brainstorm
cell therapeutics

BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI)

DISCOVER. INNOVATE. DELIVER.

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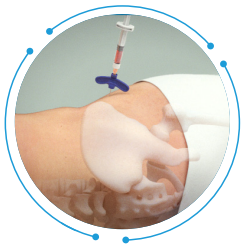

PATIENT BONE MARROW ASPIRATION

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

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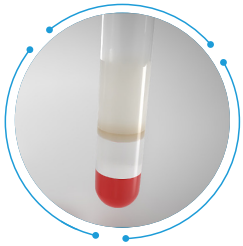

STEM CELLS ISOLATION

At the cell manufacturing center, the mesenchymal stem cells (MSCs) are isolated in tissue culture and manufactured to produce hundreds of millions of cells for treatment

BrainStorm has developed a targeted, innovative, proprietary and validated autologous cellular technology platform (NurOwn®) which is being developed and has potential for treatment of multiple neurodegenerative diseases.

Using our proprietary technology, a patient's own bone marrow is harvested, mesenchymal stem cells (MSCs) are isolated, expanded and differentiated to secrete high levels of neurotrophic factors (NTFs). The differentiated MSCs, known as MSC-NTF cells, are then harvested and used in the production of NurOwn®, which are administrated into patients by intrathecal injection. The MSC-NTF cells are not genetically modified and the manufacturing process does not use animal proteins. A validated cryopreservation process enables years of therapy from a single outpatient bone marrow harvest procedure. MSC-NTF cells leverage the inherent properties of MSC cells and also deliver multiple NTFs near the site of damage to elicit a desired biological effect and potentially delay or stabilize disease progression.

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

ALS is a relentlessly progressive neurodegenerative disease characterized by selective deterioration of cortical, brainstem and spinal cord motor neurons. As motor neurons die, patients become weaker and lose motor function. For most patients, the disease leads to death within 2 to 5 years of diagnosis. Given that multiple factors are involved in the pathogenesis of ALS, stem cell therapy could potentially target several of the important disease pathways responsible for the onset and progression of disease.

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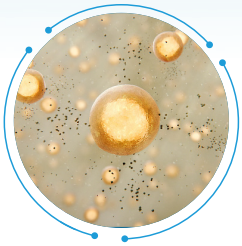

STEM CELLS EXPANSION

Hundreds of millions of MSCs are frozen (cryopreserved) in many aliquots, each containing hundreds of millions of cells and years of treatment

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STEM CELLS CRYOPRESERVATION

The frozen MSCs are thawed and induced in culture, secreting many neuron-supporting factors

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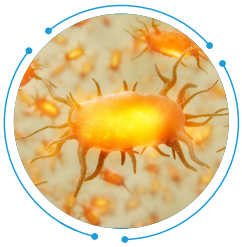

STEM CELLS DIFFERENTIATION

The culture-induced MSCs are differentiated into NurOwn® (MSC-NTF cells)

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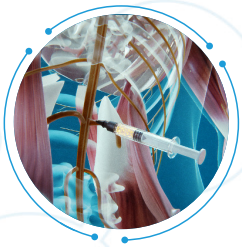

NUROWN® TRANSPLANTATION

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

BrainStorm has conducted clinical trials in participants with ALS for over 10 years, including the completion of a Phase 3, double-blind, placebo-controlled U.S. trial in 200 patients with rapidly progressing ALS in 2020. We generated a unique ALS biomarker dataset through the collection and analysis of 7 serial cerebrospinal fluid samples (CSF) in all study participants.

Progressive MS is 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.

BrainStorm has completed a Phase 2 trial in progressive MS participants generating preliminary data supporting the proposed mechanism of action in MSC-NTF in progressive MS.

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 is also actively developing proprietary 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, lower immunogenicity, and the ability to target and modify their cargo to offer truly personalized cellular therapy approaches to neurodegenerative disease.

With an experienced executive team, clinical-stage production facilities in the U.S. and an R&D team in Israel, BrainStorm is ready to deliver on the promise of autologous cellular therapy for the treatment of debilitating neurodegenerative diseases.

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

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