BrainStorm Cell Therapeutics

NASDAQ: BCLI

brainstorm
cell therapeutics

May 26, 2019

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

Clinical stage biotechnology Company

- Autologous cell therapies for neurodegenerative disease
- Proven Cellular Technology and Robust IP Portfolio

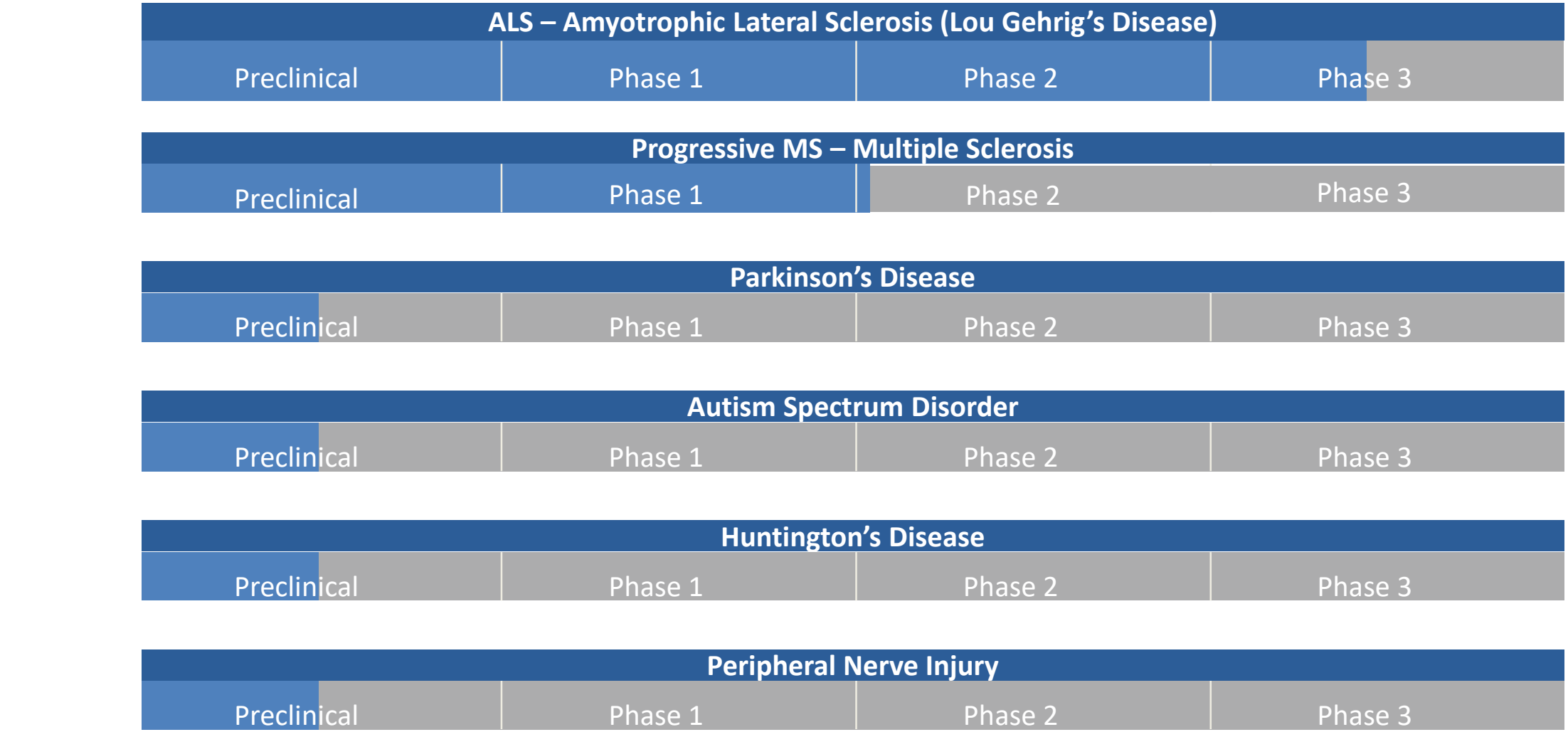
Advanced Clinical Programs

- Amyotrophic Lateral Sclerosis
  Phase 3
- Progressive MS
  Phase 2

Large Addressable Markets

- ALS
  30,000 patients
  (US)
- Progressive MS
  500,000 patients
  (US)

Brainstorm's Cellular Technology Pipeline

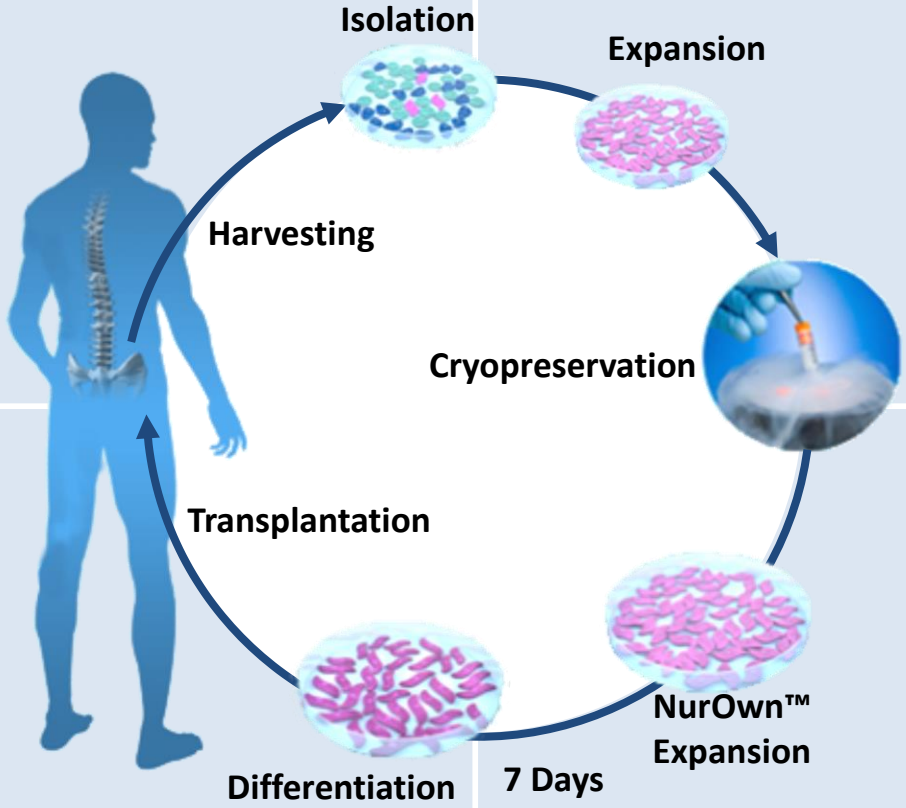


Source: Company filings, equity research, company website.

NurOwn® Process

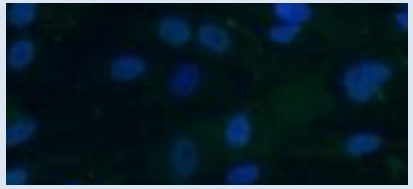
1

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



2

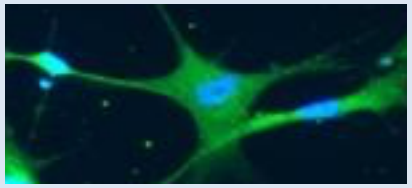
Intermediate MSC product is cryopreserved



The proprietary culture medium induces the cells to secrete additional key neurotrophic factors (MSC-NTF cells)

3

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



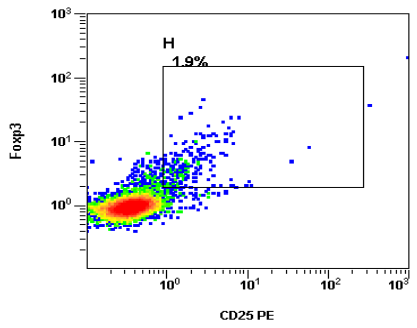
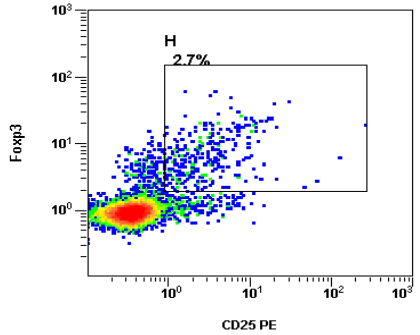
4

NurOwn® Immunomodulation (*in vitro*)

IFN-γ Secretion and T Cell Proliferation Reduced

	Activated PBMC (%)	Activated PBMC co-cultured with MSC-NTF cells (%)	% reduction
IFN-γ secretion	100	6.2 ± 2.24	93.8%
CD4+ T cells proliferation	100	45 ± 8.22	55%

T Regulatory Cells Increased

PBMC only	PBMC co-cultured with MSC-NTF
	

Data on file.

ALS Incidence

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*It is estimated that **450,000** people worldwide are living with ALS, with over **30,000** people in the U.S. suffering from this neurodegenerative condition at any given time.*

What is ALS?

Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease [(1)], is a progressive neurodegenerative disease that affects the function of nerves and muscles. This debilitating condition usually affects people aged 40 to 70, however, individuals in their 20s and 30s 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.

Someone is diagnosed with ALS every

90

minutes

6,000

New US cases per year

$6B

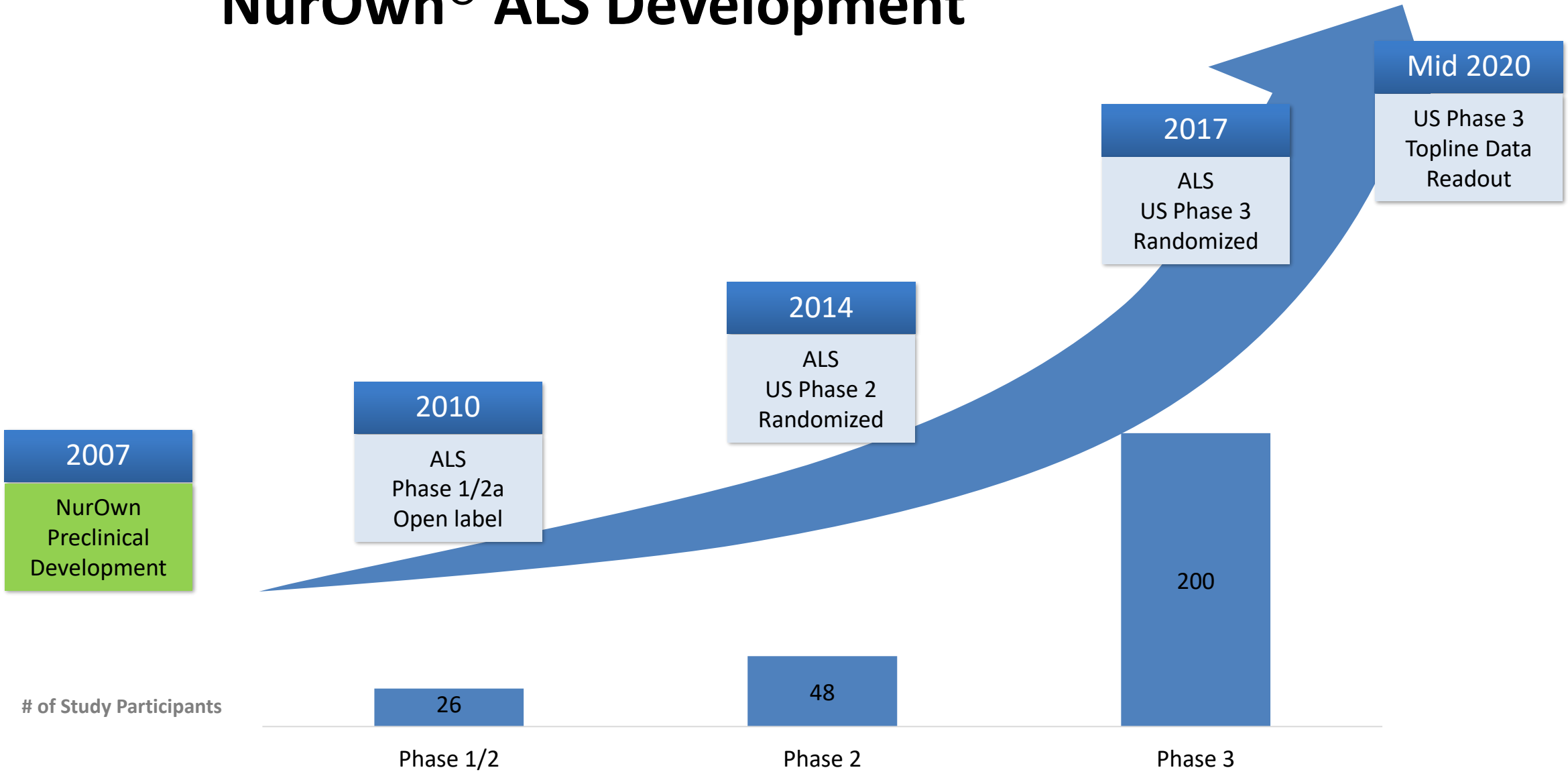
annual health care cost

30

months
Life expectancy from diagnosis

(1) Lou Gehrig was a famous American baseball player diagnosed with ALS in 1939.

NurOwn® ALS Development



ALS Phase 2 Trial Design and Safety Outcomes

Safety Design

- 48 participants (16 per site)
- Randomized 3:1
- Blinded to allocation

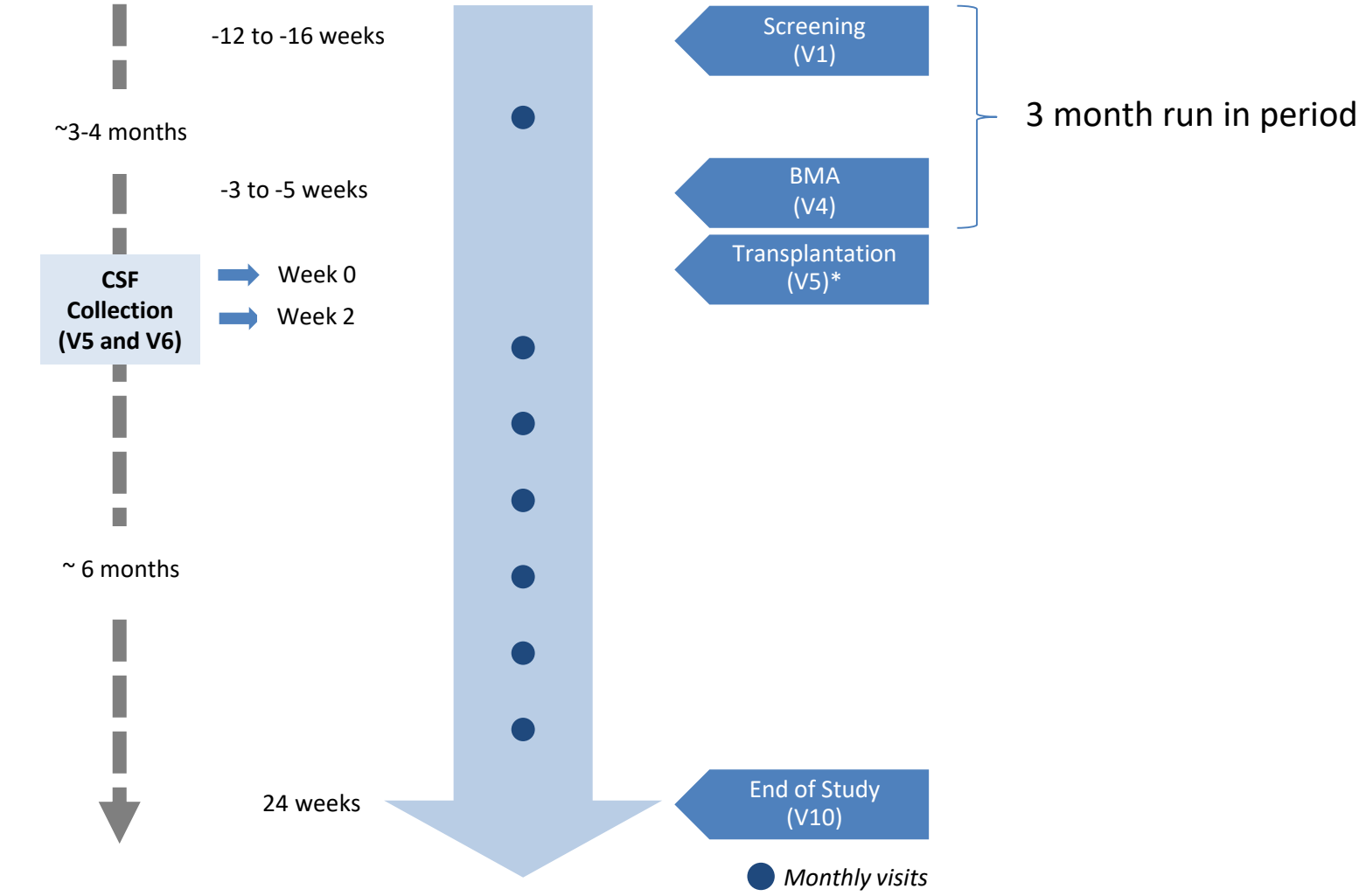
Primary Outcomes

- No deaths or treatment related SAEs
- No drop outs related to SAEs
- Most common adverse events transient and mild/moderate severity and procedure related

Efficacy

- ALSFRS-R
- SVC

Study Timeline



Phase 2 Trial – Approach to Data Analysis

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Phase 2 Trial Efficacy Analysis

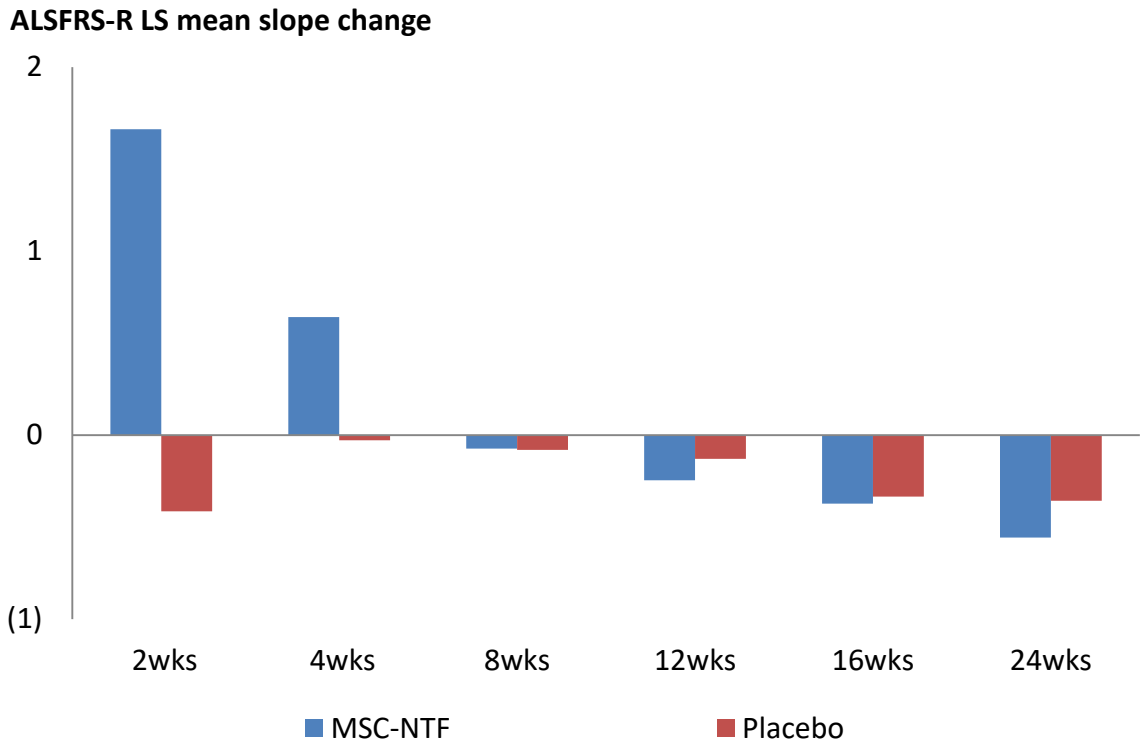
- Mean change in ALSFRS-R slope
- ALSFRS-R Responder Analysis
- Rapid progressor subgroup prespecified

ALS Rapid Progressor Subgroup

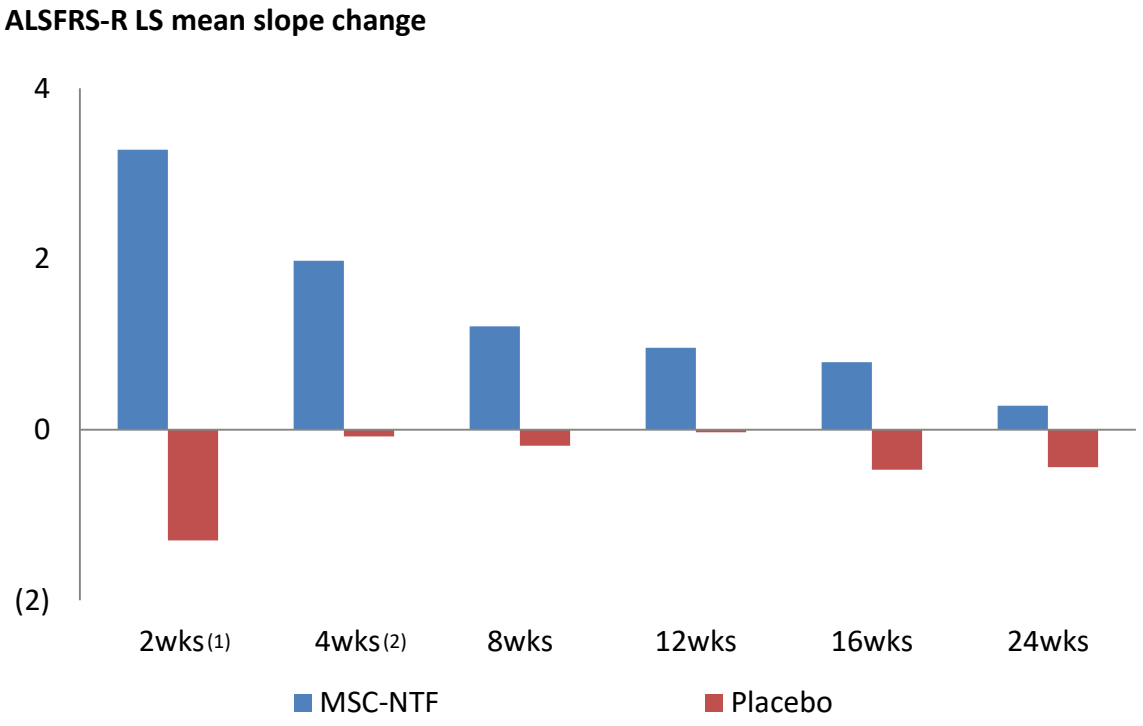
- ✓ Higher correlation of ALSFRS-R change with survival
- ✓ Higher response rate (~2x)
- ✓ Higher levels of CSF inflammatory biomarkers

ALSFRS-R slope improvement (mean pre-post LS mean slope change/month)

All participants (n=46)



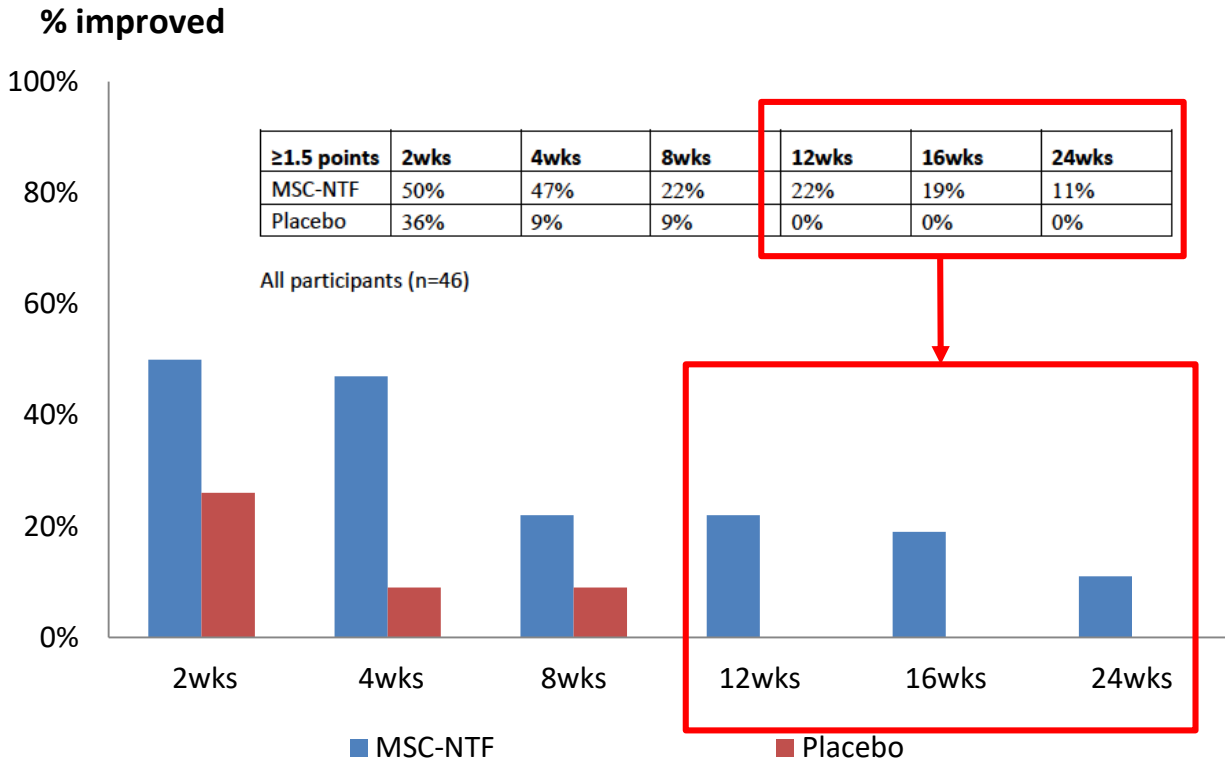
Rapid progressors (n=21)



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

Responder Analysis: ≥1.5 points/month ALSFRS-R slope improvement at each time point

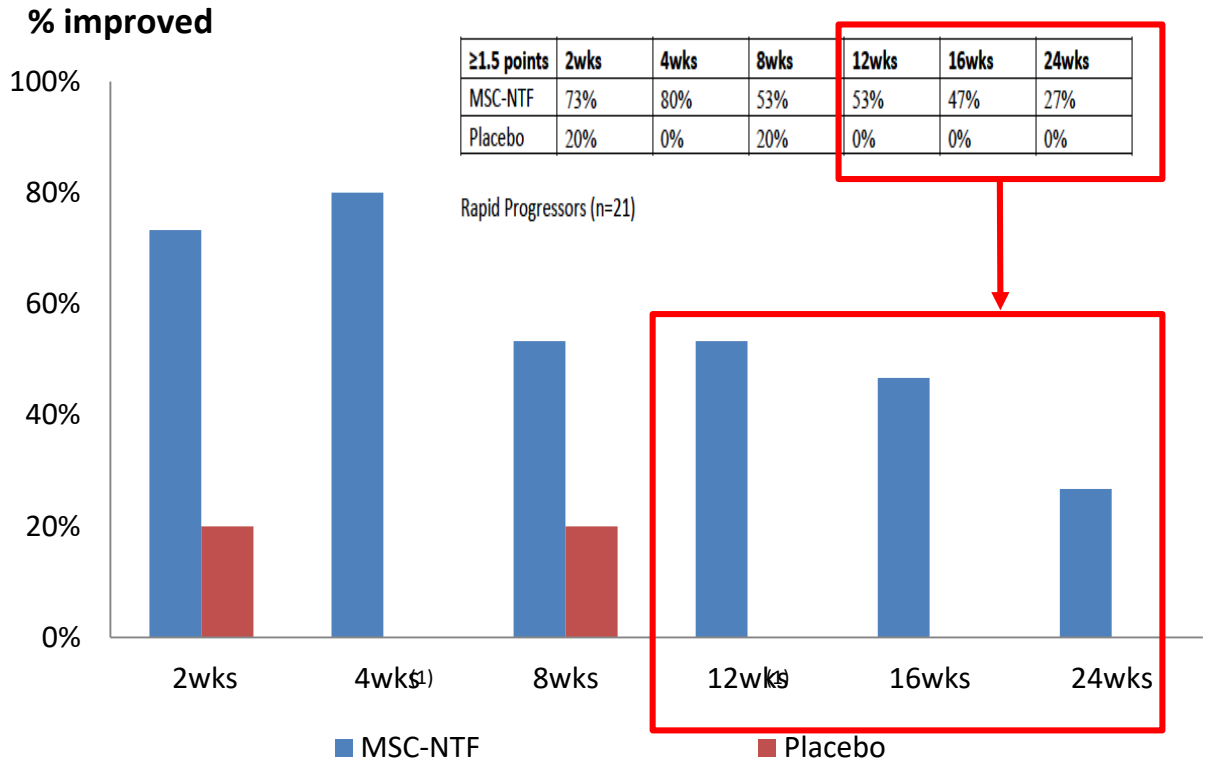
All participants (n=46)



≥1.5 points	2wks	4wks	8wks	12wks	16wks	24wks
MSC-NTF	50%	47%	22%	22%	19%	11%
Placebo	36%	9%	9%	0%	0%	0%

All participants (n=46)

Rapid progressors (n=21)

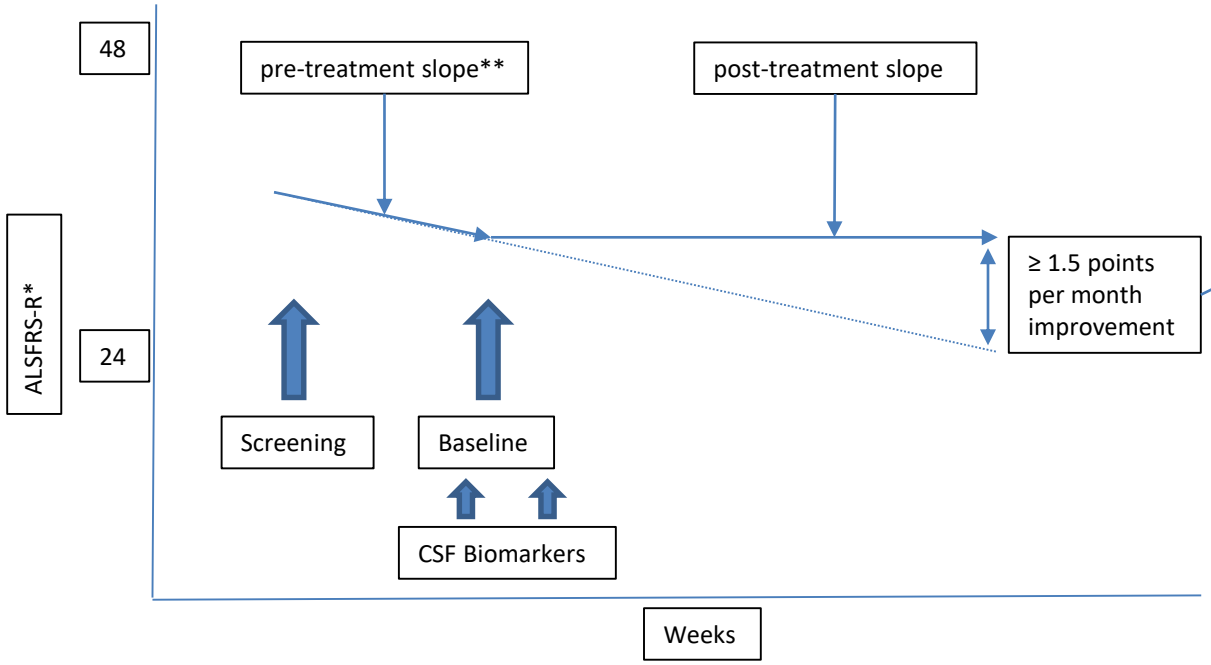


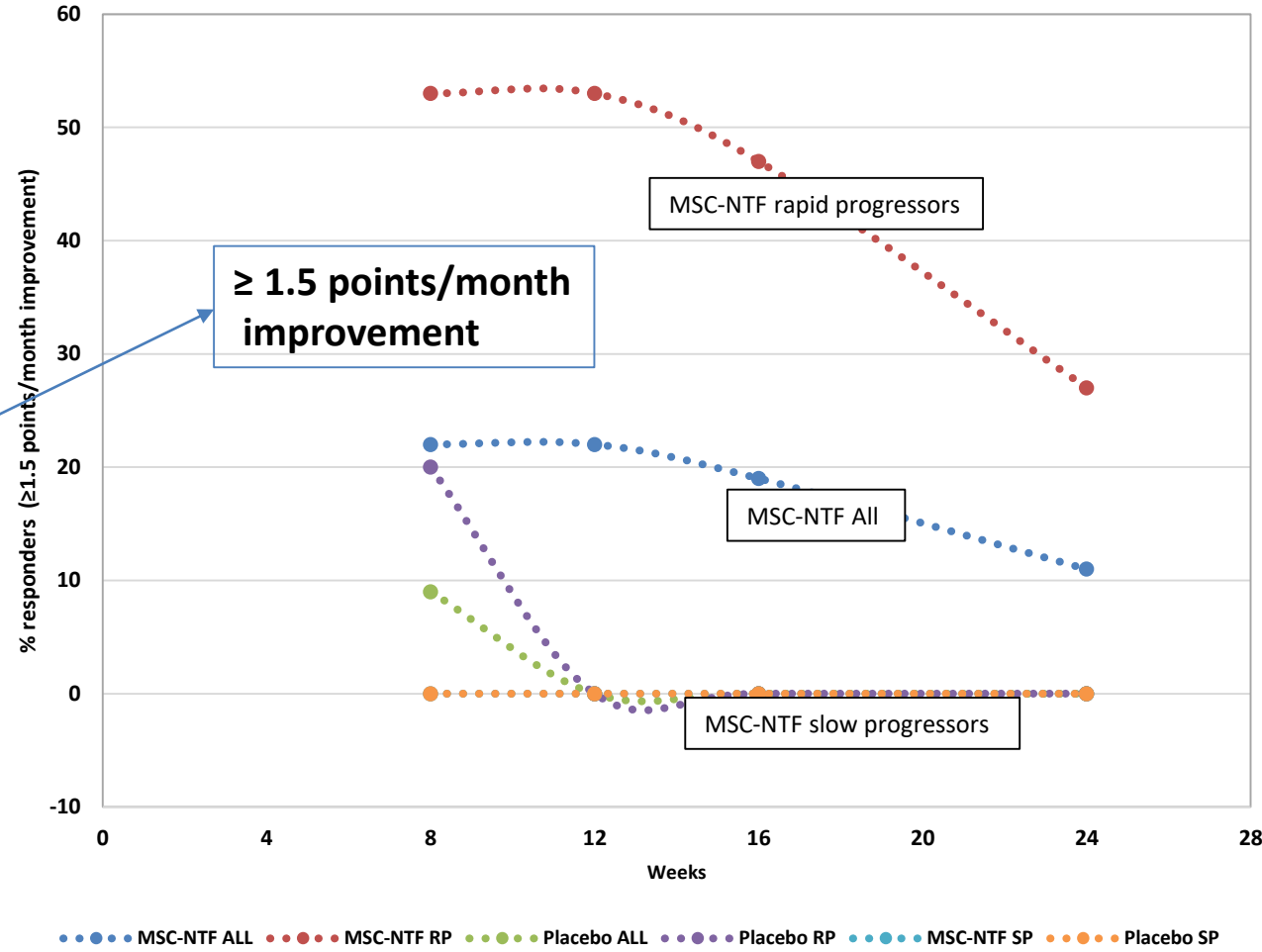
≥1.5 points	2wks	4wks	8wks	12wks	16wks	24wks
MSC-NTF	73%	80%	53%	53%	47%	27%
Placebo	20%	0%	20%	0%	0%	0%

Rapid Progressors (n=21)

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

NurOwn Phase 2 ALSFRS-R slope responder analyses





*monthly ALSFRS-R
** rapid progressor > 0.7 points/month decline

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

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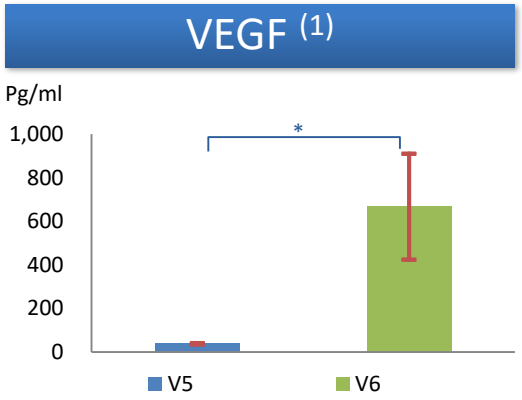
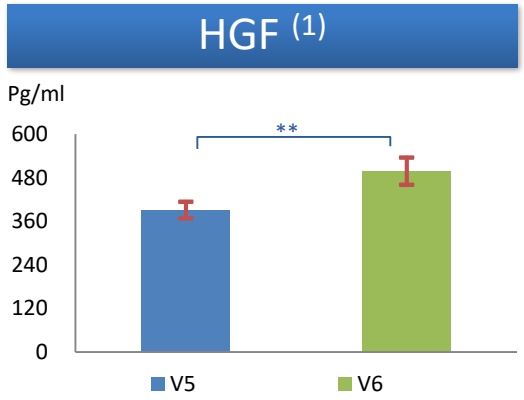
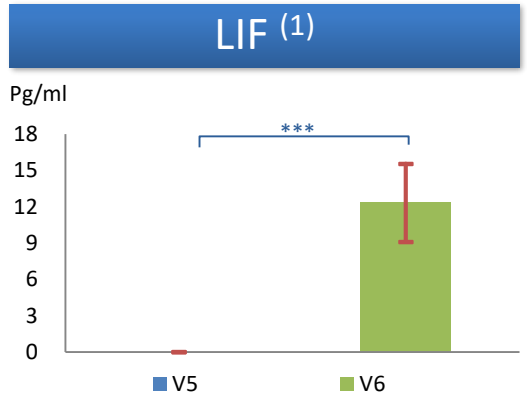
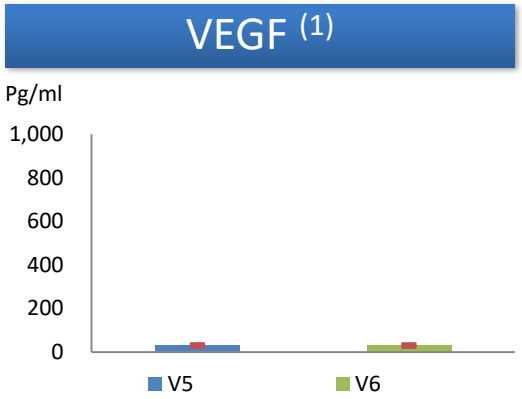
NurOwn®
(n = 26)

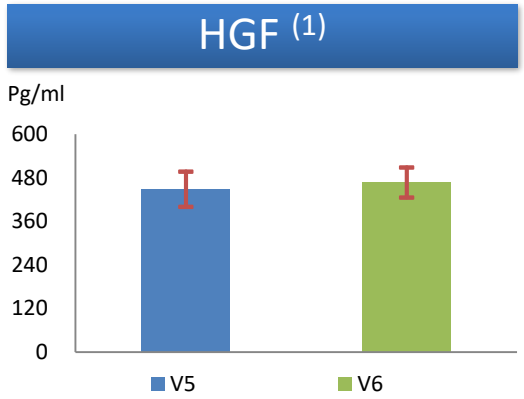


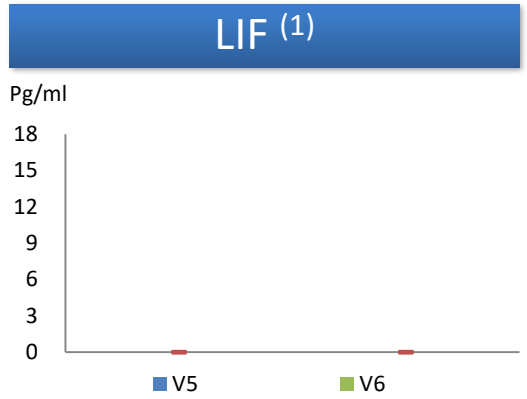




Placebo
(n = 9)







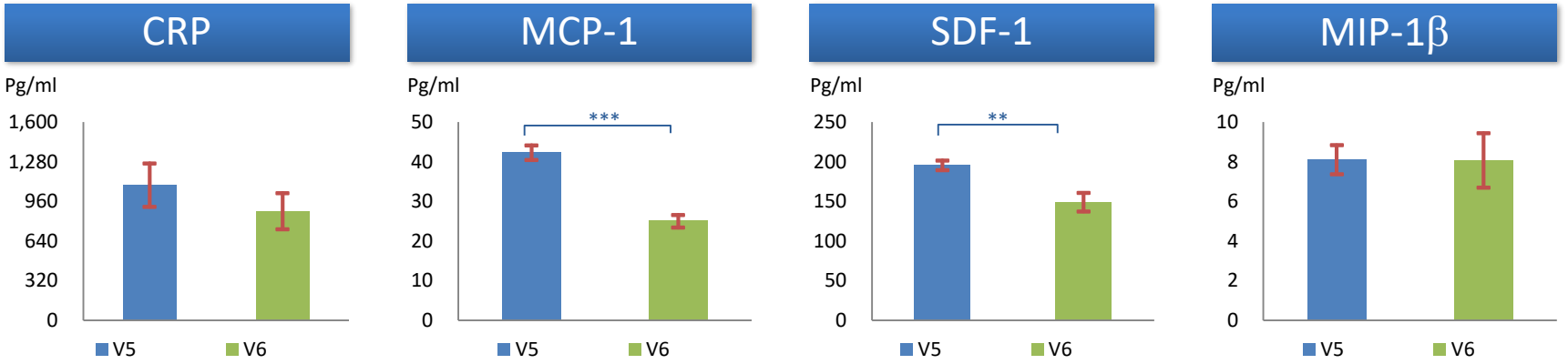
Pre transplantation

Post transplantation

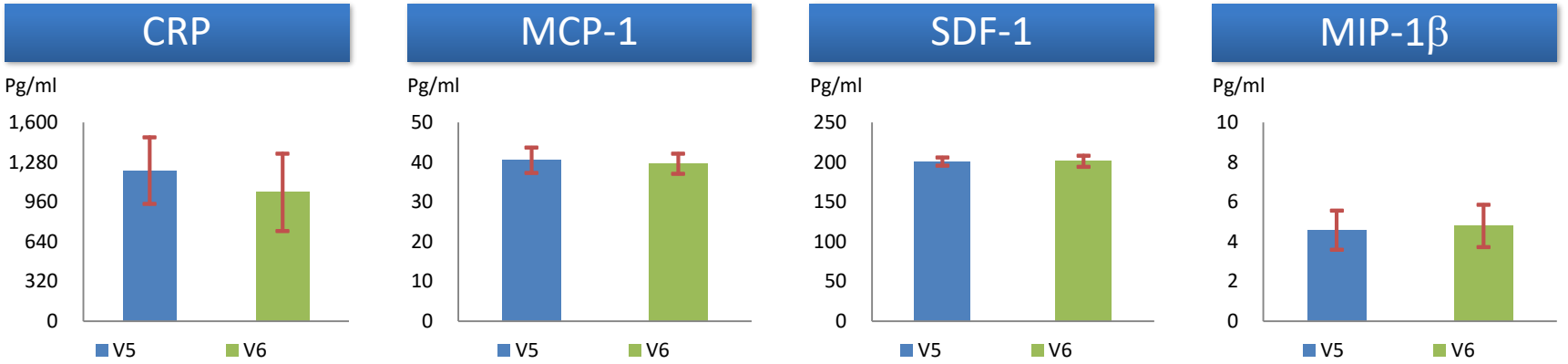
1. *Mean ± SEM. p< 0.05, p<0.01, p< 0.001 for VEGF, HGF and LIF, respectively.*

NurOwn® Phase 2 ALS Biomarkers: CSF Inflammation Significantly Decreased 2 weeks Post-Treatment Compared to Baseline

NurOwn®
(n = 26)



Placebo
(n = 9)



Pre transplantation

Post transplantation

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

NurOwn® Phase 2 ALS Trial Summary

- Intrathecal treatment was safe and well tolerated
- Repeat dosing is needed (2 month dosing interval)
- Rapid progressor subgroup showed higher efficacy
- CSF biomarker analyses confirmed mechanism of action

NurOwn® ALS Phase 3 Clinical Trial

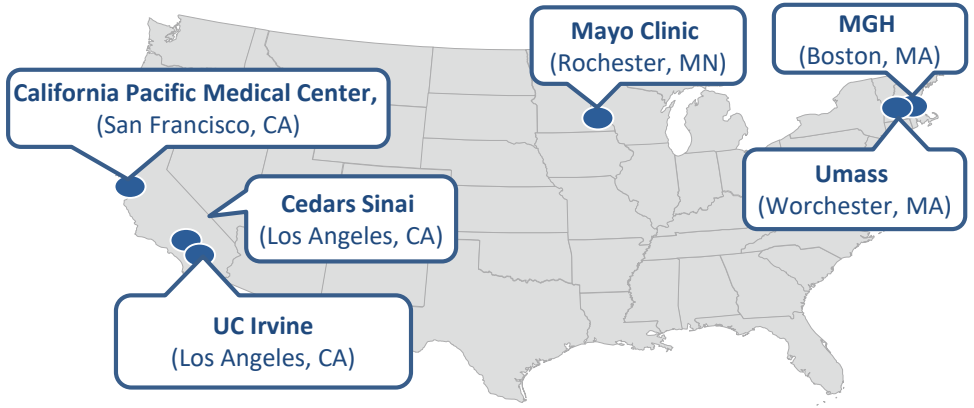
Pre-Treatment

- 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

Site Location



Outcomes

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

AAN May 2019 abstracts

Modulation of CSF Caspase-3 in MSC-NTF (NurOwn®) in a Phase-2 ALS study: correlations with CSF biomarkers and clinical response

Revital Aricha, Haggai Kaspi, Merit Cudkowicz, James Berry, Anthony Windebank, Nathan Staff, Margaret Ayo Owegi, Yossef S. Levy, Chaim Lebovits, Robert Brown, Yael Gothelf, Ralph Kern

Molecular Characterization of VEGF Secretion by MSC-NTF Cells (NurOwn®): Therapeutic Implications in ALS

Haggai Kaspi, Revital Aricha, Natalie Abramov, Yael Gothelf, Chaim Lebovits, Joseph Petroziello, Yossef S. Levi, Ralph Kern

AAN 2019 Emerging Science Data Blitz

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MODULATION OF CSF CASPASE-3 IN MSC-NTF CELLS (NUROWN®) IN A PHASE 2 ALS STUDY: CORRELATIONS WITH CSF BIOMARKERS AND CLINICAL RESPONSE

Revital Aricha[1], Haggai Kaspi[1], Merit Cudkowicz[2], James Berry[2], Anthony Windebank[3], Nathan Staff[3], Margaret Ayo Owegi[4], Yossef S. Levy[1], Chaim Lebovits[1], Robert Brown[4], Yael Gothelf[1], **Ralph Kern[1]**

1. BrainStorm Cell Therapeutics, Petach Tikva, Israel and New York, NY.

2. Massachusetts General Hospital, Boston, MA. 3. Mayo Clinic, Rochester, MN. 4. UMass Medical School, Worcester, MA.

Phase 2 Study: CSF Biomarkers and Responder Analysis

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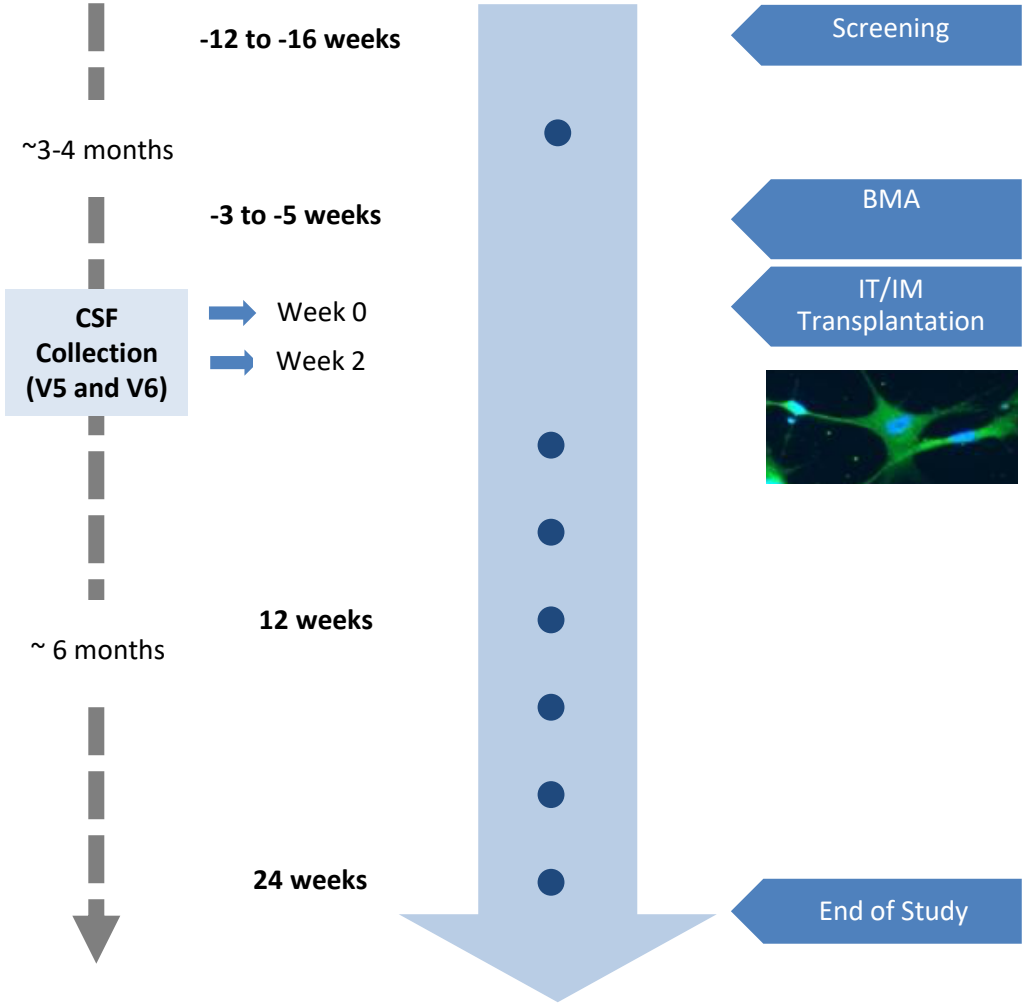
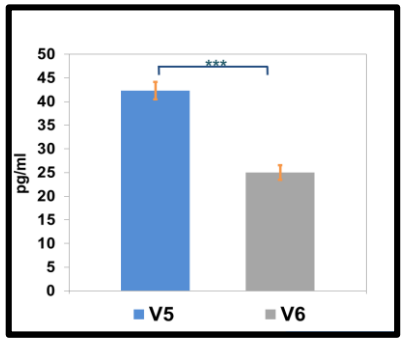
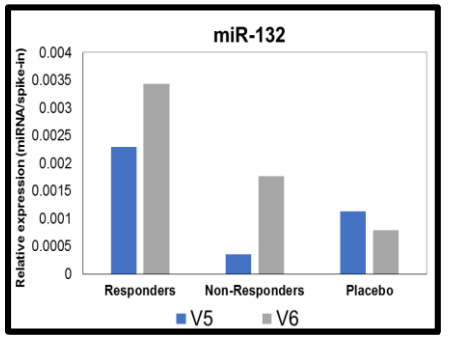
Study Design n=48 (3:1 randomization)



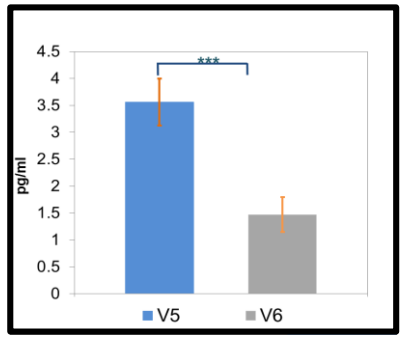
↓MCP-1



↑miR-132

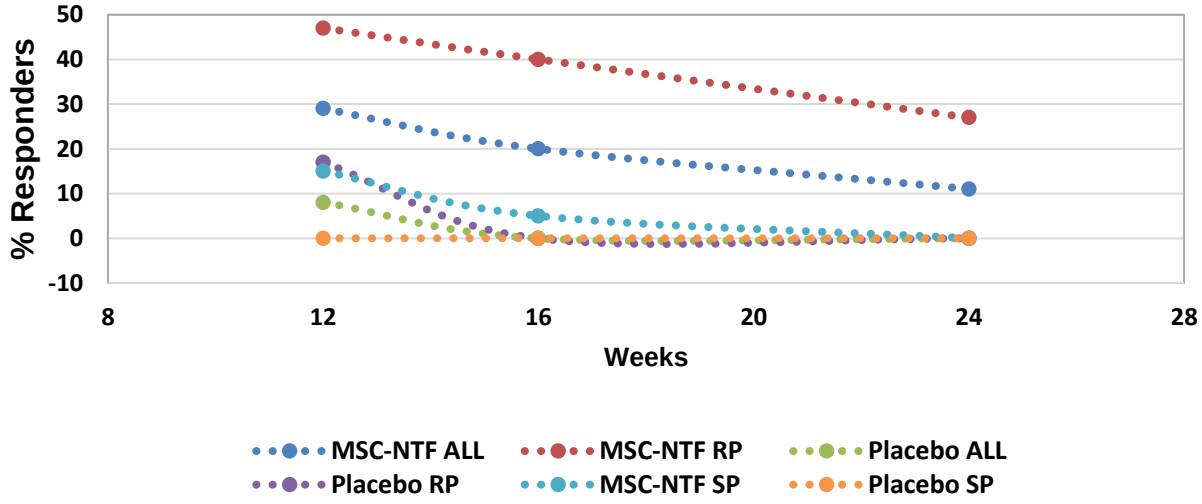


↓Caspase 3

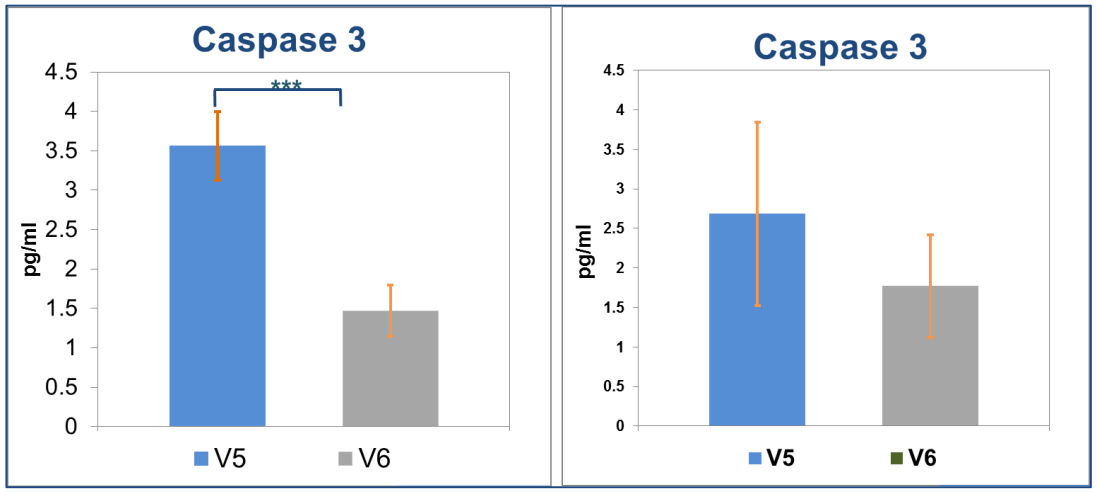


*** p< 0.001

Responder analysis: 100% ALSFRS-R slope improvement



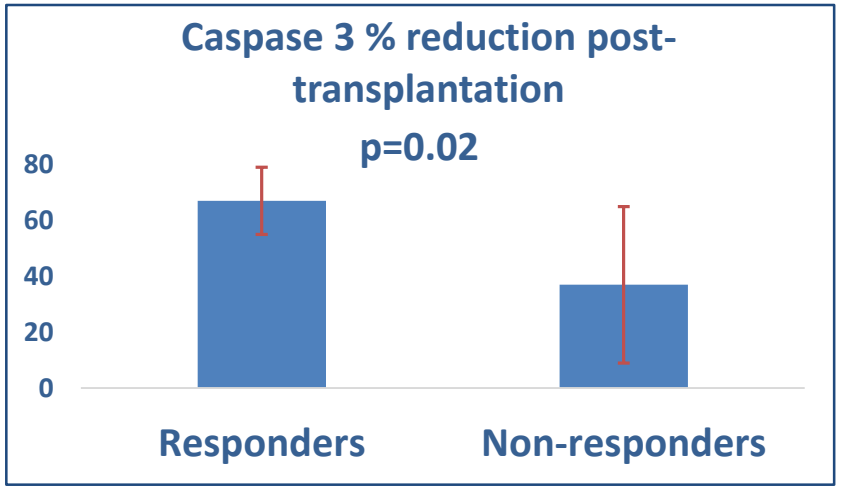
2X Greater CSF Caspase-3 % reduction in responders compared to non-responders at 12 weeks post-transplantation*



MSC-NTF cells

Placebo

*** p< 0.001



*Responder defined as ≥100% ALSFRS-R slope improvement at 12 weeks

NurOwn® (MSC-NTF cells) may tip the balance linking neuronal cell death and neuroinflammation

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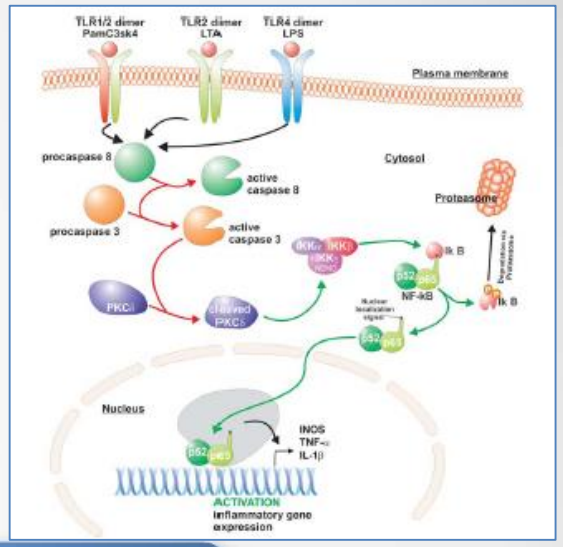
Neuronal apoptosis activates neuroinflammation via NFκ-B



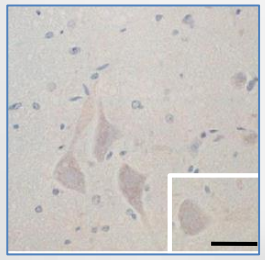
MSC-NTF Cell Neuroprotection

MSC-NTF Cell Immunomodulation

Review

The executioners sing a new song: killer caspases activate microglia

JL Venero[1], MA Burguillos[2,3], P Brundin[3] and B Joseph[*,2]



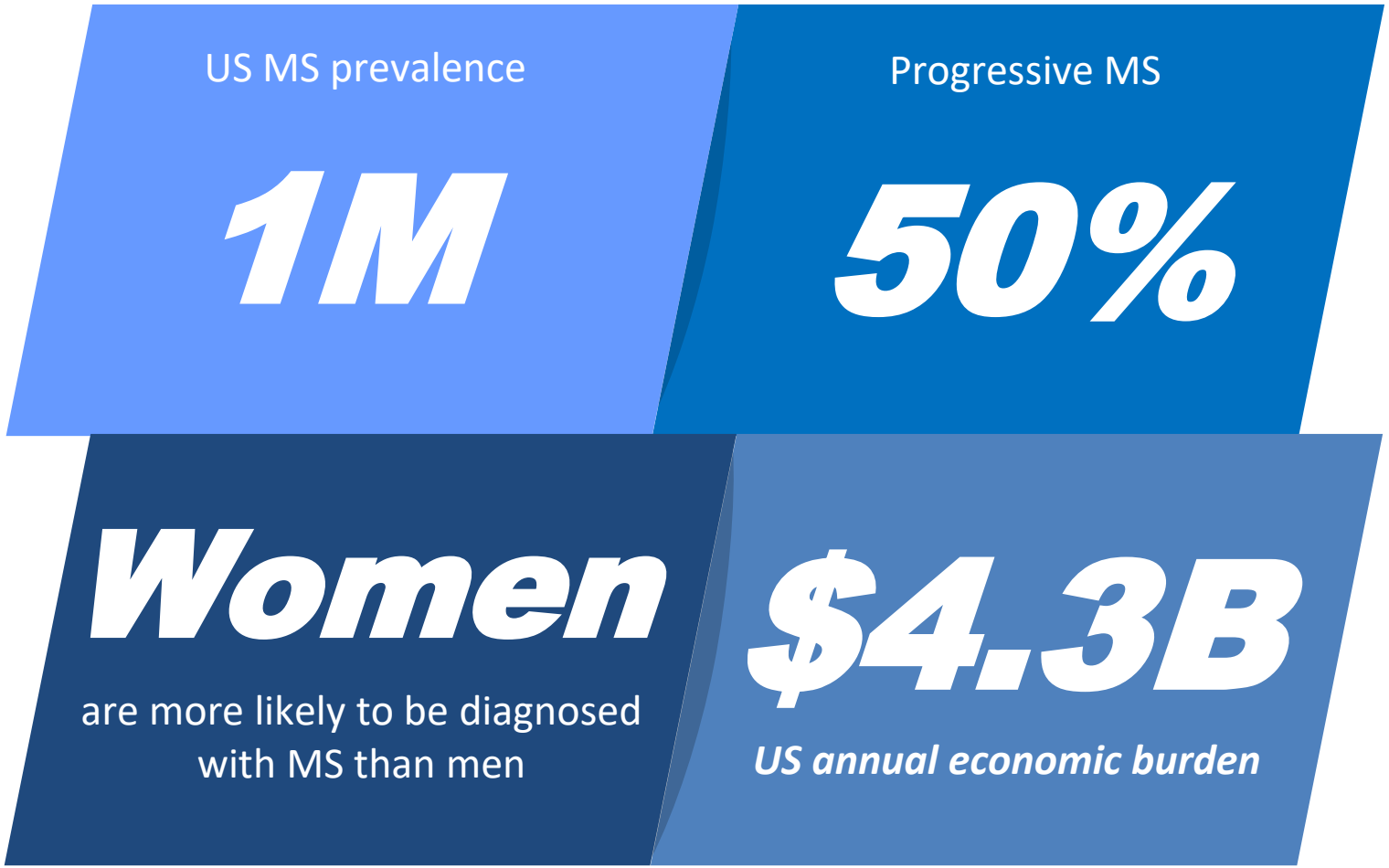
Functional Role of Caspase-1 and Caspase-3 in an ALS Transgenic Mouse Model

Mingwei Li,[1] Victor O. Ona,[1] Christelle Guégan,[2] Minghua Chen,[1] Vernice Jackson-Lewis,[2] L. John Andrews,[1] Adam J. Olszewski,[1] Philip E. Stieg,[1] Jean-Pyo. Lee,[4] Serge Przedborski,[2,3] Robert M. Friedlander[1]*

Cell Death and Differentiation 2011

Dahlke *et al. Journal of Neuroinflammation* (2015) 12:215

Progressive MS Unmet Need



Nature Review Disease Primers. November 2018

Progressive MS Rationale

Chronic/trapped CNS inflammation

- Leptomeningeal inflammation[1]
- Chronic macrophage/microglia activation[2]
- Slowly expanding/evolving lesions[3]

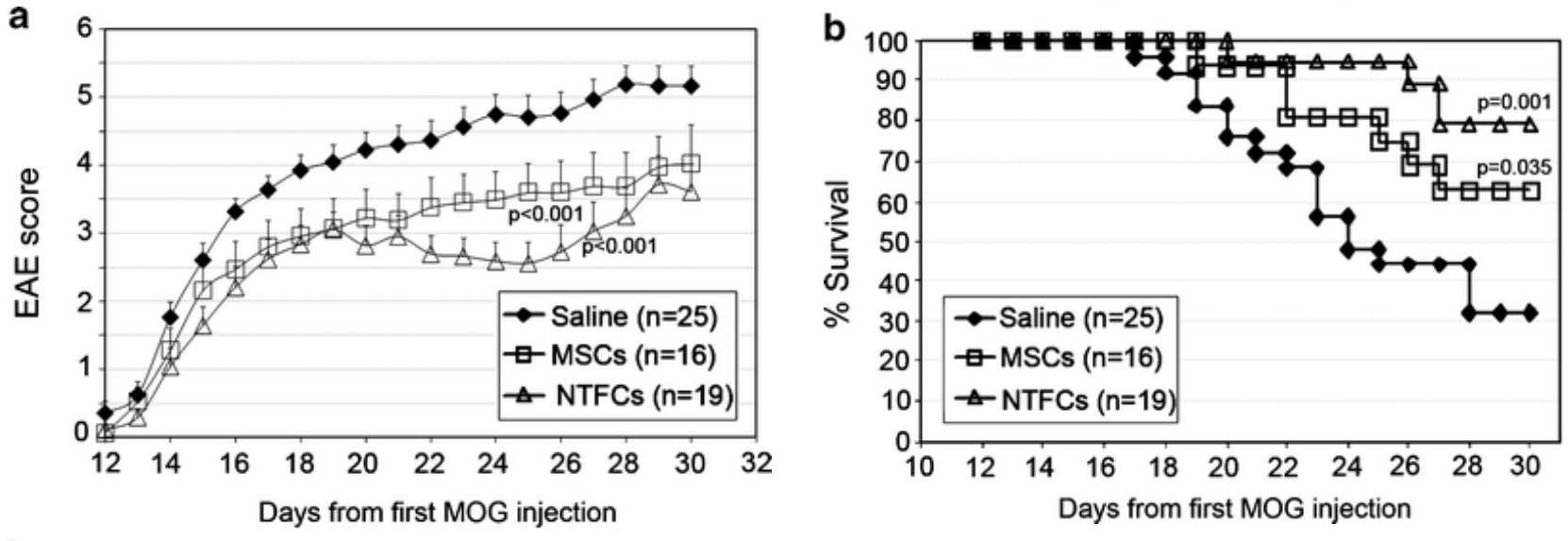
Impaired Neurotrophic Factor signaling in Progressive MS

- MS treatment failure rate correlates with BDNF methylation status[4]
- Reduced expression of BDNF in SPMS[5]
- Reduced CSF VEGF in SPMS[6]

1. Colasanti A, *et al*. *J Nucl Med* 2014;55:1112–1118;
2. Absinta M, *et al*. *Neurology* 2015;85:18–28;
3. Dal-Bianco A, *et al. Acta Neuropath* 2017;133:25–42.
4. PLOS ONE 2018
5. J Neuroimmunology 2002
6. PLOS ONE 2011

MS Preclinical

MSC-NTF vs. MSC in EAE Model



Intracerebroventricular injection of $2.5X10^5$ cells

Barhum et al 2009 J. Mol. Neur.

MS Phase 2 Clinical Trial- Timelines

- IND granted December 2018
- Repeat dosing intrathecal MSC-NTF cells (NurOwn®)
- 5 leading US MS centers
- Validated MS clinical outcomes and biomarkers
- First patient enrolled March 2019, top line data mid 2020

Brainstorm Executive Management Team

Chaim Lebovits
President and CEO

Ralph Kern, MD, MHSc
COO and CMO

Eyal Rubin
EVP, CFO

Arturo Araya
VP, Chief Commercial Officer

Mary Kay Turner
VP, Patient Advocacy and Government Affairs

Joe Petroziello BS MS
VP, Scientific and Corporate Communications

Yael Gothelf PhD.
VP, Scientific and Regulatory Affairs

Uri Yablonka
EVP, Chief Business Officer

Yossef Levy PhD.
VP, Cell Production

Revital Aricha PhD.
VP, R&D

Susan Ward PhD
Head Clinical Research Operations

BrainStorm Cell Therapeutics

NASDAQ: BCLI

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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
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