brainstorm
cell therapeutics

BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI)

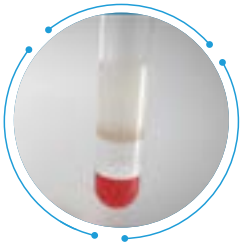
DISCOVER. INNOVATE. DELIVER.

1

PATIENT BONE MARROW ASPIRATION

Bone marrow is aspirated from the patient and shipped to BrainStorm's dedicated cell manufacturing center

2



STEM CELLS ISOLATION

At the cell manufacturing center, the mesenchymal stem cells (MSCs) are isolated in tissue culture and grown until several hundreds of millions cells are available

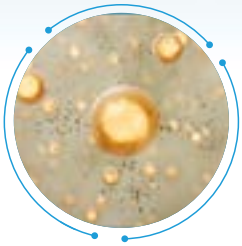
BrainStorm has developed a targeted, innovative, proprietary and validated autologous cellular technology platform (NurOwn®) to potentially address the enormous unmet medical need in the treatment of neurodegenerative diseases.

Using our proprietary technology, a patient's own mesenchymal stem cells (MSCs) are harvested from their bone-marrow, expanded and differentiated to secrete high levels of neurotrophic factors (NTFs). The differentiated MSCs, known as NurOwn (MSC-NTF) cells, are then harvested and prepared for administration into the same patient by intrathecal injection. The MSC-NTF cells are not genetically modified, and the manufacturing process is free of animal proteins. A validated cryopreservation process enables multiple years of therapy from a single outpatient bone marrow harvest procedure. MSC-NTF cells effectively deliver multiple NTFs and immunomodulatory cytokines near the site of damage to modulate the disease microenvironment and potentially modify disease progression.

BrainStorm has two lead clinical indications – amyotrophic lateral sclerosis (ALS) and progressive multiple sclerosis (MS).

A Phase 3, double-blind, placebo-controlled trial was completed at six top ALS Centers of Excellence in the United States. The trial enrolled 200 patients with ALS, a relentlessly progressive neurodegenerative disease characterized by selective deterioration of cortical, brainstem and spinal cord motor neurons leading to loss of function and for most patients, death

3



STEM CELLS EXPANSION

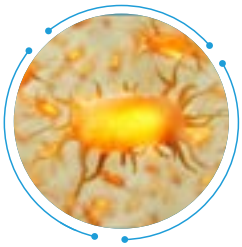
Cells are expanded to reach enough numbers to provide multiple years of treatment

4

STEM CELLS CRYOPRESERVATION

Expanded cells are cryopreserved and stored for future use to produce NurOwn (MSC-NTF cells)

5



STEM CELLS DIFFERENTIATION

Cells (in culture) are induced to differentiate into NurOwn (MSC-NTF cells) and able to produce and release Neurotrophic Factors

6

NUROWN® ADMINISTRATION

NurOwn is then administered back into the patient's cerebrospinal fluid at the clinic (using a standard lumbar puncture procedure)

within 3 to 5 years of diagnosis. Multiple factors, including neuroinflammation and neurodegeneration are involved in the pathogenesis of ALS, and stem cell therapy could potentially target these important disease pathways responsible for progression of disease. The Phase 3 study has been published in *Muscle & Nerve* (Cudkowicz et al 2022) along with an erratum (Erratum 2022).

NurOwn has received Fast-Track designation from the U.S. Food and Drug Administration (FDA) for the treatment of ALS. Both the U.S. FDA and the European Medicines Agency (EMA) have granted NurOwn Orphan Status.

BrainStorm completed a U.S. Phase 2 trial in progressive MS, a chronic neuroinflammatory and neurodegenerative disorder that affects the brain and spinal cord. MS most often begins as a relapsing-remitting condition (85%). Approximately 50% of relapsing MS patients eventually develop progressive disease with worsening neurological function and disability, and 10% of patients with MS progress from onset without initial relapsing-remitting symptoms. There are no available therapies for progressive MS that effectively halt the progression of established disability or give rise to functional improvement. This open-label Phase 2 study of 18 progressive MS patients has been published in *Multiple Sclerosis Journal* (Cohen et al 2022).

BrainStorm is also actively developing proprietary NurOwn-derived MSC exosome technology. Exosomes are small membrane-bound vesicles known to deliver biological molecules between cells to regulate important cellular and tissue functions in the nervous and immune systems. Exosomes have numerous practical advantages including ease of handling, low immunogenicity, and the ability to target and modify their cargo to offer truly personalized therapy approaches to neurodegenerative disease and other indications.

With an experienced executive team, expanding US-based team, production facilities in the U.S. and an R&D team and production facilities in Israel, BrainStorm is ready to lead a new era where cellular therapies are part of the arsenal to combat debilitating neurodegenerative diseases.

brainstorm cell therapeutics

BrainStorm Cell Therapeutics Inc.
1325 Avenue of Americas NY, NY 10019

Phone: +1 201 488 0460
www.brainstorm-cell.com