

BrainStorm Cell Therapeutics

NASDAQ: BCLI



brainstorm
cell therapeutics

November 2018

Forward Looking Statement

Statements in this announcement other than historical data and information 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, risks associated with BrainStorm's limited operating history, history of losses; minimal working capital, dependence on its license to Ramot's technology; ability to adequately protect the technology; dependence on key executives and on its scientific consultants; ability to obtain required regulatory approvals; 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.

Brainstorm at a Glance

Targeted, innovative, proprietary and validated autologous cellular technology platform for the treatment of neurodegenerative disease

Actively recruiting ALS phase 3 Clinical Trial, an orphan disease with no existing cure and limited treatment options

Large addressable market - over 40 million patients in main therapeutic targets (ALS, MS, Parkinson's disease, Huntington's disease and Autism Spectrum Disorder)

Strong financial position - \$19million of cash and cash commitments

Robust IP portfolio

1

Manufacturing process begins with a bone marrow aspiration to harvest adult MSCs from the patient

- Stem cells are isolated and then transferred to a cGMP clean room, where they are cultured with a proprietary growth medium
- Expanded MSCs are cryopreserved and then thawed prior to the seven day differentiation process

2

Patient-derived MSCs secrete neurotrophic factors and anti-inflammatory cytokines

- Promotes neuronal survival through neuroprotection and immunomodulation

4

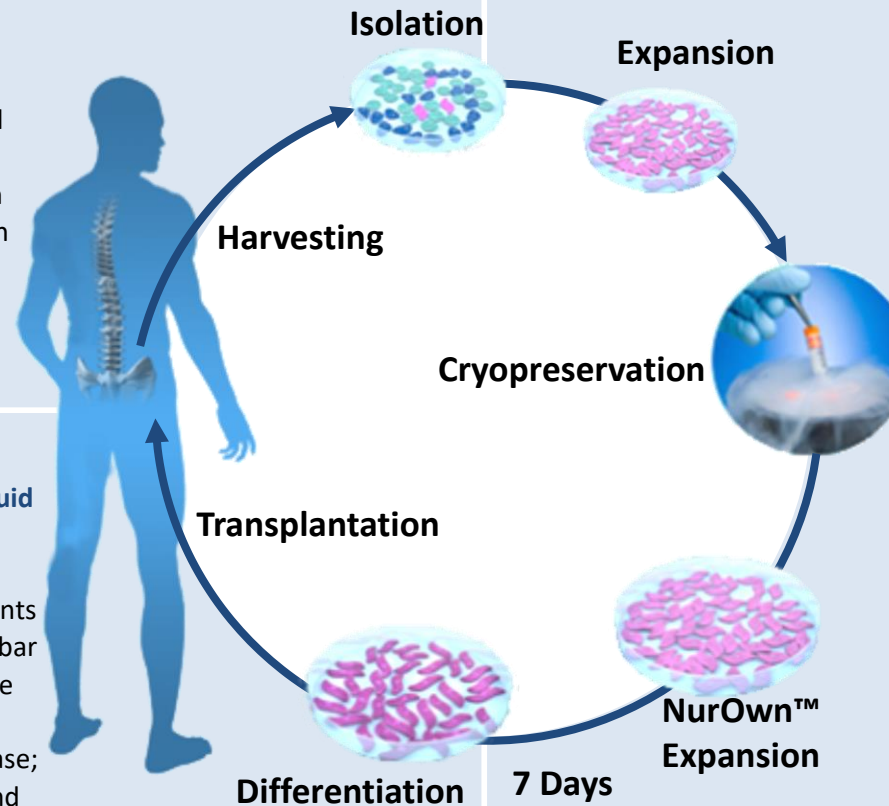
The cells are injected into the cerebrospinal fluid (CSF) of patients

- NurOwn® cells identity and potency are confirmed prior to injection back into patients
- The injection procedure is by standard lumbar puncture and targets the cells at or near the site of neurodegeneration and disease
- Applications include: ALS; Parkinson's disease; Huntington's disease; Multiple Sclerosis; and Autism Spectrum Disorder

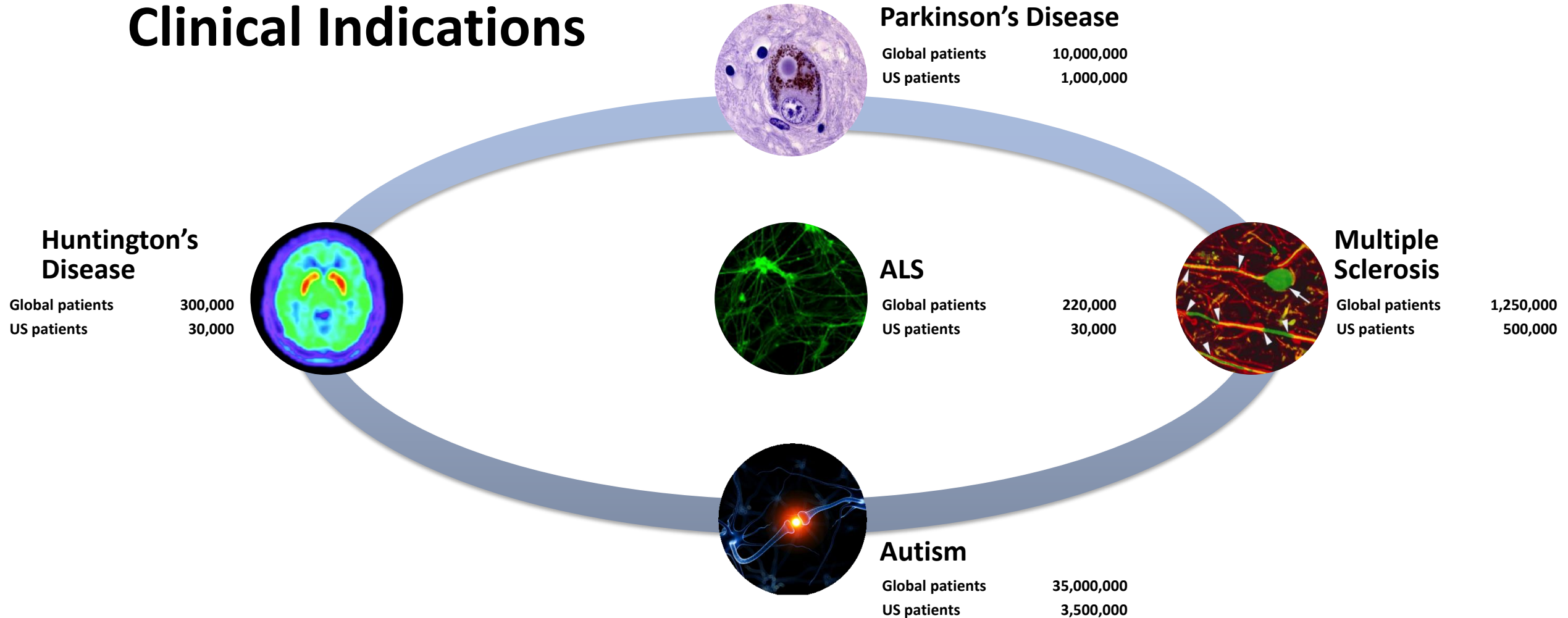
3

The proprietary culture medium induces the cells to secrete additional key neurotrophic factors

- Glial-derived neurotrophic factor (GDNF), brain-derived neurotrophic factor (BDNF), vascular endothelial growth factor (VEGF), and hepatocyte growth factor (HGF). The resulting cells are referred to as MSCs that secrete neurotrophic factors (MSC-NTF cells)
- MSC-NTF cells are autologous and unlikely to induce an immune response



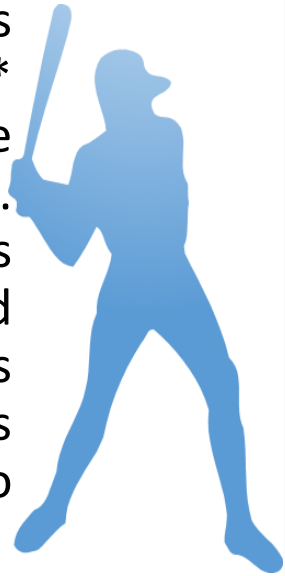
NurOwn® - Potential Clinical Indications



NurOwn® successfully evaluated in preclinical models of neurodegenerative disease

What is ALS?

Amyotrophic Lateral Sclerosis (ALS) or Lou Gehrig's disease* is a progressive, incurable disease of the nervous system. The condition usually affects those aged between forty and seventy, however, individuals in their twenties and thirties have also been known to develop ALS.



Future Predictions

Researchers have predicted that the number of worldwide ALS cases will increase by 69% in 2040, compared to 2015. The main cause of this projected increase is due to an ageing population, particularly in developing nations.

* Lou Gehrig was a famous American baseball player diagnosed with ALS in 1939

ALS at a Glance

It is estimated that around 45,000 people worldwide are living with ALS, with other 30,000 people in the USA suffering from the condition at any given time.



Someone is diagnosed

with ALS every **90**
minutes

Average age of diagnosis is

55

Men

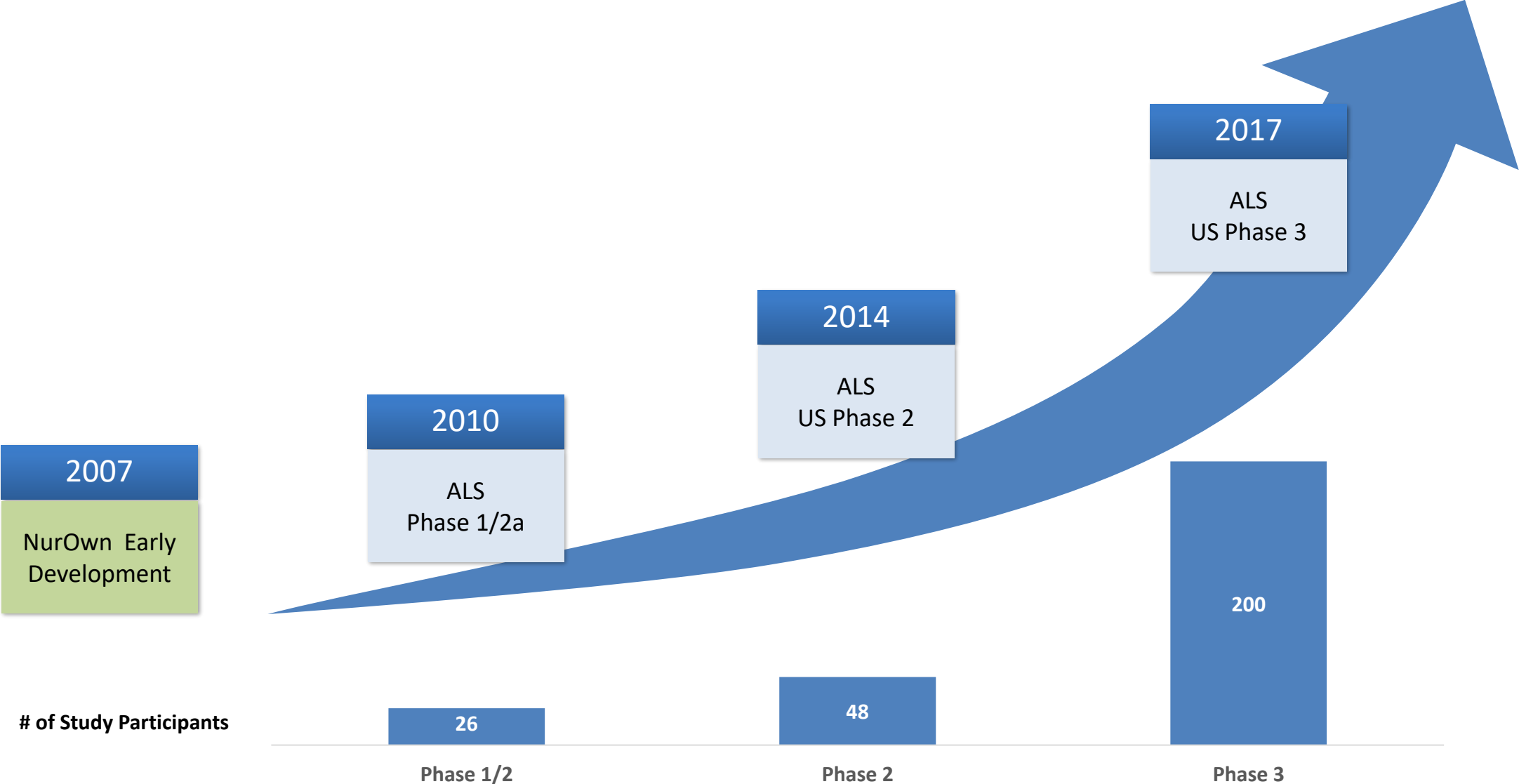
are more likely to be diagnosed
with ALS than women

Worldwide, ALS affects white
males aged

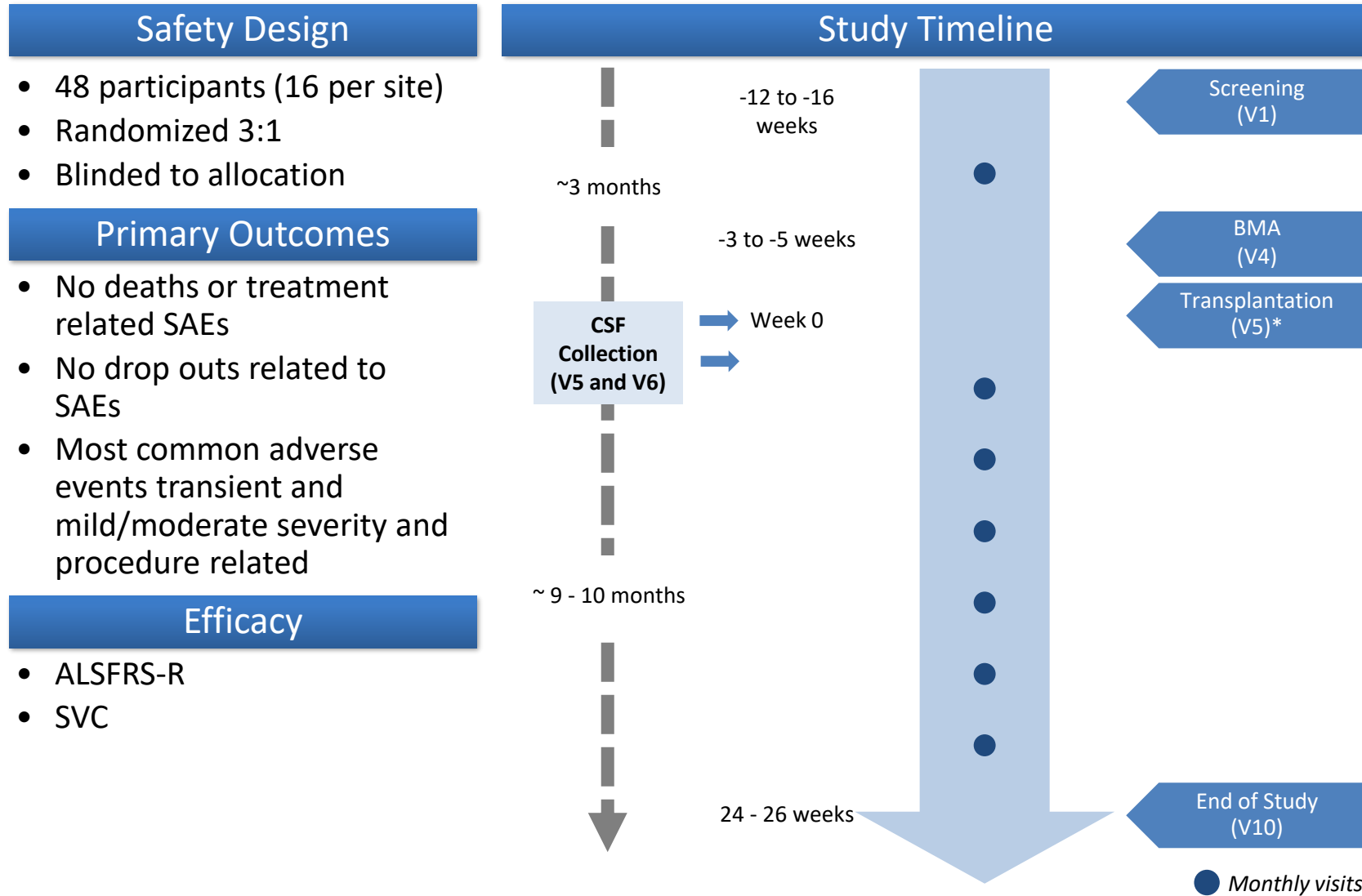
60+

more than any other group

NurOwn® ALS Development

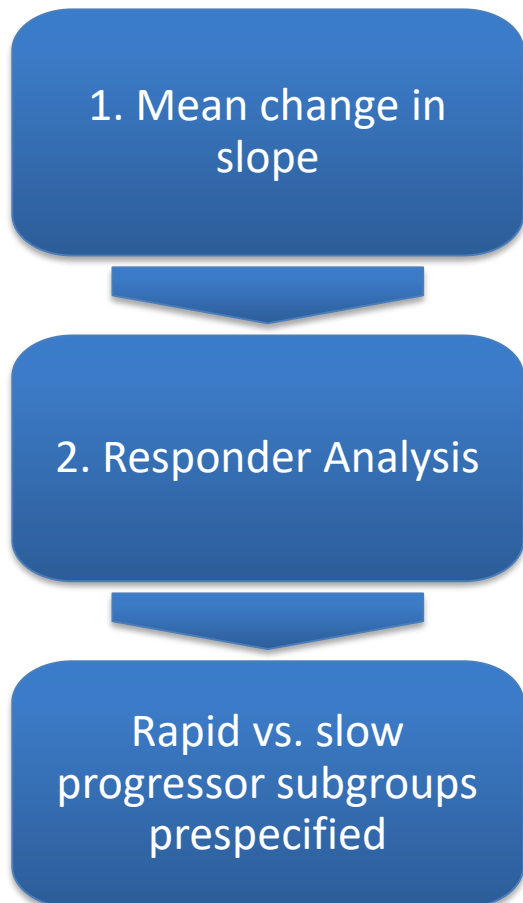


ALS Phase 2 Trial Design



Phase 2 Trial – Approach to Data Analysis

Phase 2 Trial: 3 Types of Efficacy Analysis



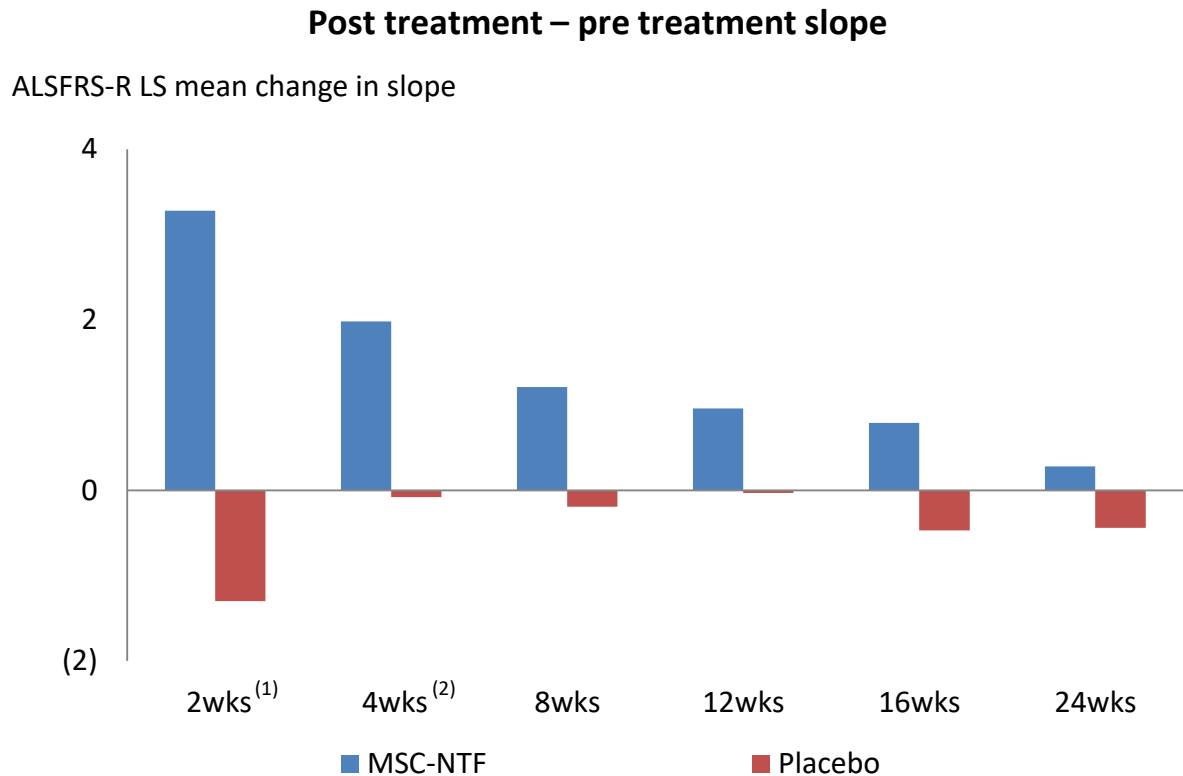
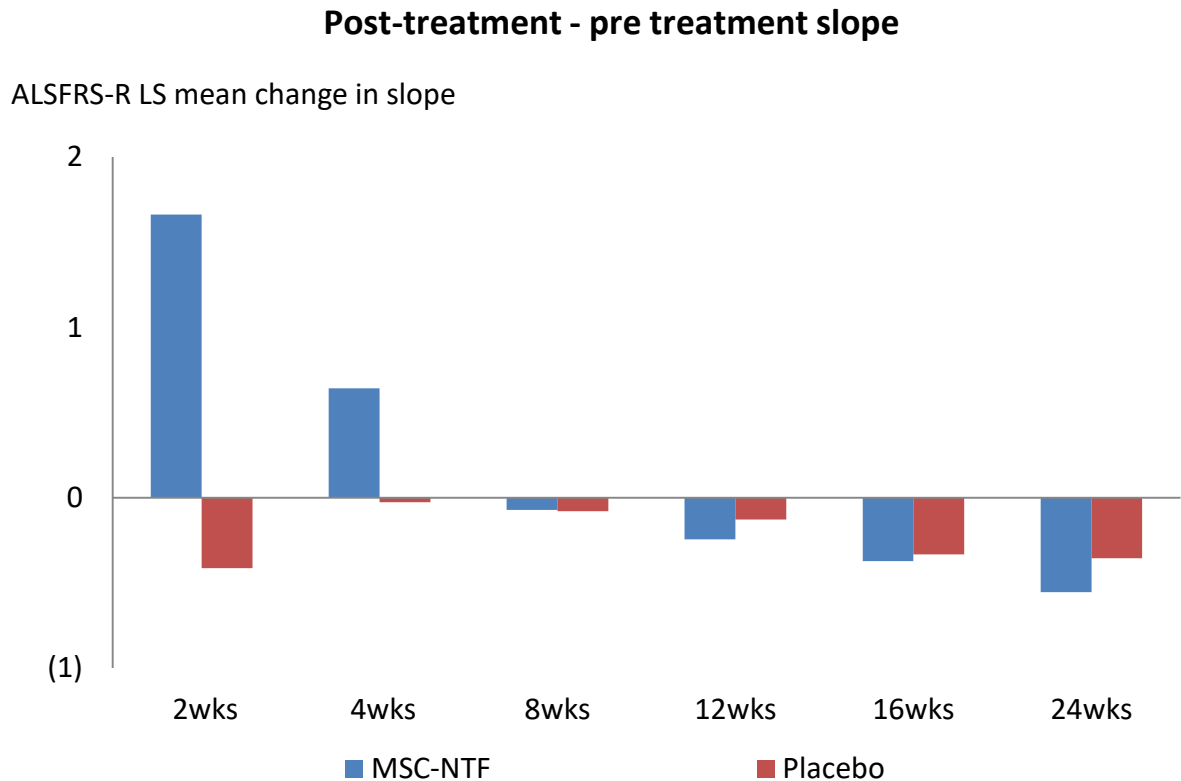
ALS Rapid Progressor Subgroup Has Different Characteristics

- ✓ Change in ALS function in rapid progressors more closely predicts survival and quality of life
- ✓ Higher response rate in rapid progressors enables smaller study
- ✓ Rapid progressors show more inflammation in relevant disease biomarkers

1. NurOwn® Phase 2: ALSFRS-R slope improvement (mean slope change/month)

All participants (n=46)

Rapid progressors (n=21)



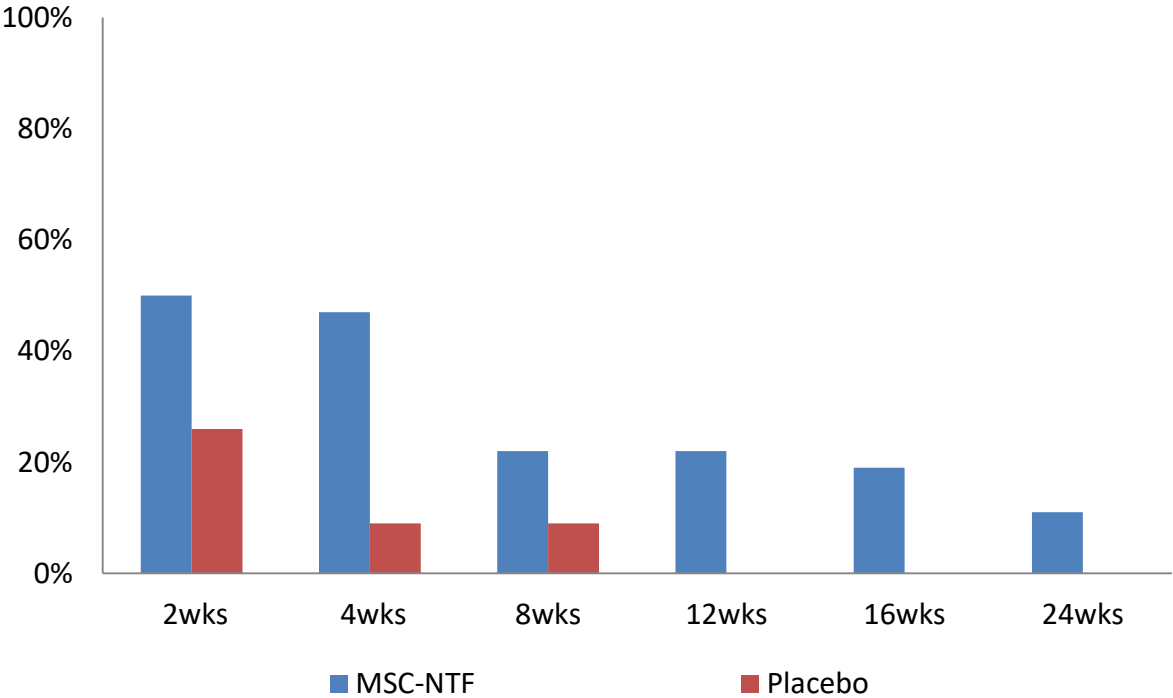
1. $p=0.021$
2. $P=0.033$

2. NurOwn® Phase 2: Responder Analysis: (≥1.5 points/month ALSFRS-R slope improvement)

All participants (n=46)

ALSFRS-R ≥ 1.5 points improvement/month in
post-treatment slope compared to pre-treatment slope

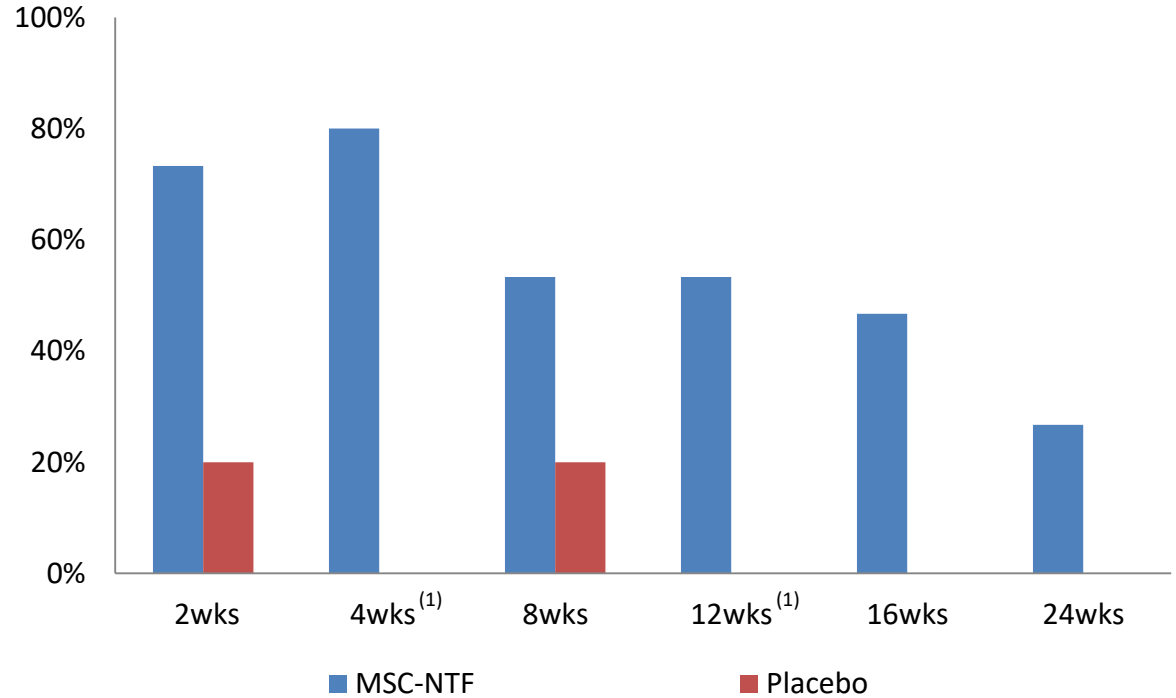
% patients with ≥ 1.5 point improvement/month



Rapid progressors (n=21)

ALSFRS-R ≥ 1.5 points improvement in post-treatment slope
compared to pre-treatment slope

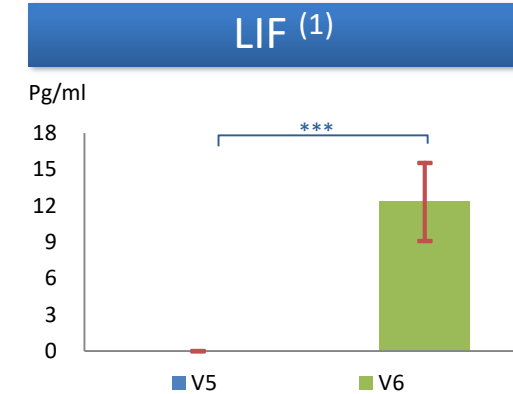
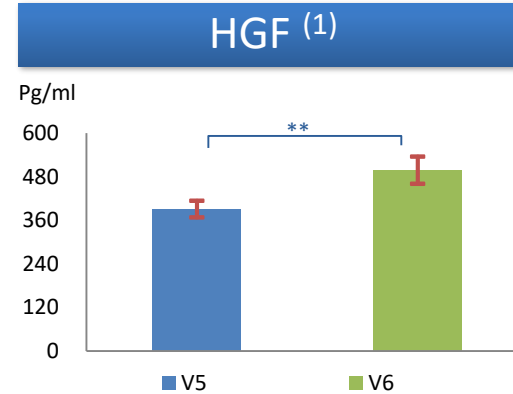
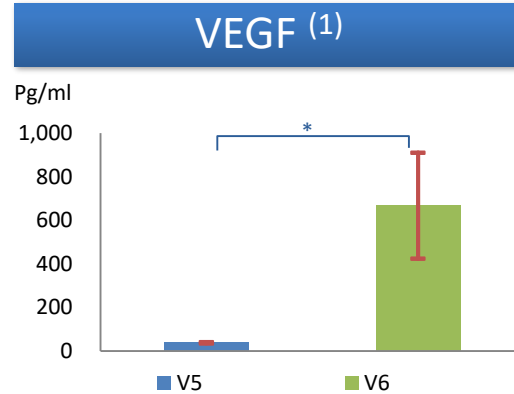
% patients with ≥ 1.5 point improvement/month



1. p<0.05 (two-sided Fisher's exact test)

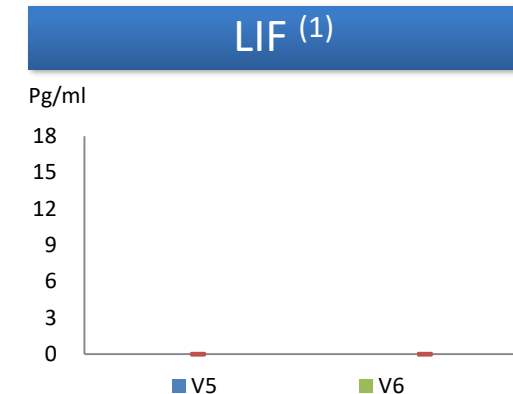
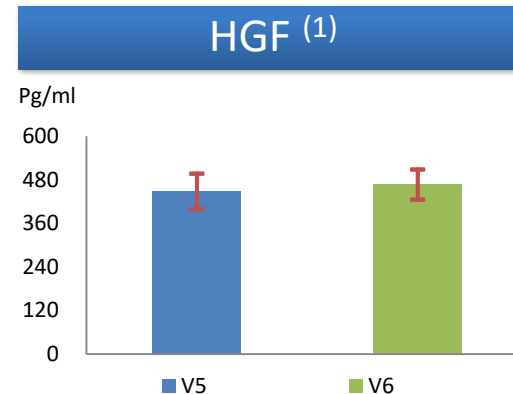
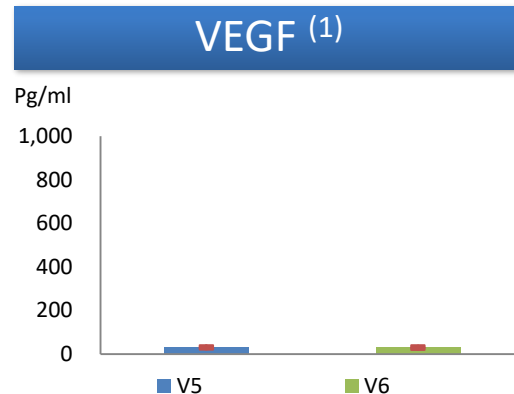
NurOwn® Phase 2 ALS Trial: CSF NTFs Significantly Increased 2 Weeks Post- Treatment Compared to Baseline

NurOwn®
(n = 26)

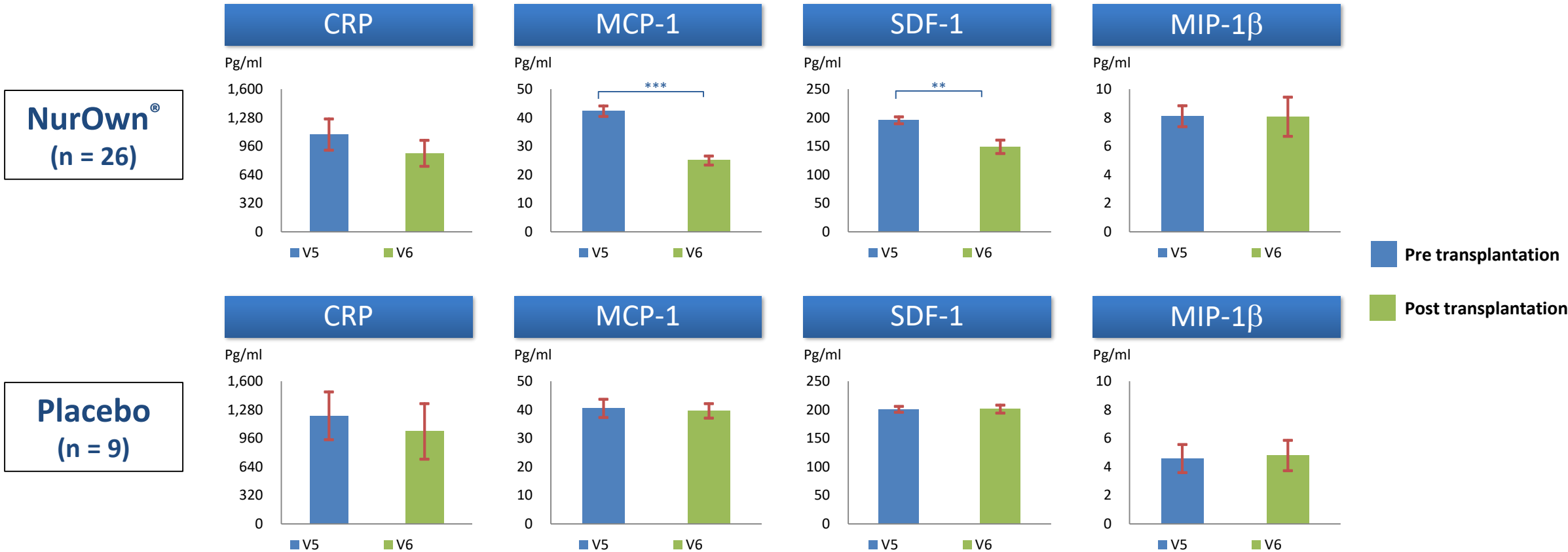


■ Pre transplantation
■ Post transplantation

Placebo
(n = 9)



NurOwn® Phase 2 ALS Trial: CSF Inflammatory Markers Significantly Decreased 2 weeks Post-Treatment Compared to Baseline

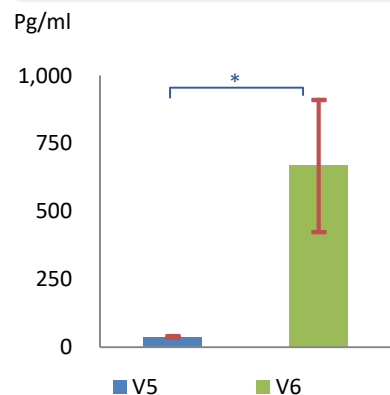


1. Mean ± SEM. $p < 0.01$, $p < 0.001$ for [], respectively.

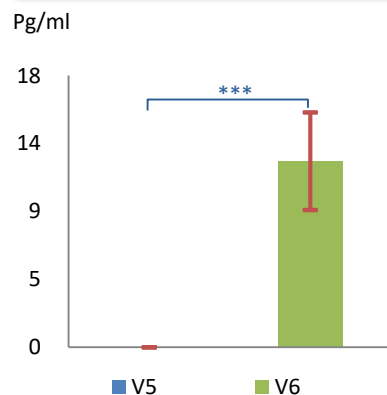
Phase 2 ALS Trial Summary



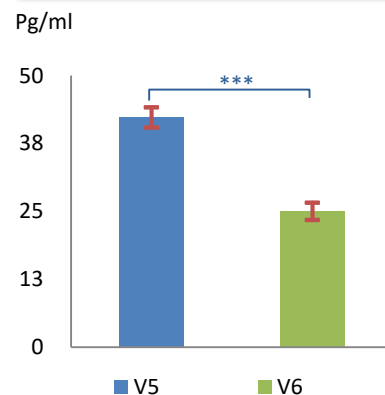
VEGF



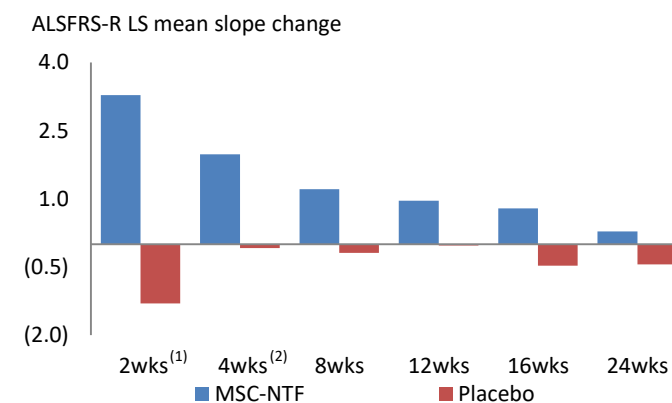
LIF



MCP-1



Change from Post-treatment to pre-treatment slope



1. $p=0.021$
2. $P=0.033$

NurOwn® ALS Phase 3 Clinical Trial

Pre-Treatment

- Inclusion criteria
 - Less than 60 years of age
 - SVC > 65%
 - ALS ≤ 2 years
 - Rapid progressors
- Exclusion criteria
 - Edaravone
 - Ventilation
 - Feeding tube
- Randomization
- Bone Marrow Aspiration

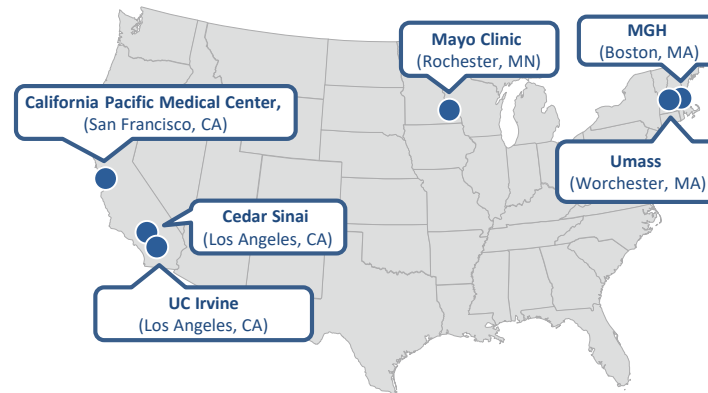
Treatment

- N=200 patients
 - Enrollment completed by mid-2019
- 1:1 randomization
- Study duration: 11.5 months
 - Seven months post-first transplantation
- Top-line data expected mid 2020

Outcomes

- ALSFRS-R responder analysis
- Safety
- ALSFRS-R change from baseline
- SVC
- Tracheostomy-free survival
- CSF/biomarkers (seven samples over six months)

Site Location





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BrainStorm Cell Therapeutics

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Thank You

Appendix

Additional Professional Board Members

June S. Almenoff MD PhD

- Chief Operating Officer & Chief Medical Officer of Innovate Biopharmaceutical
- Formerly President and CMO of Furiex Pharmaceuticals and Board member of Tigenix NV (TIG)

Tony Polverino PhD

- CSO - Kite Pharmaceuticals

Scientific Advisory Board

Jerold Chun, M.D., PhD -Chair

- Neuroscientist, Professor and Senior Vice President of Neuroscience Drug Discovery, Sanford Burnham Prebys Medical Discovery Institute, San Diego CA.

Stanley H. Appel, M.D

- Peggy and Gary Edwards Distinguished Endowed Chair for the Treatment and Research of ALS, Department of Neurology, Neurological Institute, Houston Methodist Hospital, Houston TX.

Amit Bar-Or, M.D.

- Presidential Endowed Chair at the University of Pennsylvania (UPenn/CHOP), Director of the Centre for Neuroinflammation and Experimental Neurotherapeutics and Chief, MS Division, Philadelphia PA.

IP Portfolio

Patent Name/ Int. App. No.	Pending Jurisdictions	Allowed Jurisdictions	Granted Jurisdictions	Expiry Date
ISOLATED CELLS AND POPULATIONS COMPRISING SAME FOR THE TREATMENT OF CNS DISEASES/PCT/IL2006/000699	US		Europe, US	2030
MESENCHYMAL STEM CELLS FOR THE TREATMENT OF CNS DISEASES PCT/ IL2009/000525		Hong Kong	US, Europe, Israel	2032
METHODS OF GENERATING MESENCHYMAL STEM CELLS WHICH SECRETE NEUROTROPHIC FACTORS / PCT/IL2013/050660	Europe, Hong Kong, Israel, Canada, Brazil, Japan	Israel	US, Japan	2038
METHOD OF QUALIFYING CELLS /PCT IL2015/050159	US, Europe, Hong Kong, Israel, Canada, Brazil, Japan			2040
Methods of treating ALS PCT/IL2017/050801	PCT			2042