



## The ALS Association, I AM ALS Award BrainStorm Cell Therapeutics \$500,000 for ALS Biomarker Study

June 9, 2020

### Research Study to Use Data and Samples from NurOwn® Phase 3 Clinical Trial

WASHINGTON, June 9, 2020 /PRNewswire/ -- [The ALS Association](#) and [I AM ALS](#) announced today that the organizations have awarded a combined grant of \$500,000 to [BrainStorm Cell Therapeutics](#) (NASDAQ: BCLI), a biotechnology company, to support an amyotrophic lateral sclerosis (ALS) biomarker research study. The grant will be used to draw insights from data and samples collected from patients enrolled in BrainStorm's ongoing phase 3 clinical trial of its NurOwn® treatment, to further understanding of critical biomarkers associated with treatment response for people with ALS.



The study is designed to evaluate how NurOwn interacts with its targets in the brain and spinal cord and to explore the changes in the biomarkers that may correlate with response to the drug treatment. Biomarkers are any measurable substance in the body that change over time (such as cholesterol or blood pressure) and that correlate with disease processes or treatment response. If successful, this study will help confirm that the ALS treatment NurOwn works in the way it is intended and will help inform our larger understanding of ALS biomarkers.

"This grant to BrainStorm marks an important step forward in establishing how exactly NurOwn works in the body," said Calaneet Balas, President and CEO of The ALS Association. "This research is also important to our overall pursuit of identification and validation of ALS biomarkers. We hope NurOwn is ultimately proven effective in treating ALS and we stand ready to support BrainStorm in its plan to apply for a biologics license for NurOwn."

Danielle Carnival, CEO of I AM ALS commented, "We need to move with urgency in all of our efforts to deliver treatments and cures for ALS. This biomarker research will help us more expeditiously understand the effectiveness of NurOwn, while possibly unlocking discoveries that provide clues for other promising treatments. We are at a pivotal time for ALS research in pursuit of treatment solutions and will do whatever we can, together, to drive new answers and new hope for patients."

The joint award to BrainStorm consists of a \$400,000 grant from The ALS Association and a \$100,000 grant from I AM ALS. As part of this agreement, BrainStorm has agreed to share data and samples with the ALS community so that the results can be independently validated and to advance other ALS research.

Chaim Lebovits, CEO of BrainStorm stated, "We sincerely appreciate the scientific recognition and generous support from The ALS Association and I AM ALS and we are excited through this study to further an already strong partnership between The ALS Association, I AM ALS and Brainstorm. This critical research study involves one of the largest and most robust clinical trial collections of CSF biomarkers. Data generated from this study will increase our understanding of how NurOwn® therapy impacts ALS disease progression and may identify patients who benefit the most from this form of therapy. We also hope that this research study will benefit the broader ALS scientific community as we collectively advance towards our shared goal of delivering much needed treatments."

#### 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 recently received U.S. FDA acceptance to initiate a Phase 2 open-label multicenter trial in progressive MS and enrollment began in March 2019.

#### About The ALS Association

The ALS Association is the largest private funder of ALS research in the world. The Association funds global research collaborations, provides assistance for people with ALS and their families through our nationwide network of chapters and certified clinical care centers, and advocates for better public policies for people with ALS. The ALS Association builds hope and enhances quality of life while urgently searching for new treatments and a cure. For more information about The ALS Association, visit our website at [www.als.org](http://www.als.org).

#### About I AM ALS

Founded in 2019 by husband-wife team Brian Wallach and Sandra Abrevaya, I AM ALS was born out of their desire to change the future for Brian and the thousands of other ALS patients in the world. I AM ALS brings together patients, advocates, organizations and scientists to deliver critical and innovative resources for patients, empower and mobilize patients and their networks to lead the fight for cures, and transform the public understanding of ALS with a goal of flooding the research pipeline with new, lifesaving drugs. A cure is possible ... if we work together to re-imagine the fight against ALS. Learn more here: [www.iamals.org](http://www.iamals.org).

#### **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 (U.S. FDA) and the European Medicines Agency (EMA) in 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. The Phase 2 study of autologous MSC-NTF cells in patients with progressive MS (NCT03799718) started enrollment in March 2019. For more information, visit the company's website at [www.brainstorm-cell.com](http://www.brainstorm-cell.com)

#### **About ALS**

ALS is a disease that attacks cells in the body that control movement. It makes the brain stop talking to the muscles, causing increased paralysis over time. Ultimately, ALS patients become prisoners within their own bodies, unable to eat, breathe, or move on their own. Their mind, however, often remains sharp so they are aware of what's happening to them.

**Contact: Brian Frederick**  
**The ALS Association**  
**(202) 464-8612**  
[bfrederick@alsa-national.org](mailto:bfrederick@alsa-national.org)

**Contact: Kathleen Rooney**  
**I AM ALS**  
**(312) 529-0391**  
[Kathleen@iamals.org](mailto:Kathleen@iamals.org)

 View original content: <http://www.prnewswire.com/news-releases/the-als-association-i-am-als-award-brainstorm-cell-therapeutics-500-000-for-als-biomarker-study-301072580.html>

SOURCE Brainstorm Cell Therapeutics Inc