

BrainStorm Cell Therapeutics

NASDAQ: BCLI



brainstorm
cell therapeutics

February 2020

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	ADVANCED STAGE CLINICAL PROGRAMS	LARGE ADDRESSABLE MARKETS
Potential to be first-in-class autologous stem cell therapy for ALS and other neurodegenerative diseases	Repeat Dose Phase 3 ALS trial fully enrolled	ALS 30,000 patients (US) 450,000 (Worldwide)
Experienced US management team; R&D in Israel	Repeat Dose Phase 2 Progressive MS Trial actively enrolling	Progressive MS 500,000 patients (US) 1,250,000 (Worldwide)
Robust IP portfolio	Robust Phase 2 clinical data in ALS; promising preclinical data in other neurodegenerative disease	Neurodegenerative disease prevalence expected to increase as population ages

Brainstorm's Pipeline

ALS – Amyotrophic Lateral Sclerosis (Lou Gehrig's Disease)				
Preclinical	Phase 1	Phase 2	Phase 3	

Progressive MS – Multiple Sclerosis				
Preclinical	Phase 1		Phase 2	Phase 3

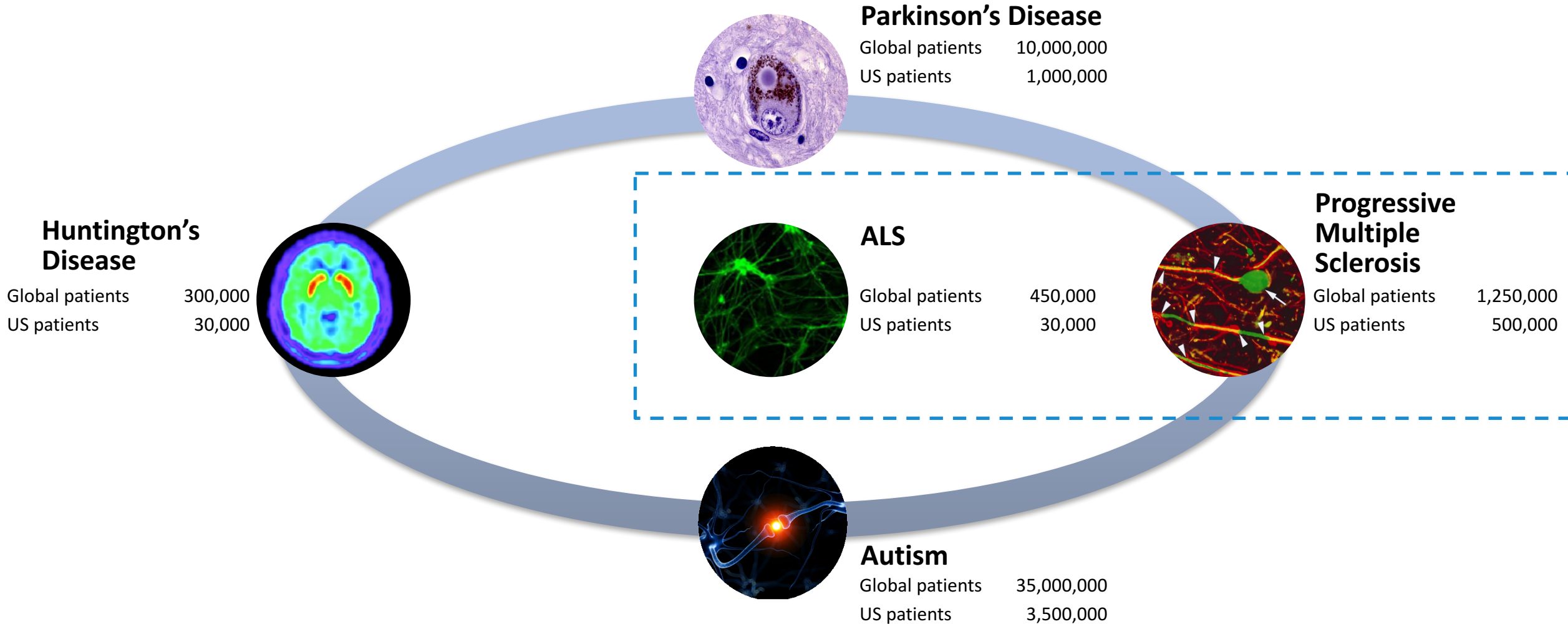
Parkinson's Disease				
Preclinical	Phase 1	Phase 2	Phase 3	

Autism Spectrum Disorder				
Preclinical	Phase 1	Phase 2	Phase 3	

Huntington's Disease				
Preclinical	Phase 1	Phase 2	Phase 3	

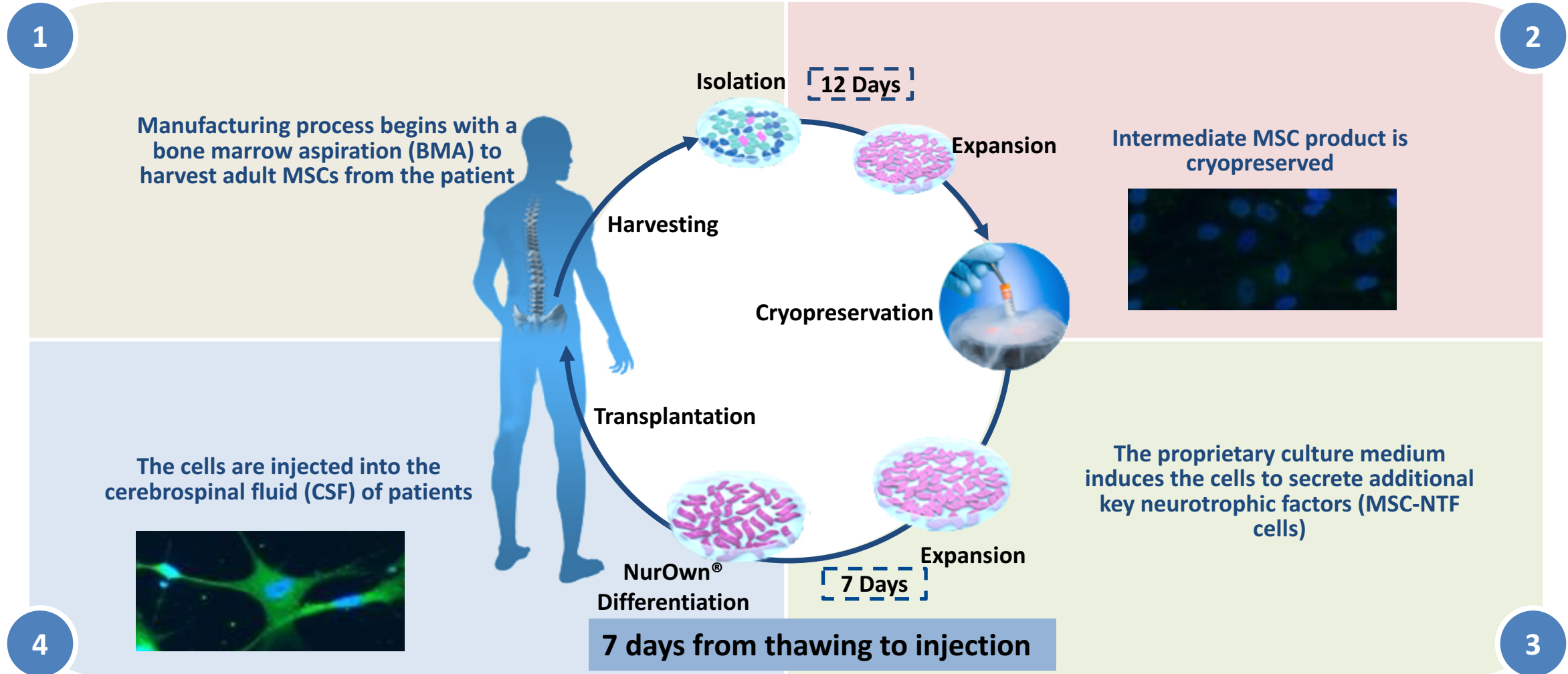
Peripheral Nerve Injury				
Preclinical	Phase 1	Phase 2	Phase 3	

NurOwn® - A Platform Technology Across CNS



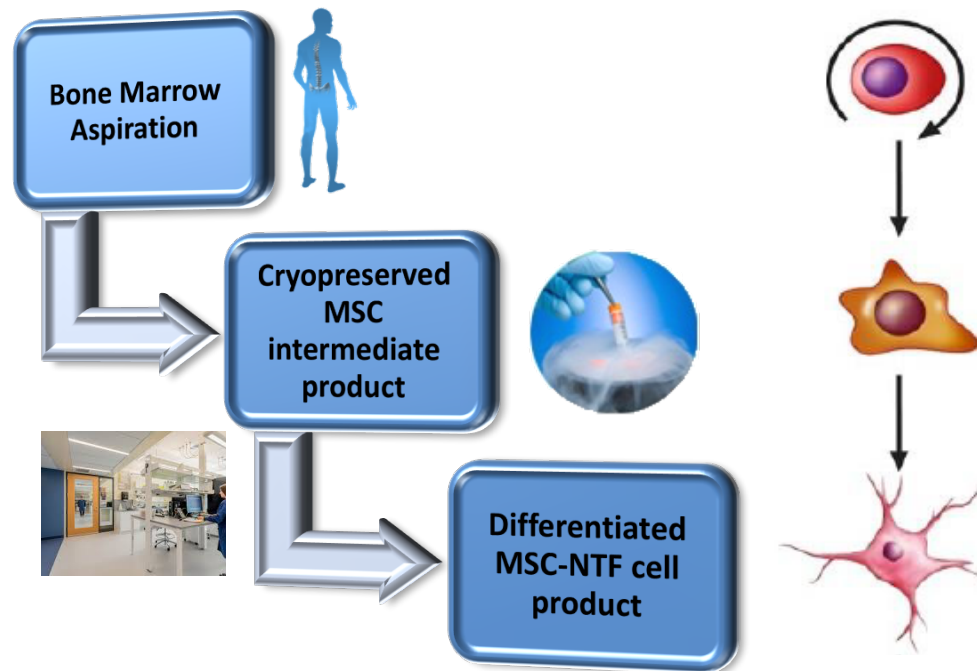
NurOwn® is successfully evaluated in preclinical models of various neurodegenerative disease

NurOwn® Process

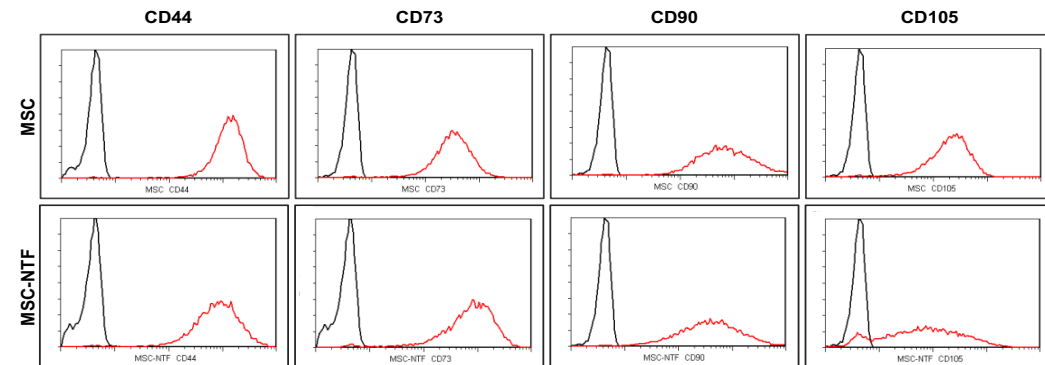


Cryopreserved intermediate product brings us very close to the convenience of allogeneic with the established safety of autologous

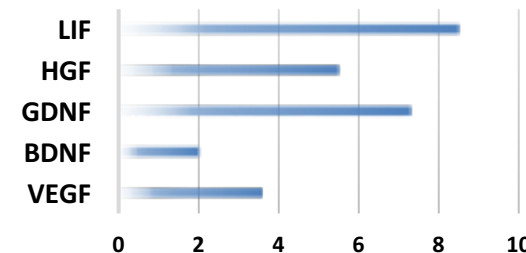
NurOwn® (MSC-NTF Cells) Technology



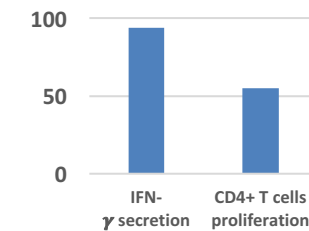
MSC Cell Identity (Surface Markers)



Neuroprotection (Fold Increase NTFs MSC-NTF vs. MSC)

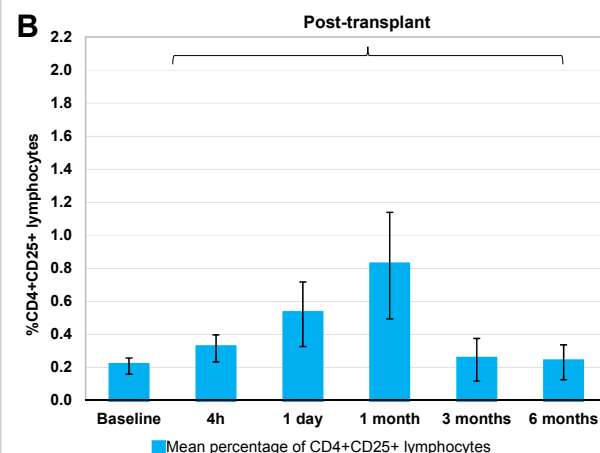
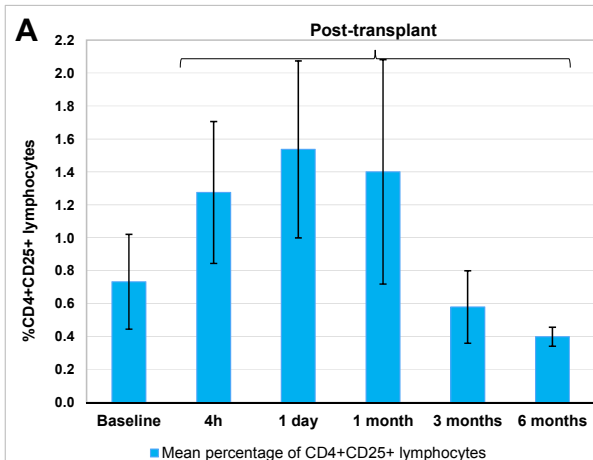


Immunomodulation Co-culture MSC-NTF and PBMCs (% Reduction)



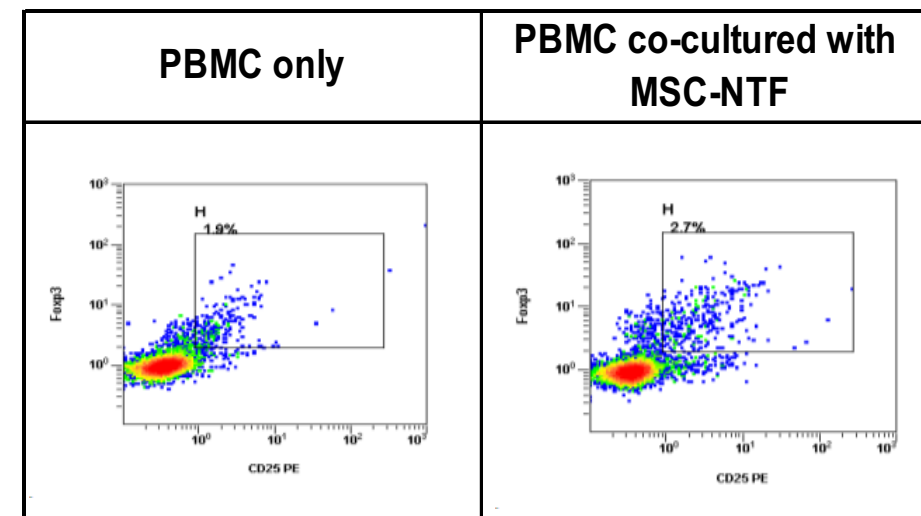
NurOwn[®] increases Treg Cells

T Regulatory Cells Increased in Phase 1/2a

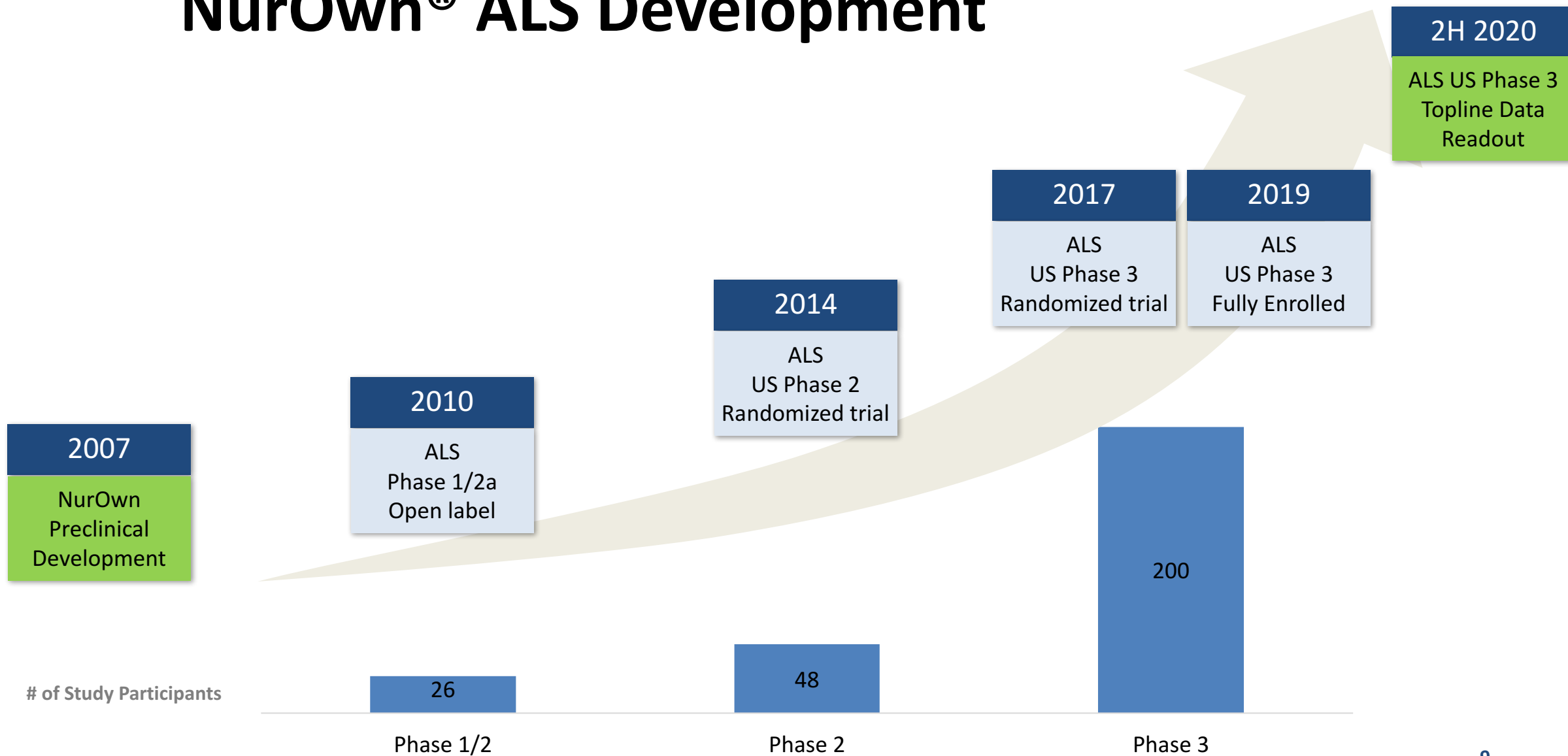


Mean percentage $\pm$ SEM of peripheral blood lymphocytes stained positive for CD4 and CD25 surface markers (double staining) using FACS analysis, in ALS patients treated with MSC-NTF cells, in the Phase 1/2 trial (A) and in the Phase 2a (B) study at the indicated pre- (baseline) and post-treatment time- points.

T Regulatory Cells Increased In-vitro



NurOwn® ALS Development



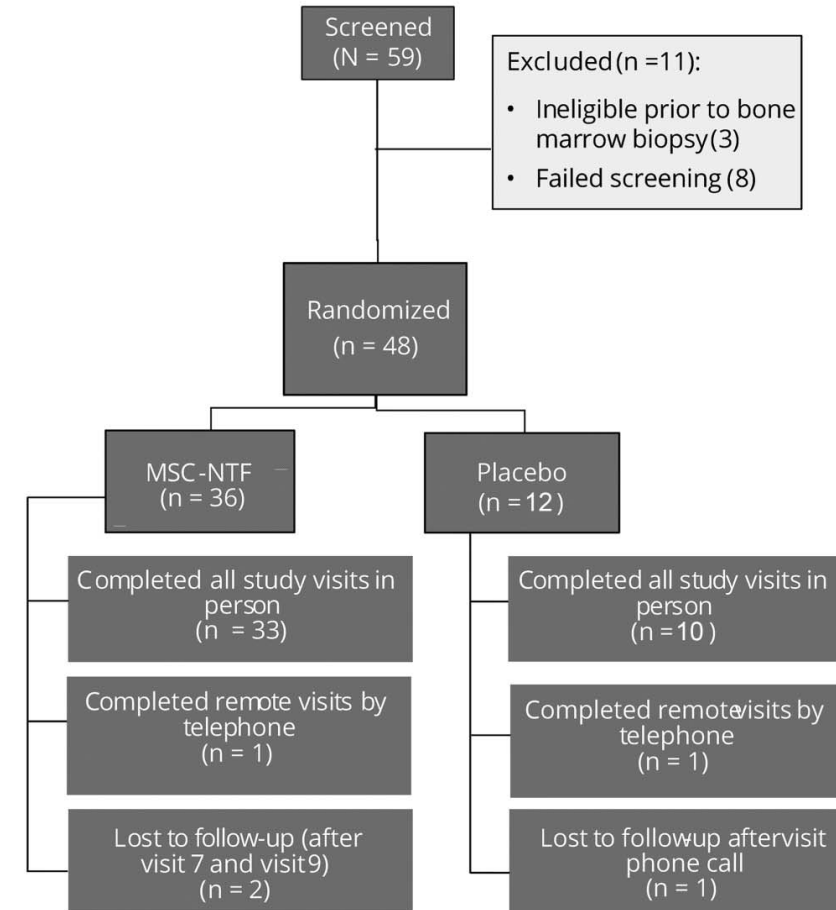
NurOwn, phase 2, randomized, clinical trial in patients with ALS

Safety, clinical, and biomarker results

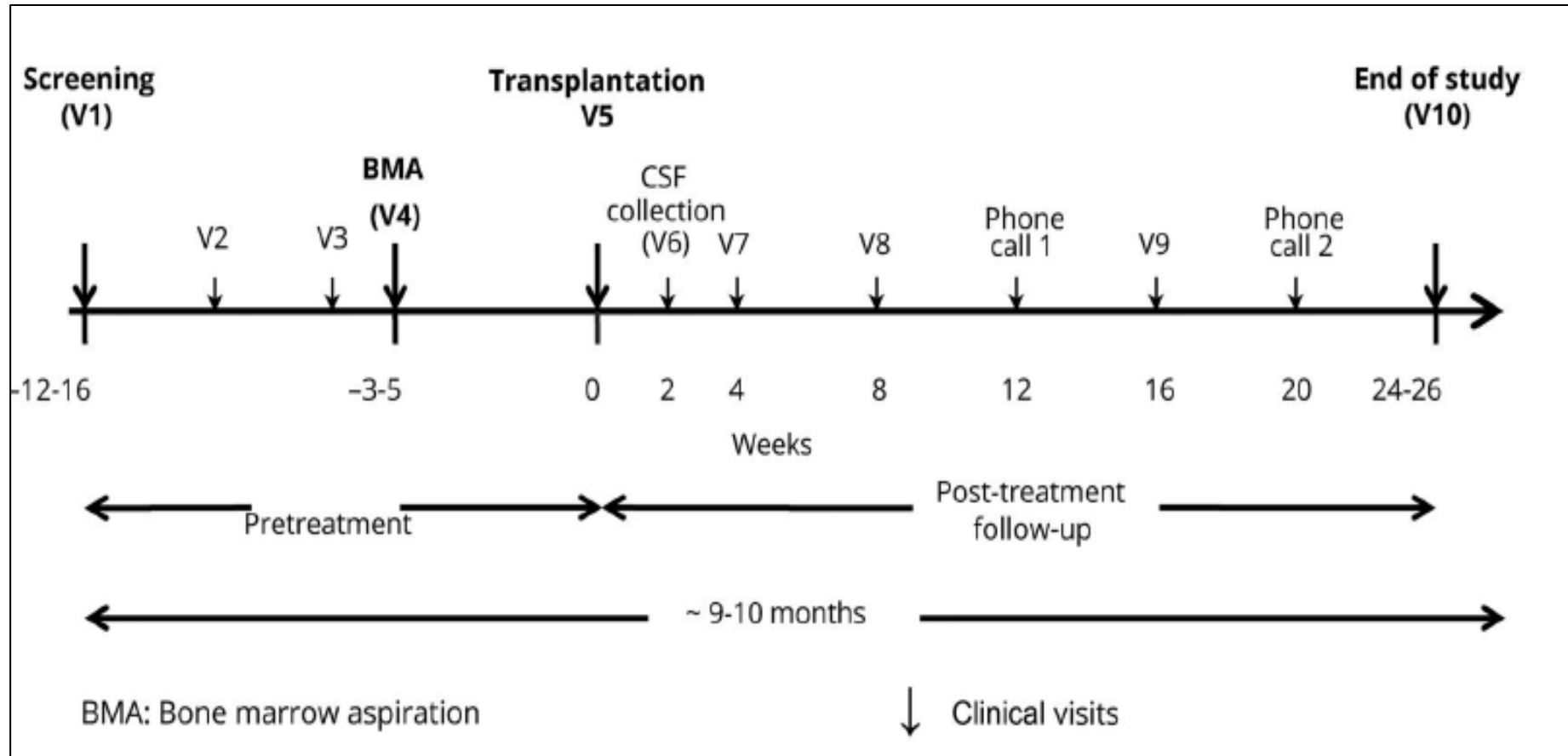
James D. Berry, MD, Merit E. Cudkowicz, MD, Anthony J. Windebank, MD, Nathan P. Staff, MD, Margaret Owegi, MD, Katherine Nicholson, MD, Diane McKenna-Yasek, Yossef S. Levy, PhD, Natalie Abramov, MSc, Haggai Kaspi, PhD, Munish Mehra, PhD, Revital Aricha, PhD, Yael Gothelf, PhD, and Robert H. Brown, DPhil, MD

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Phase 2 Study Design



Phase 2 Clinical Trial Demographics: Baseline Characteristics Balanced

Table 1 Demographics and baseline characteristics by treatment group

	MSC-NTF (n = 36)	Placebo (n = 12)	All participants (n = 48)
Sex			
Male	25 (69.4)	10 (83.3)	35 (72.9)
Female	11 (30.6)	2 (16.7)	13 (27.1)
Age, y	50.3 (11.90)	53.5 (9.11)	51.1 (11.27)
El Escorial criteria			
Possible	3 (8.3)	1 (8.3)	4 (8.3)
Laboratory-supported probable	5 (13.9)	1 (8.3)	6 (12.5)
Probable	16 (44.4)	7 (58.3)	23 (47.9)
Definite	12 (33.3)	3 (25.0)	15 (31.3)
ALS medical history, months since diagnosis	9.00 (5.57)	9.01 (4.63)	9.00 (5.31)
ALS medical history, months since first symptom ^a	17.62 (3.79)	16.75 (3.10)	17.40 (3.62)

Abbreviations: ALS = amyotrophic lateral sclerosis; ALSFRS-R = Revised ALS Functional Rating Scale; MSC = mesenchymal stem cell; NTF = neurotrophic factor. Data are presented as n (%) or mean (±SD). Percentages are based on the number of participants in a given treatment group for the population being analyzed.

^a The site of ALS onset was not tracked in the course of the study.

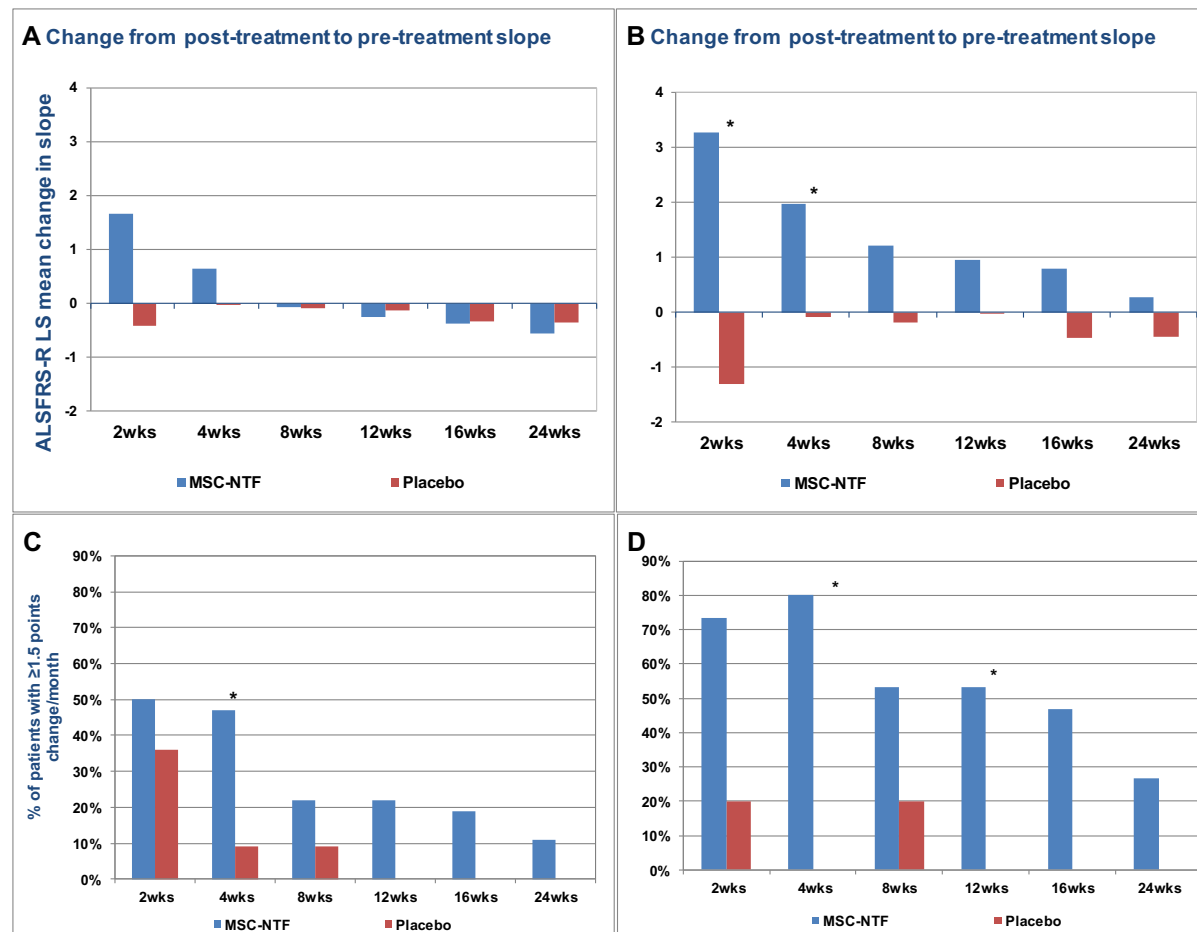
ALSFRS-R Efficacy Outcomes

All n=46

Rapid Progressors n=21

Mean ALSFRS-R
Post-pre slope
change

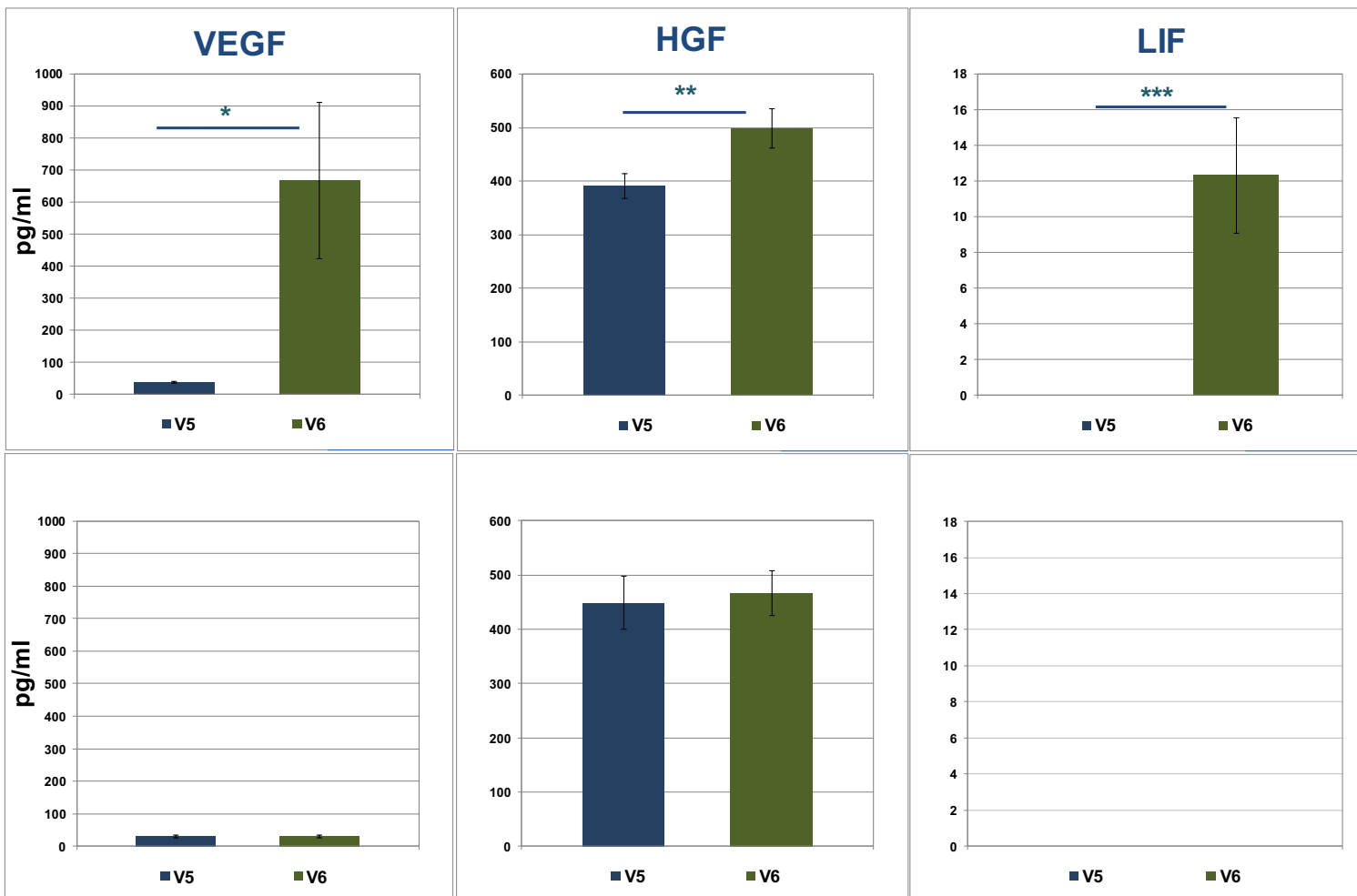
Proportion of
Responders showing
 ≥ 1.5 points/month
ALSFRS-R slope
improvement



Biomarkers

CSF Neurotrophic Factors Increased Post-Treatment

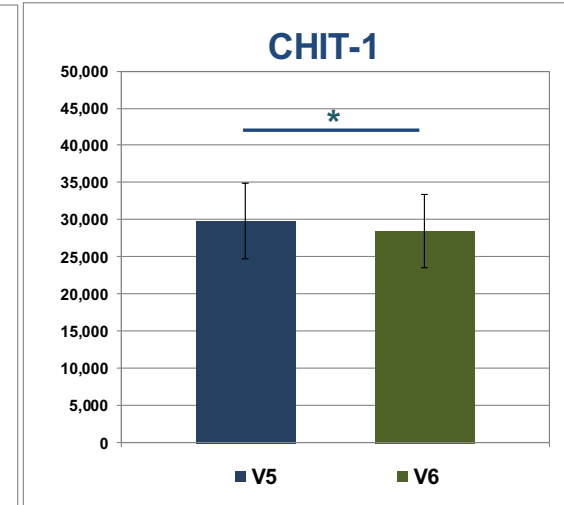
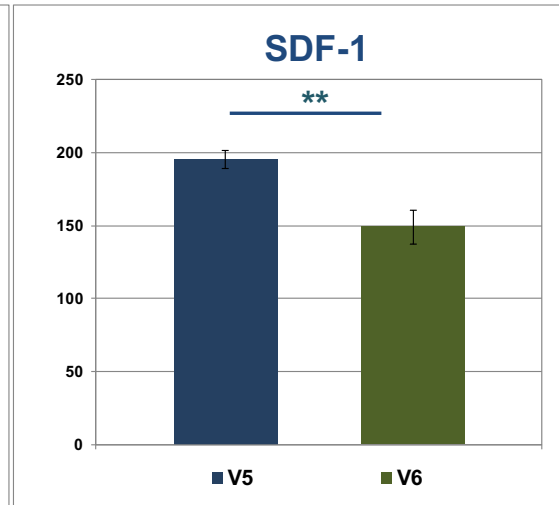
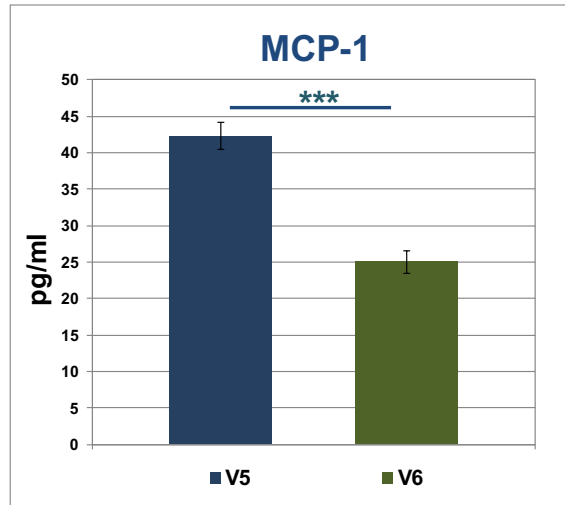
NurOwn[®]
(n = 26)



■ V5 -Pre transplantation
■ V6 - Post transplantation

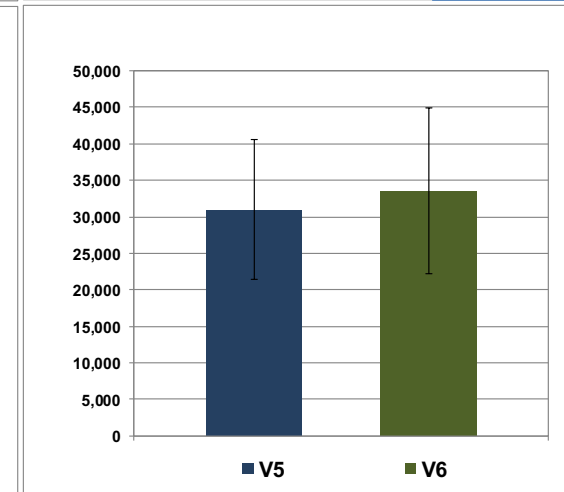
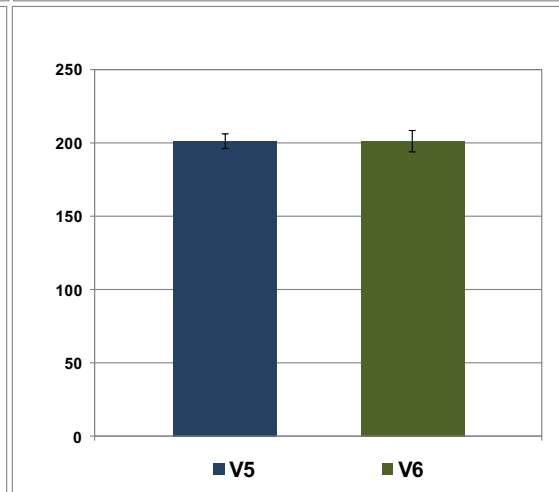
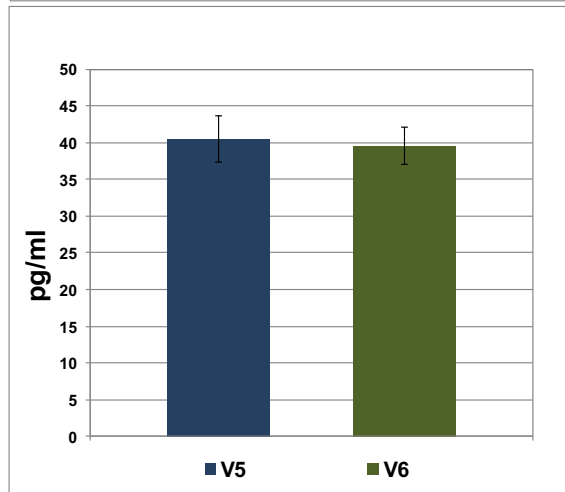
CSF Inflammatory Biomarkers Reduced Post-Treatment

NurOwn[®]
(n = 26)



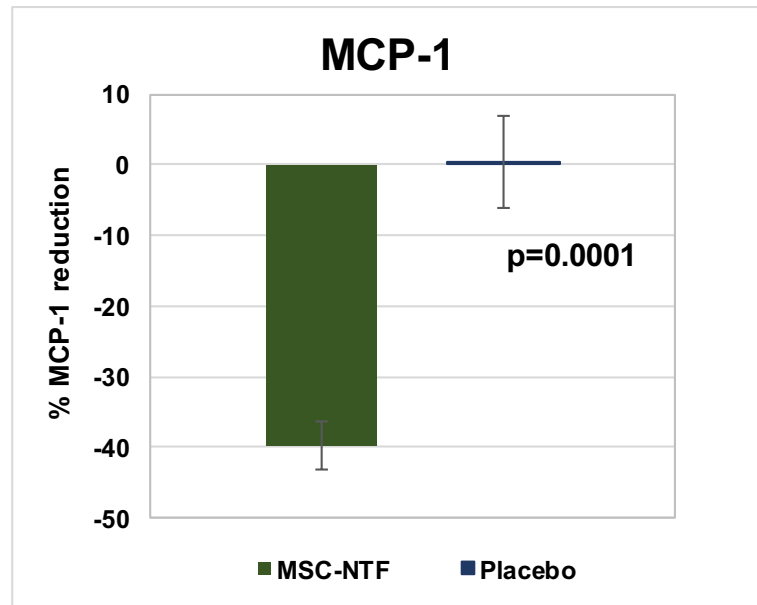
■ V5 -Pre transplantation
■ V6 - Post transplantation

Placebo
(n = 9)

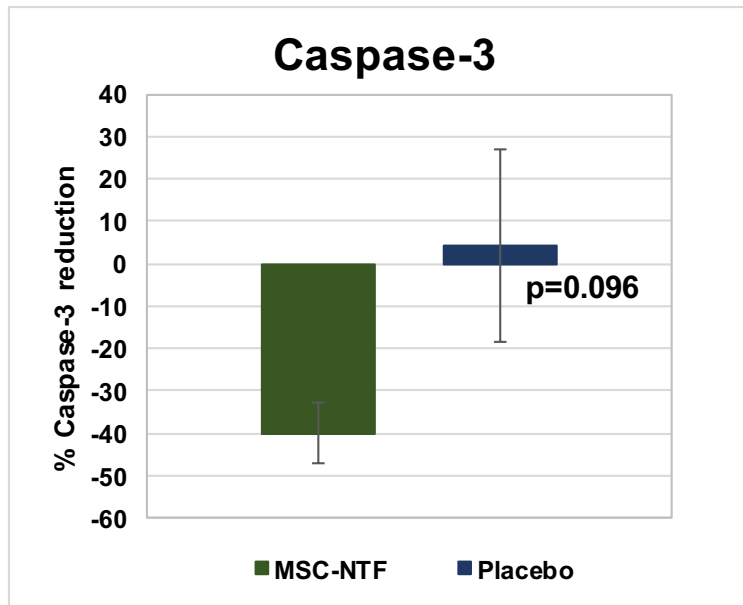


Post-treatment % reduction CSF MCP-1, Caspase-3 and SDF-1

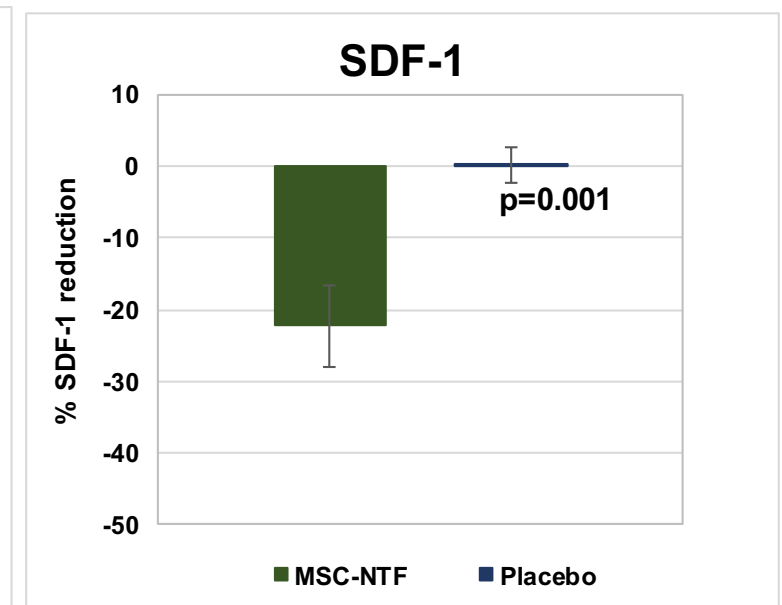
MCP-1 (40%)



Caspase-3 (40%)

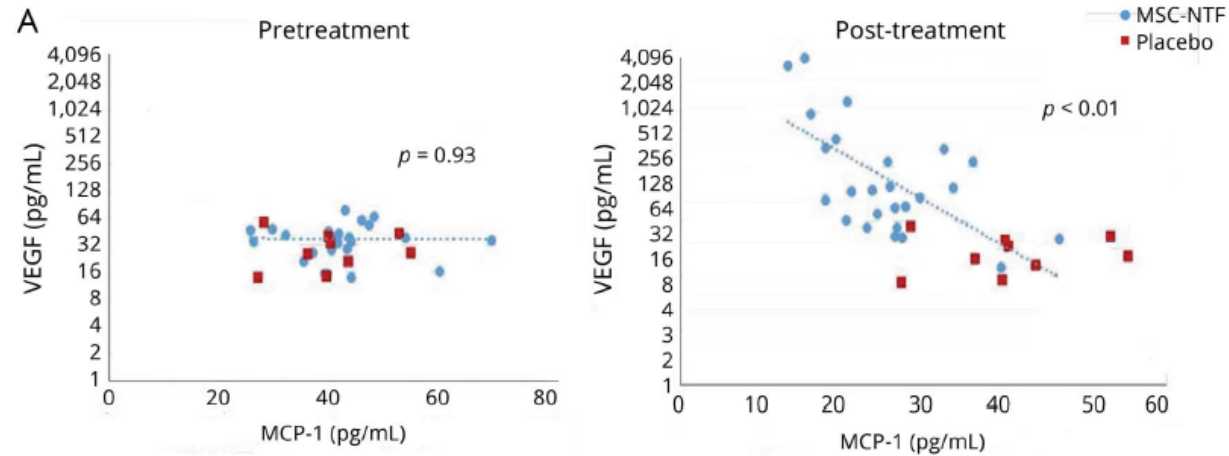


SDF-1 (22%)

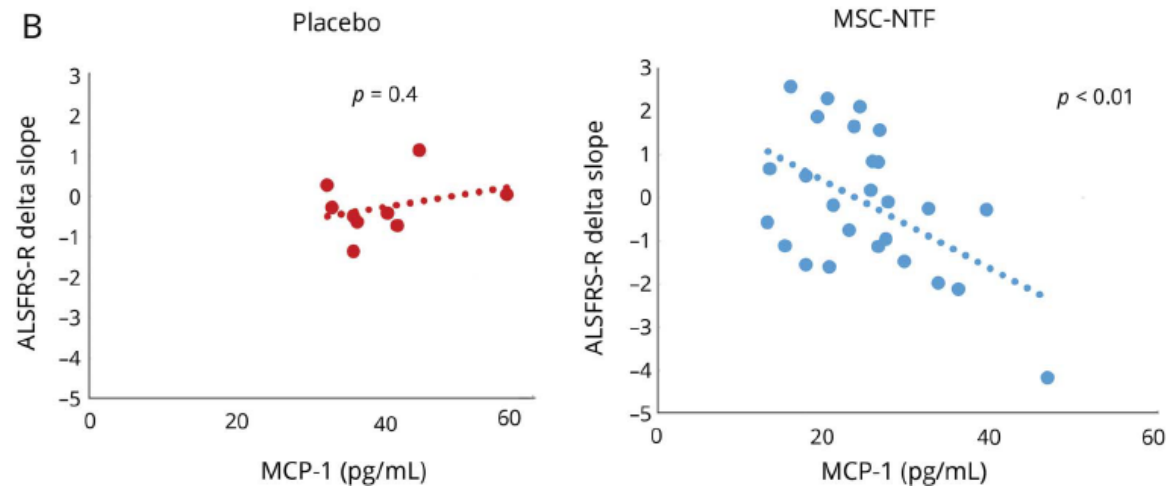


Phase 2 Clinical Trial: Biomarker Correlations

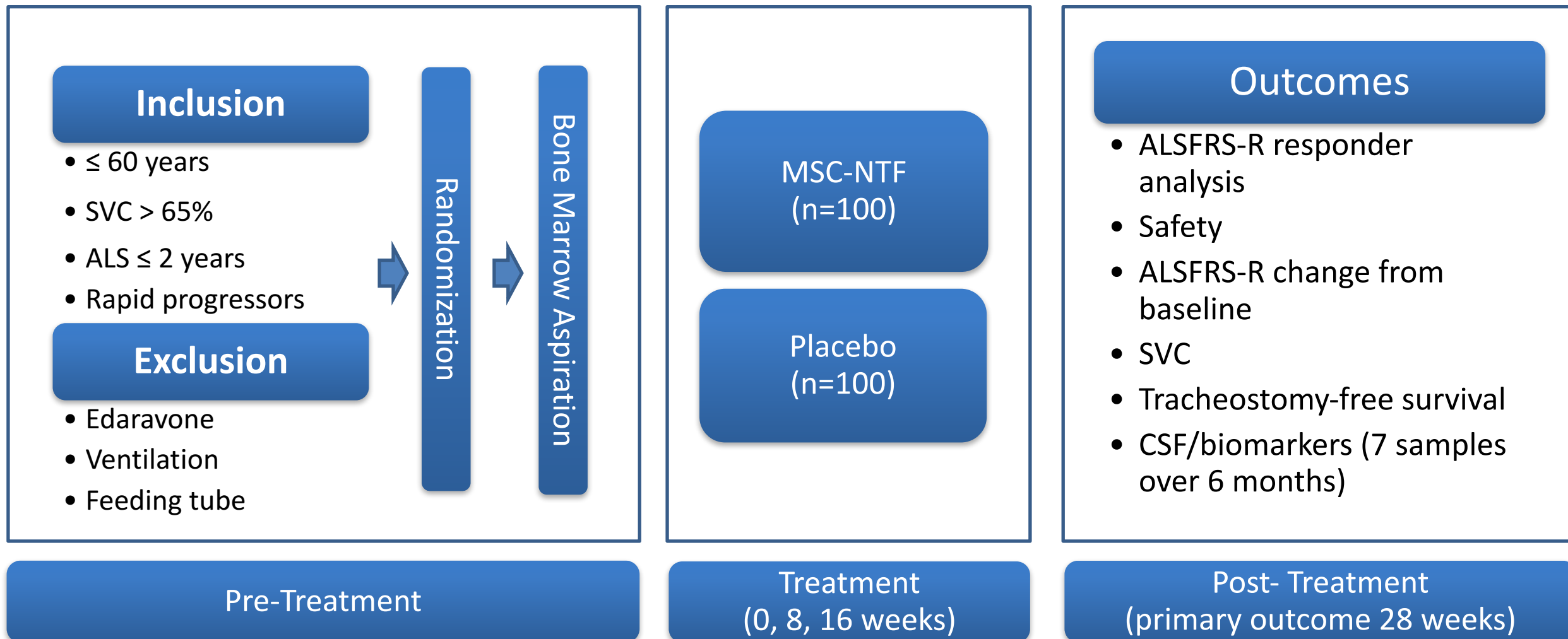
CSF MCP-1 inverse
correlation with
VEGF



CSF MCP-1 inverse
correlation with
ALSFRS-R



NurOwn® ALS Phase 3 Study



Phase 3 ALS Clinical Trial Status



- **Phase 3 enrollment completed October 2019**
- **DSMB safety review conducted end of October 2019**
 - Trial to continue
 - No protocol changes
- **Agreement with FDA on potential regulatory pathways for approval in ALS- February 2020**
- **Seeking additional grant support for innovative biomarker studies in ALS- ongoing**
- **Top line data Q4, 2020**

Phase 2 Progressive MS Clinical Trial Status



- **IND granted December 2018**
- **Repeat intrathecal dosing MSC-NTF cells every 2 months**
- **Validated clinical endpoints and biomarkers**
- **5 clinical trial sites in US**
- **First subjects enrolled March 2019**
- **DSMB safety review conducted end of December 2019**
 - **Trial to continue; No protocol changes**
- **Top Line data Q4, 2020**

Brainstorm Senior Leadership Team

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EVP & Chief
Financial Officer**

**Uri Yablonka
EVP & Chief
Business Officer**

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**Mary Kay Turner
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Thank You