Rapid Reshore & Development and BrainStorm Cell Therapeutics Announce Agreement to Advance Construction of BrainStorm's U.S. Manufacturing Facility

RR&D to lead site selection and design
Site analyses to begin immediately

PHILADELPHIA and NEW YORK, Oct. 26, 2020 /PRNewswire/ -- Rapid Reshore & Development (RR&D), an alliance of three specialized firms, and BrainStorm Cell Therapeutics, Inc (NASDAQ: BCLI), a leading developer of adult stem cell therapies for neurodegenerative diseases, announced that BrainStorm has selected RR&D as its partner to expedite site selection and design services for a state-of-the-art manufacturing facility for NurOwn® (autologous MSC-NTF) in the U.S.

BrainStorm is investigating NurOwn as a potential treatment for neurodegenerative diseases such as amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS). BrainStorm's most advanced clinical program for NurOwn is in ALS, which is currently being evaluated in a pivotal Phase 3 clinical trial.

BrainStorm seeks to locate, design and construct a new commercial manufacturing facility in the U.S. to prepare for potential commercialization. RR&D, a three-firm services alliance consisting of EwingCole, Facility Logix and Biggins, Lacy, Shapiro & Company, will identify the location and develop the design of BrainStorm's new commercial manufacturing facility.

"We're thrilled to be working with BrainStorm on this project and to have the opportunity to deliver this critical work to our region," said EwingCole CEO, Jared Loos, PE, AIA. "We embrace the spirit of creating potentially life-changing technology and we will do everything we can to move the project forward in an efficient and yet responsible manner."

BrainStorm intends to use the facility primarily for cell therapy production. RR&D will provide custom, streamlined project management, site selection analysis and design/construction management services throughout the project's lifecycle.

Chaim Lebovits, Chief Executive Officer of BrainStorm Cell Therapeutics commented, "Our decision to partner with RR&D was driven by the strong capabilities of the individual partners and their holistic approach to planning, site selection and design services. The expansion of BrainStorm's manufacturing capabilities is a key part of our broader corporate strategy to prepare for potential regulatory approvals of NurOwn and becoming a commercial organization. This new partnership follows our recently announced agreement with Catalent Pharma Solutions to manufacture NurOwn at a scale large enough to meet potential commercial needs at the time of launch. The dedicated, state-of-the-art manufacturing facility developed by RR&D will provide us with important long-term autonomy and strategic flexibility, including the capacity to supply NurOwn for additional disease indications beyond ALS. Together these two partnerships will help ensure that BrainStorm has the manufacturing capacity to meet the needs of patients today and well into the future."

Site selection analyses will begin immediately with the goal of identifying locations that offer a cost-effective solution for BrainStorm's new manufacturing facility. At the same time, the design team will begin developing a conceptual design of the manufacturing facility, based upon input from BrainStorm's process, engineering, and scientific staff, by defining the main steps of the production process and Current Good Manufacturing Practices (cGMP) requirements. The approximately 50,000 square-foot building will contain manufacturing suites, complementary support and infrastructure, and the ability to expand the facility to 100,000 square feet to anticipate future programmatic needs.

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.

About Rapid Reshore & Development:

Rapid Reshore & Development is an alliance of expert firms providing confidence and support throughout the life sciences industry, representing an evolution from transaction-driven service models to a holistic focus on client needs, integrating an interdisciplinary team customized for a variety of individual projects. To optimize and strengthen confidence in decision-making and speed-to-market, Rapid Reshore & Development alliance was formed to deliver best-in-class professionals with deep experience in all aspects of life sciences' project planning, site selection, design and execution including financial, labor market, development incentives, real estate, design and engineering, and construction management. For additional information, visit: www.rapidreshore.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.

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Additional assets available online: Photos (1)

https://ir.brainstorm-cell.com/2020-10-26-Rapid-Reshore-Development-and-BrainStorm-Cell-Therapeutics-Announce-Agreement-to-Advance-Construction-of-BrainStorms-U-S-Manufacturing-Facility