSTherCell, Catalent added expertise in autologous and allogeneic cell therapy development and manufacturing to position it as a premier technology, development and manufacturing partner for innovators across the entire field of advanced biotherapeutics. Catalent has a global cell and gene therapy network of dedicated, large-scale clinical and commercial manufacturing facilities, and fill-finish and packaging capabilities located in both the U.S. and Europe. An experienced partner, Catalent Cell & Gene Therapy has worked with industry leaders across 70+ clinical and commercial programs.

About Catalent

Catalent is the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, cell and gene therapies, and consumer health products. With over 85 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable global clinical and commercial product supply. Catalent employs approximately 14,000 people, including around 2,400 scientists and technicians, at more than 45 facilities, and in fiscal year 2020 generated over $3 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit www.catalent.com

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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 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 (FDA) and the European Medicines Agency (EMA) for the treatment of amyotrophic lateral sclerosis (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 (MS). The Phase 2 study of autologous MSC-NTF cells in patients with progressive MS (NCT03799718) completed enrollment in August 2020. 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 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, 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.

Media Contacts:

Catalent

Chris Halling
+44 (0)7580 041073
chris.halling@catalent.com

Richard Kerns
+44 (0) 161 728 5880
richard@nepr.agency

BrainStorm Cell Therapeutics
Investor Relations:
Corey Davis, Ph.D.
LifeSci Advisors, LLC
Phone: +1 646-465-1138
cdavis@lifesciadvisors.com

Media:
Paul Tyahla
SmithSolve
Phone: + 1.973.713.3768
Paul.tyahla@smithsolve.com

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