BrainStorm Cell Therapeutics

NASDAQ: BCLI

brainstorm
cell therapeutics

COMPANY UPDATE

August 2017

Chaim Lebovits, CEO

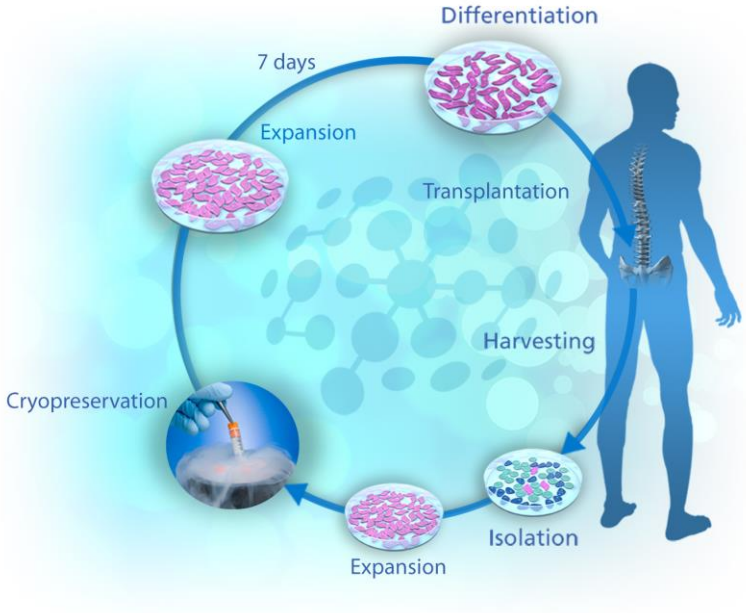
Ralph Z. Kern MD, MHSc, COO/CMO

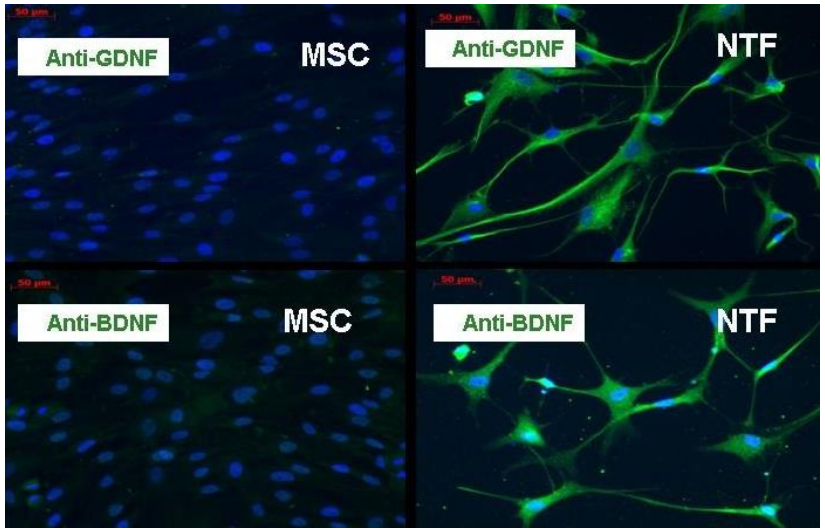
Safe Harbor Statement

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.

NurOwn® technology





Photomicrograph Courtesy Prof D. Offen, Tel Aviv University

- **NurOwn® cells are autologous (vs. allogeneic)**
- **NurOwn® cells consistently secrete high levels of multiple NTFs and are immunomodulatory**
- **NurOwn® cells are delivered by intrathecal injection**

Bone marrow is harvested and MSCs are isolated from the total bone marrow population

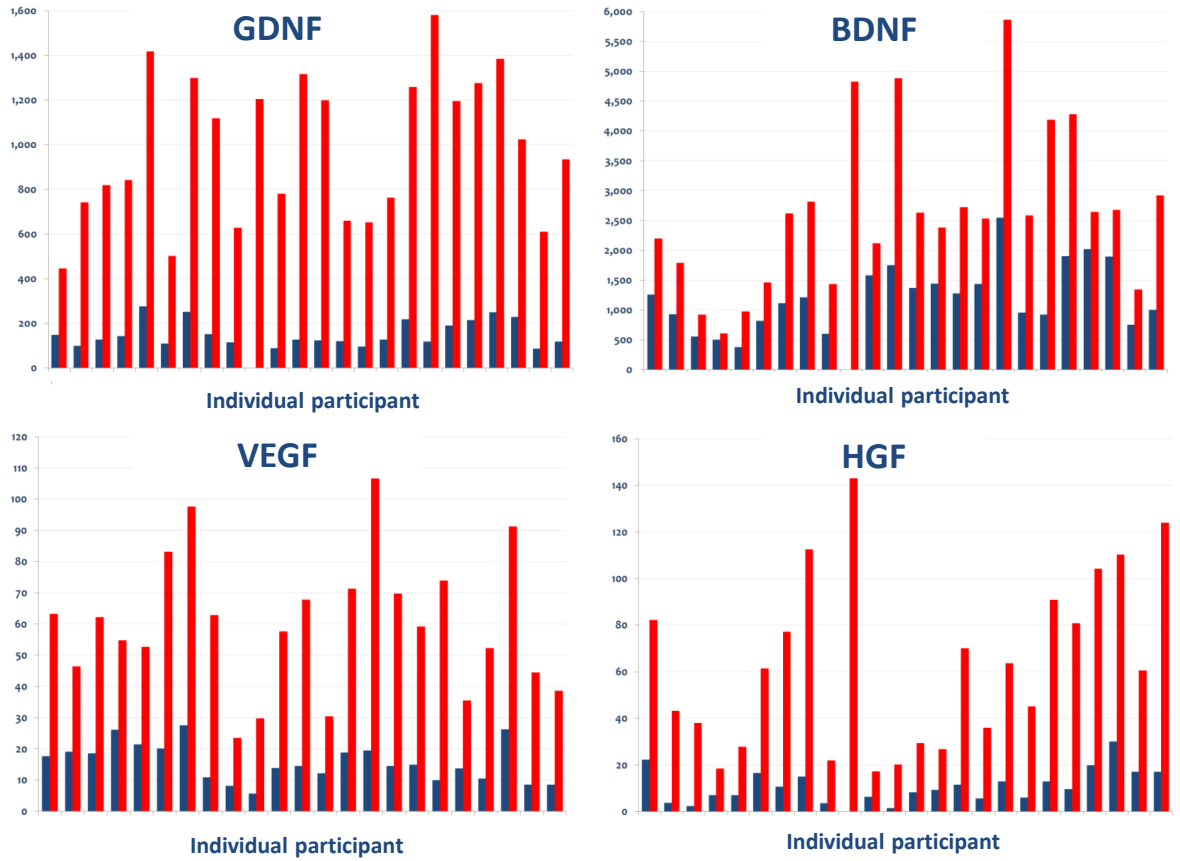
MSCs are expanded ex-vivo and cryopreserved

MSCs are thawed and induced to differentiate into NurOwn® (MSC-NTF secreting cells) (7 days)

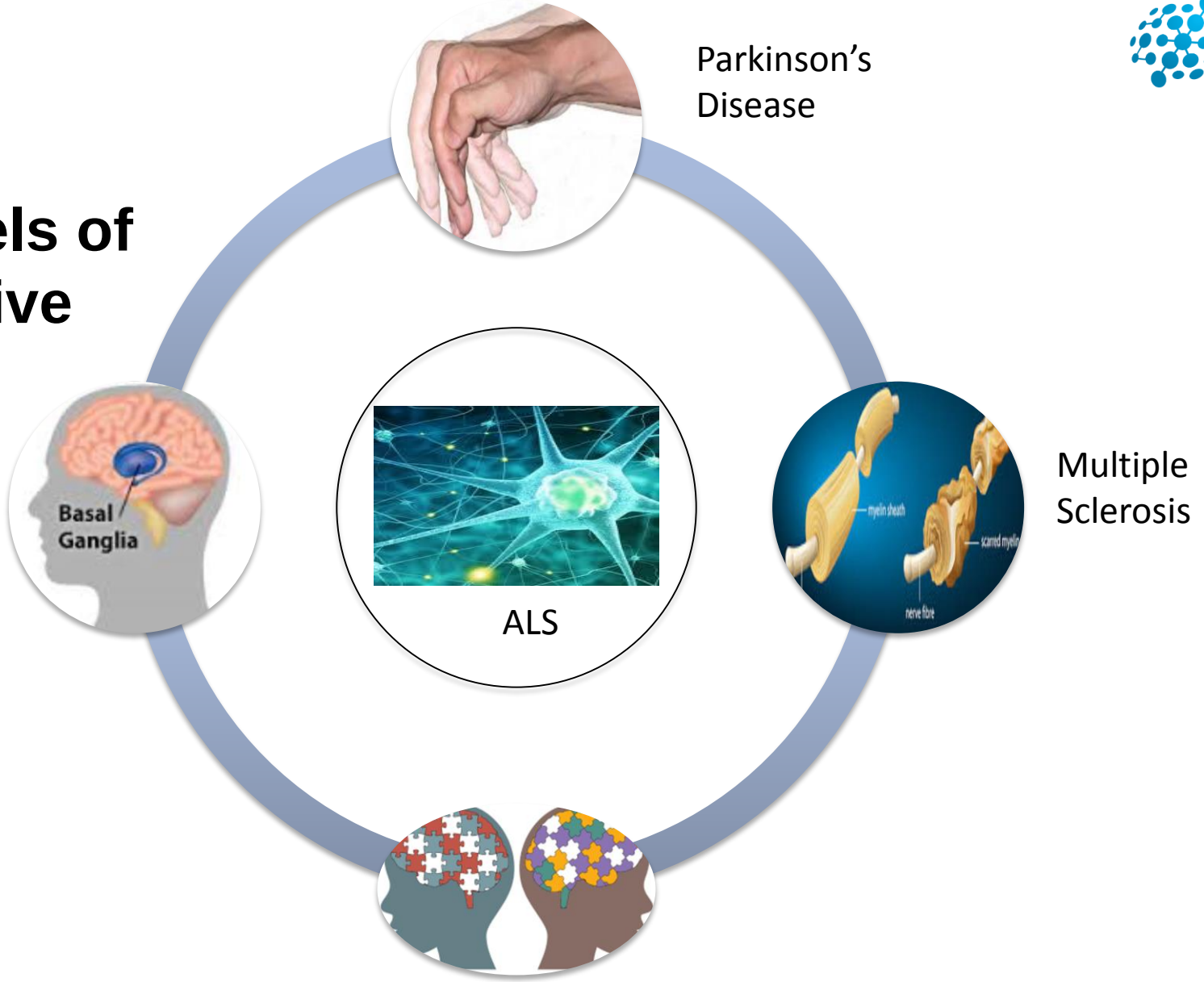
MSC-NTF cells are characterized for identity and potency and transplanted back into the patient by IT administration

NurOwn® shows enhanced *in-vitro* NTF secretion *(ALS patients and donor cell paired samples)*

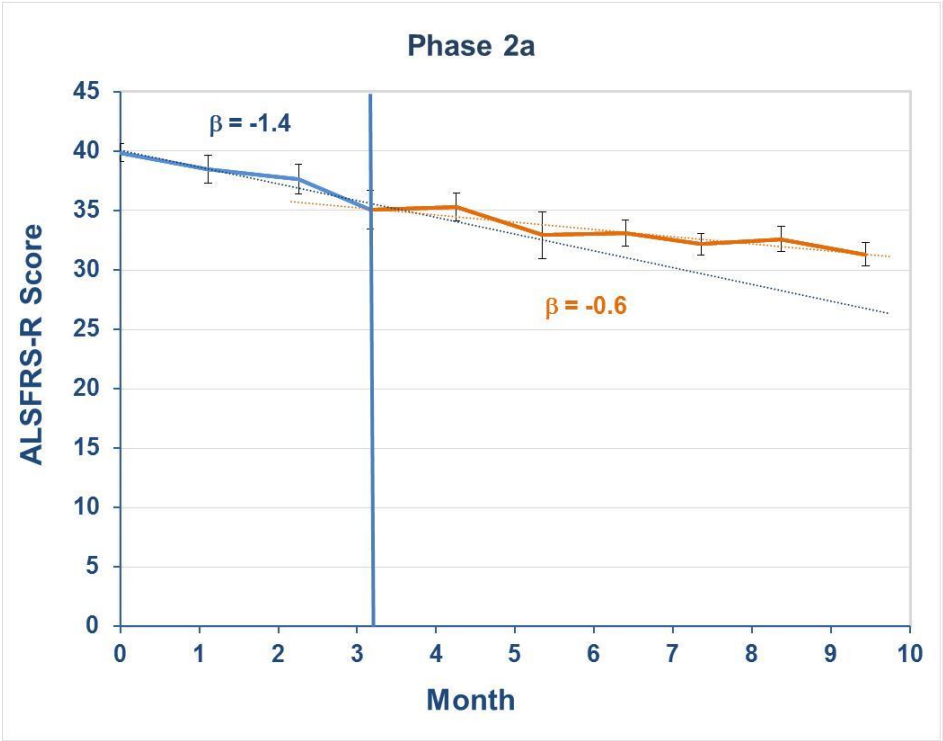
Enhanced in-vitro neurotrophic-factor secretion differentiates NurOwn® from MSC cells of origin in ALS patients

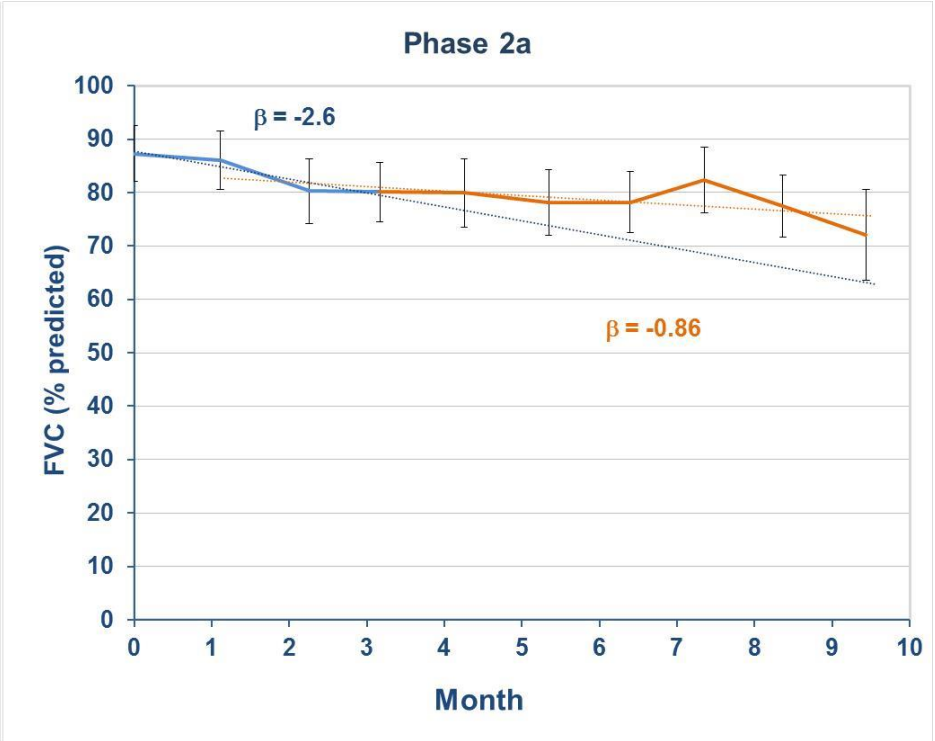


NurOwn® successfully evaluated in preclinical models of neurodegenerative disease



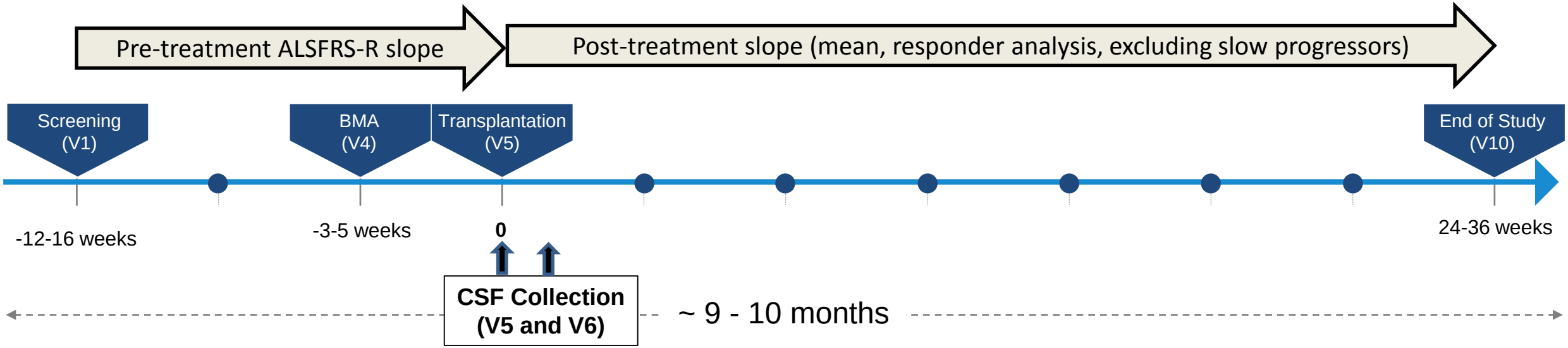
NurOwn® Phase 2a ALS Study:
Improvement in ALSFRS-R slope and FVC





The mean (±SEM) of the ALSFRS-R score and FVC (% predicted) of patients with ALS treated by combined intrathecal and intramuscular administration in the phase 2a study. β is the slope determined by linear regression analysis of the pretreatment and post-treatment slopes.

NurOwn® BCT-001-US Phase 2 Clinical Trial
Study Design



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

- IM: 24 injections (12 into R biceps, 12 into R triceps); 2 million cells each
- IT: **125 million cells in 4mL**

BMA*: Bone Marrow Aspirations*

Monthly visits

Phase 2 ALS Study participant disposition and demographics- Baseline characteristics balanced

Disposition	MSC-NTF (N=36)	Placebo (N=12)	All Participants (N=48)
Analysis Populations	n (%)	n (%)	n (%)
Safety (ITT*)	36 (100.0)	12 (100.0)	48 (100.0)
Study Completion			
Completed	33 (91.7)	10 (83.3)	43 (89.6)
Discontinued	3 (8.3)	2 (16.7)	5 (10.4)

Demographics	MSC-NTF (N=36)	Placebo (N=12)	All Participants (N=48)
Sex	n (%)	n (%)	n (%)
Male	25 (69.4)	10 (83.3)	35 (72.9)
Female	11 (30.6)	2 (16.7)	13 (27.1)
Age (years)	Descriptive Statistics		
n	36	12	48
Mean (SD)	50.3 (11.9)	53.5 (9.11)	51.1 (11.27)

* ITT analyses included all participants

Ref. Tables 14.1.1.1, 14.1.2.2

NurOwn® BCT-001-US ALS Clinical Trial: *Endpoints*

- **Primary:**
  - **Safety and tolerability**
- **Secondary:**
  - **ALSFRS-R**
  - **Slow vital capacity (SVC)**
- **Exploratory:**
  - **Muscle strength (HHD)**
  - **CSF Biomarkers (added after the 1st 8 participants)**

NurOwn® BCT-001-US ALS Clinical Trial:
Treatment was Safe and Well-Tolerated

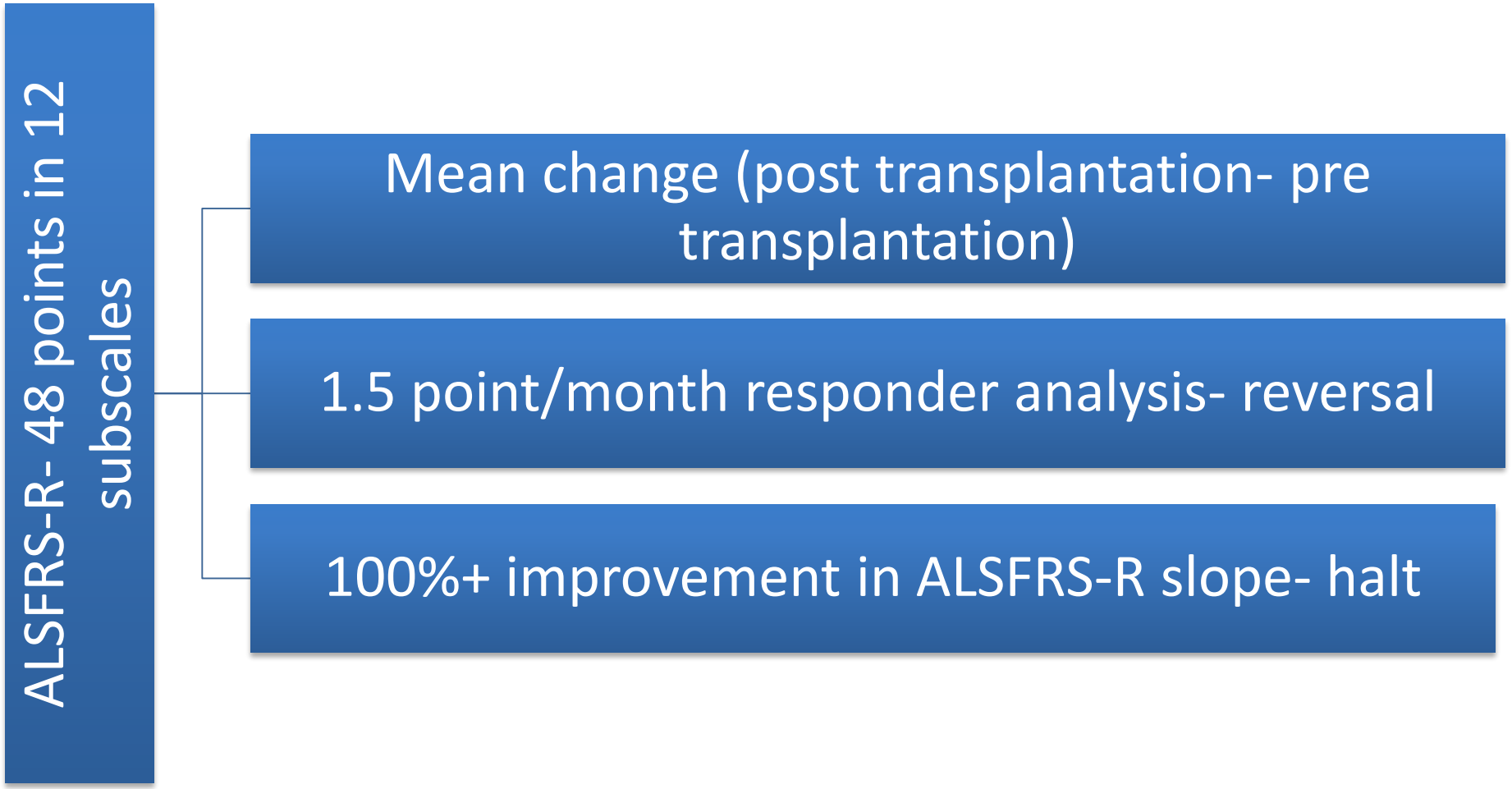
- **No deaths**
- **No treatment-related SAEs observed**
- **No dropouts related to AEs**
- **Most common adverse events (>15%; most mild/mod severity):**

Adverse Event	NurOwn® (%)	Placebo (%)
Headache and Procedural Headache	80.6	66.7
Back Pain	72.2	8.3
Pyrexia	33.3	0
Arthralgia	33.3	0
Injection Site Pain	27.8	8.3
Constipation	25	8.3
Pain in Extremity	22.2	0
Neck Pain	19.4	0
Myalgia	16.7	0
Cough	16.7	0
Nausea	16.7	0

- **Post-therapy SAEs related to disease progression (e.g. G-tubes) were more frequent in the MSC-NTF cells group.**

Ref. Table 14.3.1.2

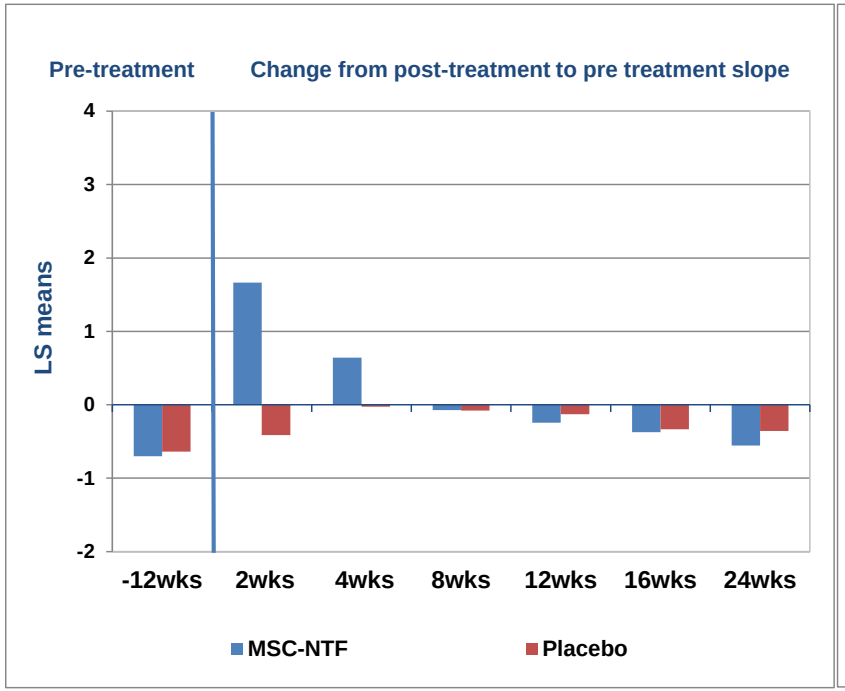
Phase 2 ALSFRS-R efficacy outcomes:



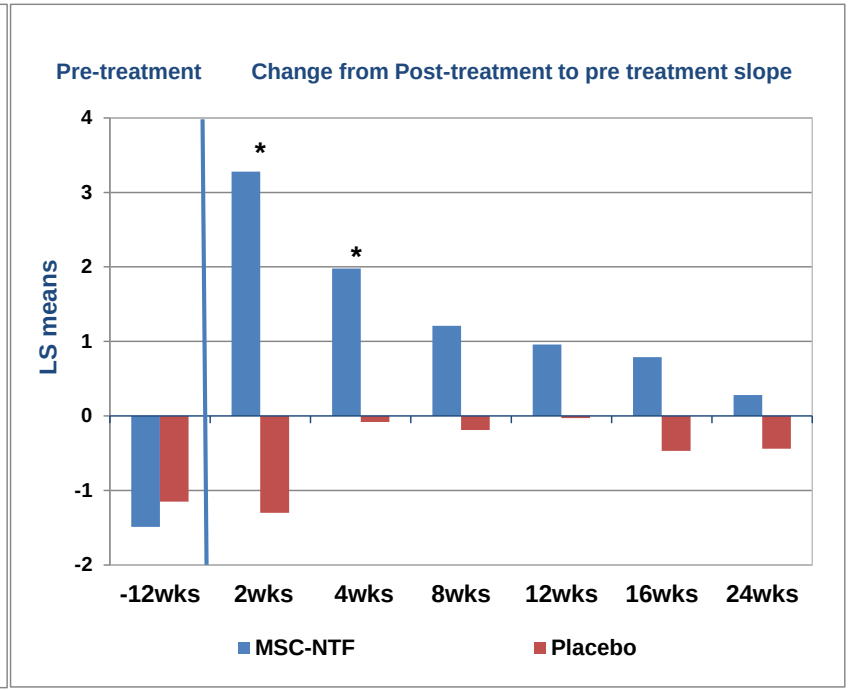
NurOwn® Phase 2 ALSFRS-R Slope Change:

Cell therapy produced improvement in mean ALSFRS-R slope

All participants (n=46)



Excluding Slow progressors (n=21)

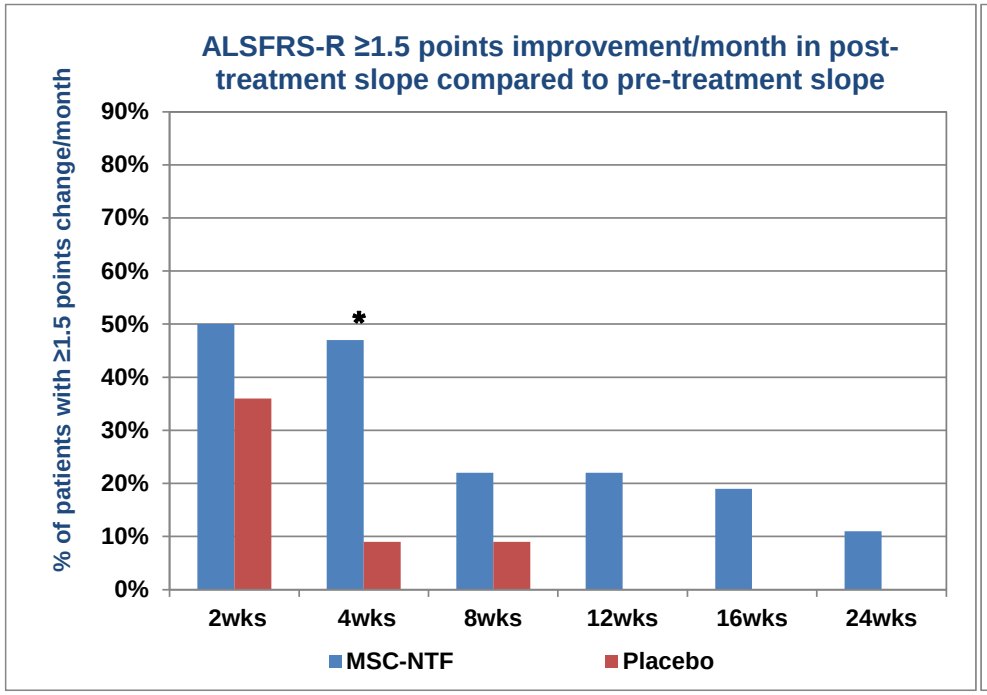


* p<0.05 (two-sided t test)

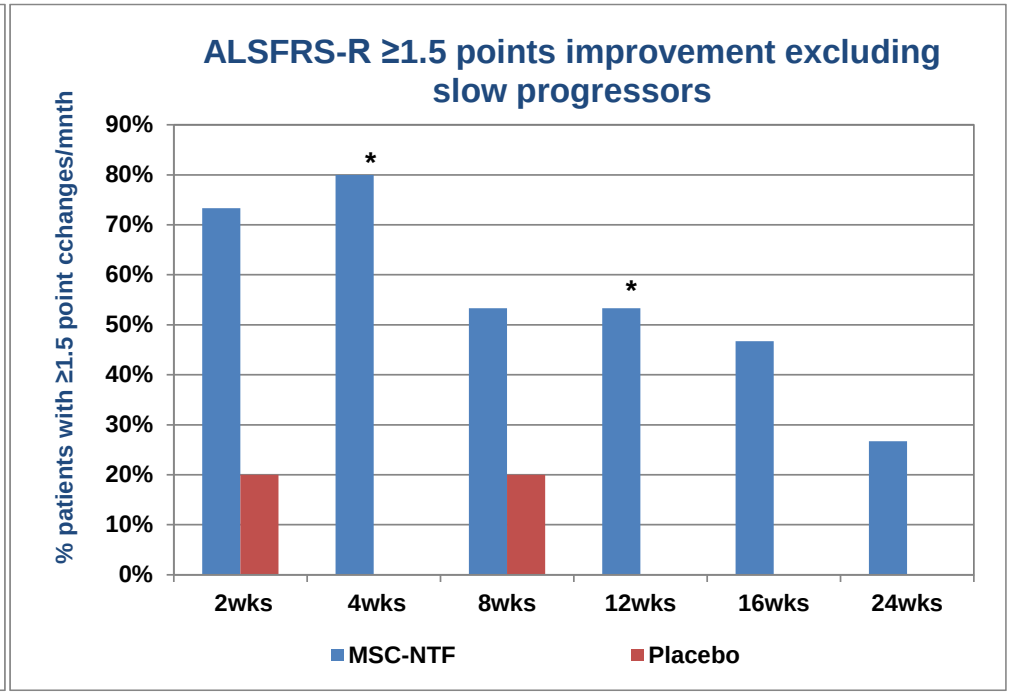
NurOwn® Phase 2 Responder Analysis:

More participants in the NurOwn® cell therapy group showed ≥1.5 points/month improvement

All participants (n=46)



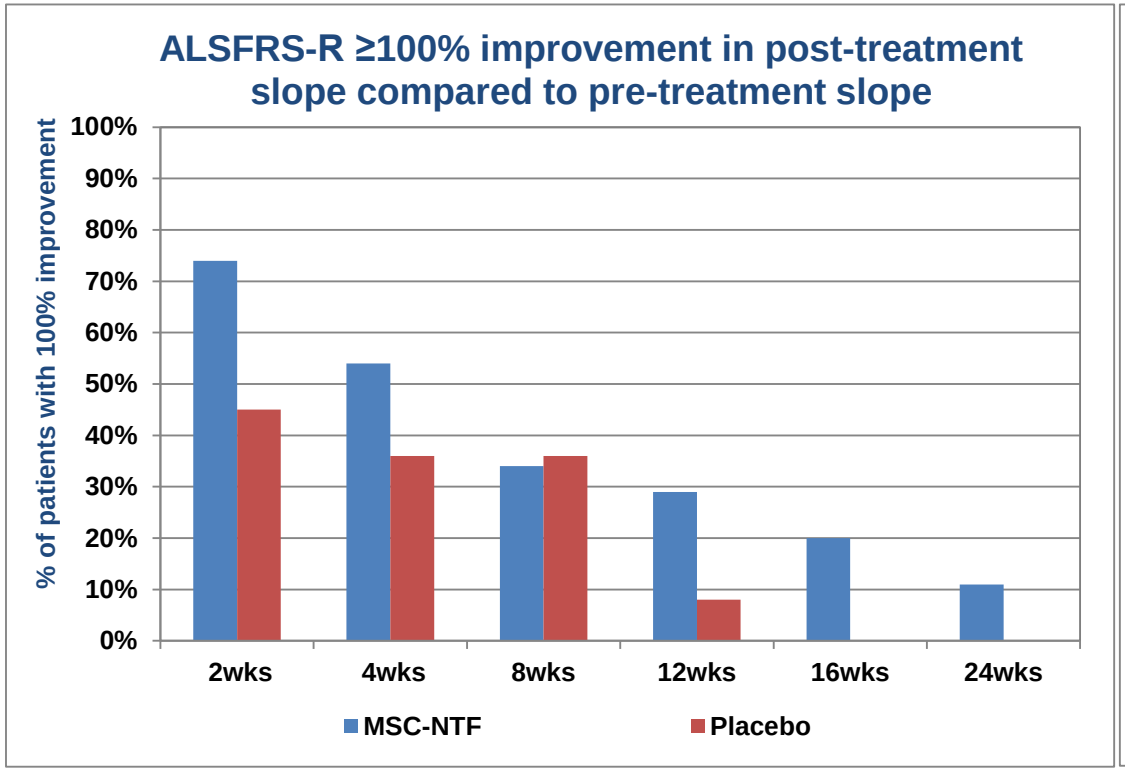
Excluding slow progressors (n=21)



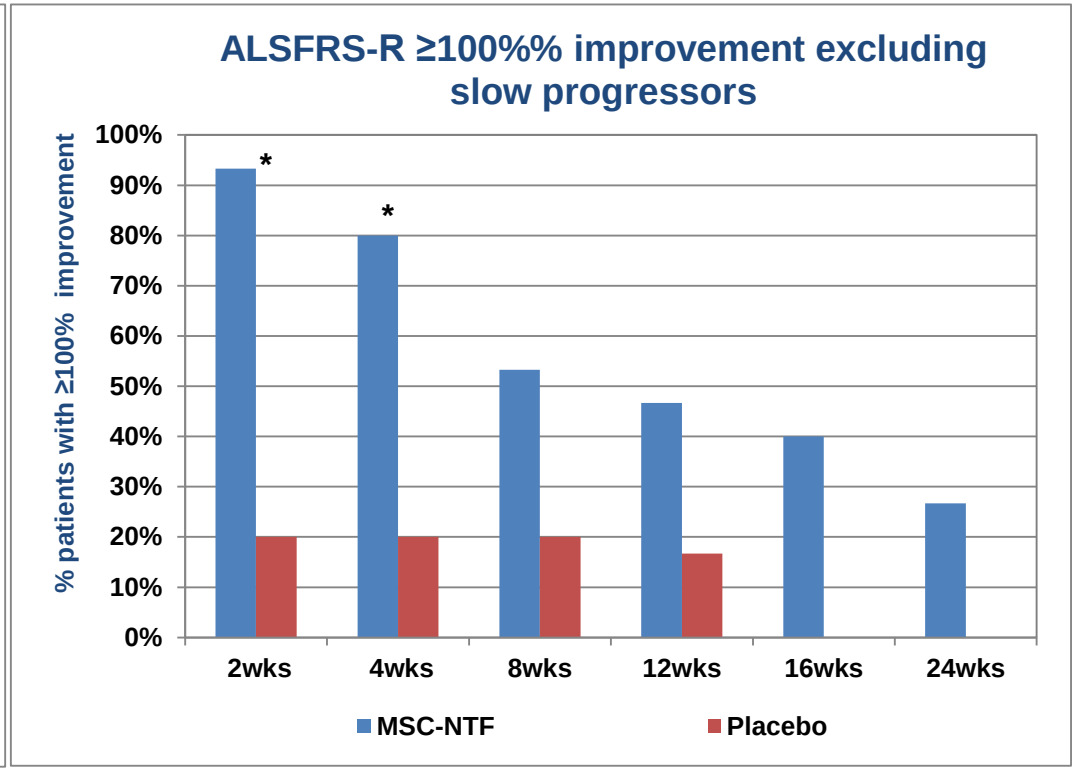
* p<0.05 (two-sided Fisher's exact test)

NurOwn® Phase 2 ALS Study Responder Analysis:
>=100% slope improvement

All participants (n=46)



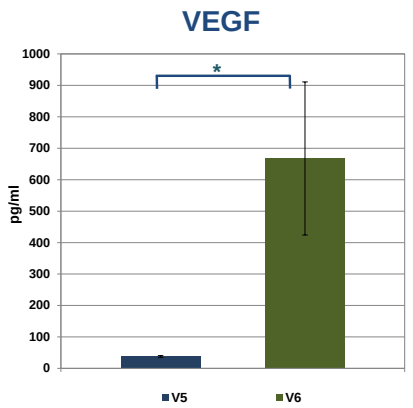
Excluding slow progressors (n=21)

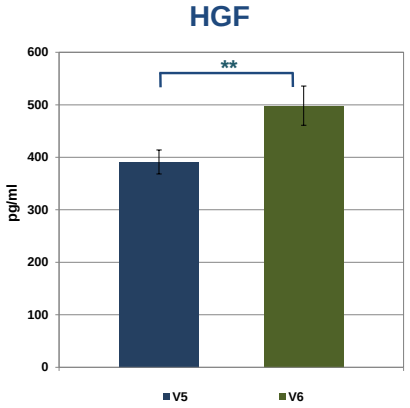


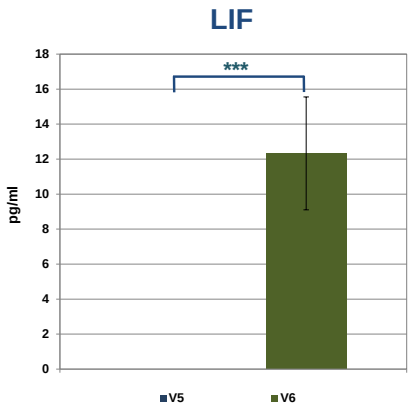
* p<0.05 (two-sided Fisher's exact test)

NurOwn® Phase 2 ALS Study:
CSF NTFs Significantly Increased 2 Weeks Post-Treatment

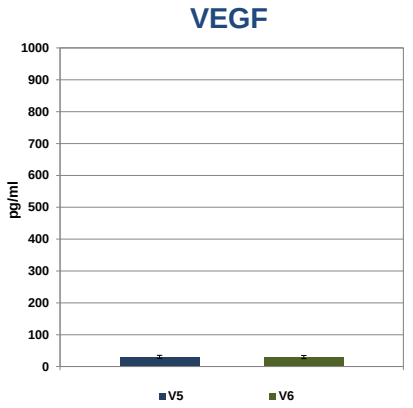
NurOwn®
(n = 26)

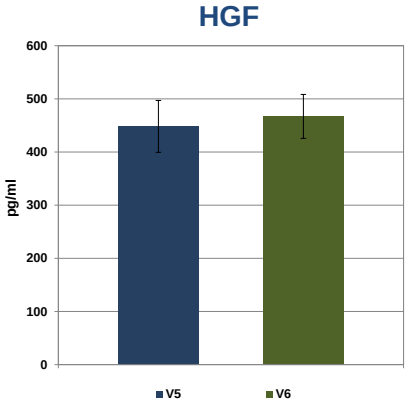


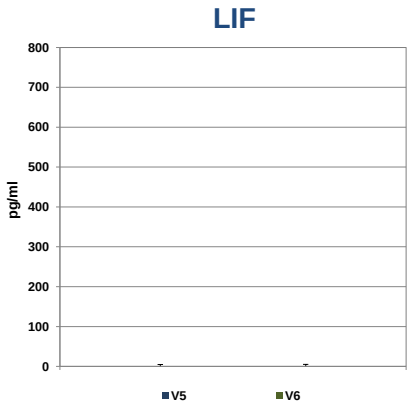




Placebo
(n = 9)







Pre transplantation

Post transplantation

Mean ± SEM
*** p< 0.05 ** p<0.01 *** p< 0.001**

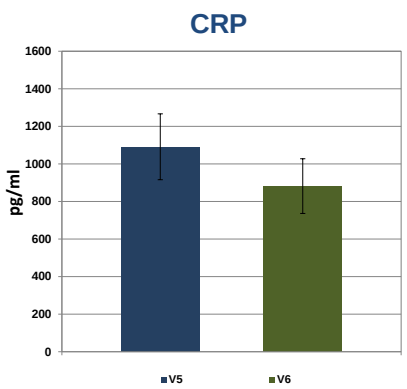
NurOwn® Phase 2 ALS Study:
CSF Inflammatory Markers Decreased Post-Treatment

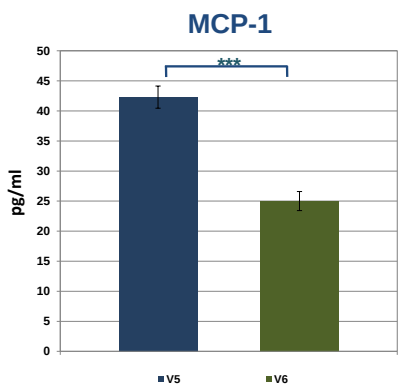
CSF MCP-1, SDF- markers of neuroinflammation

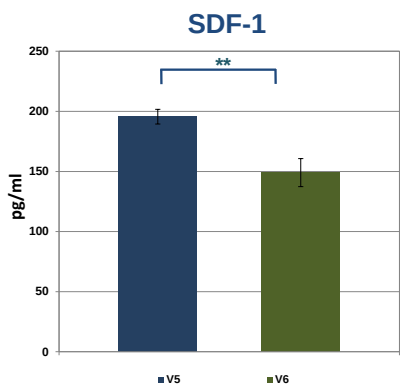
Pre transplantation

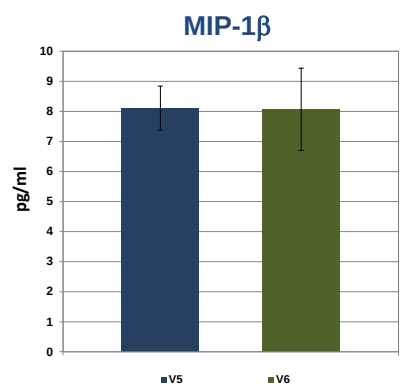
Post transplantation

NurOwn®
(n = 26)

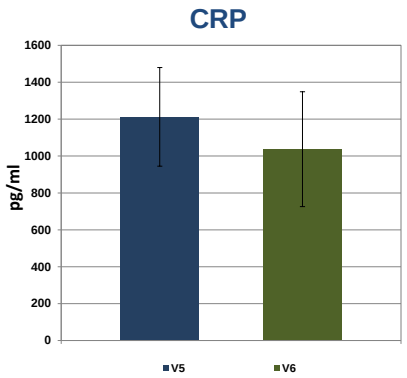


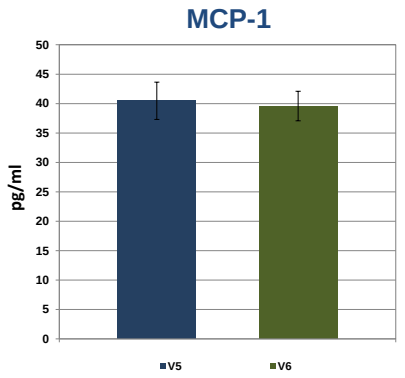


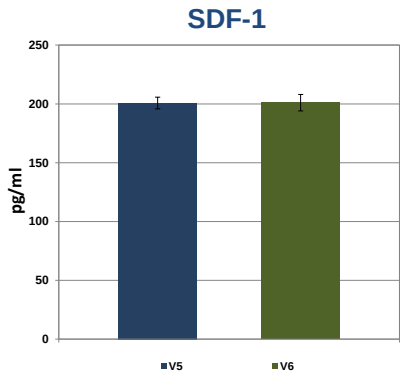


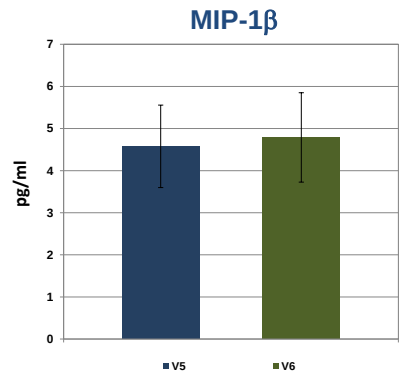


Placebo
(n = 9)







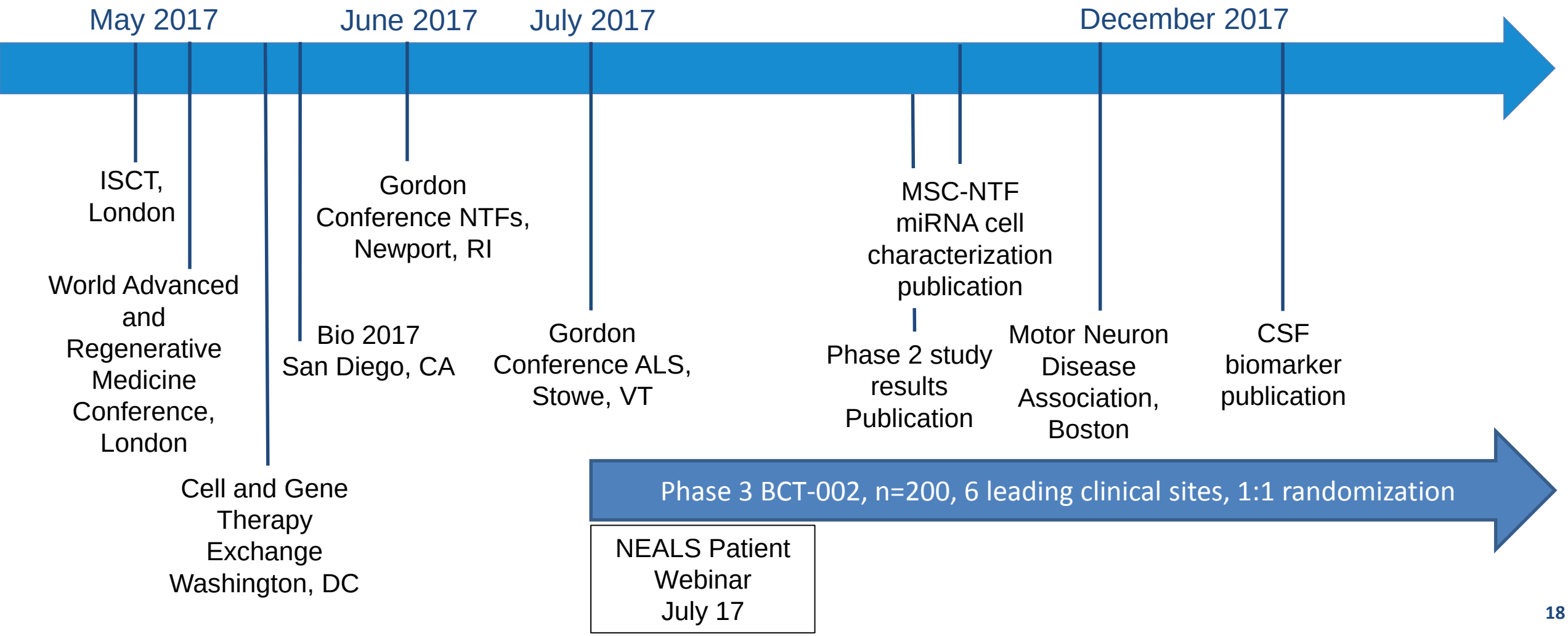


Mean ± SEM ** p<0.01 *** p< 0.001

NurOwn® Phase 3 ALS Study (BCT-002-US)

- **Randomized, double-blind, placebo-controlled, multi-dose trial**
- **WCT selected as CRO, Patient Webinar July 17th**
- ***200 participants;* 1:1 randomization; *6 leading clinical sites***
- **Study design**
  - ***3 month baseline* to determine ALSFRS-R slope**
  - ***3 doses* over first 4 months, *28 week double-blind clinical follow-up* after first dose**
  - **ALS participants *excludes slow progressors (<3 points decline over 12 weeks)***
  - **Primary outcome measure- ALSFRS responder analysis (*slope change/month)***
- **City of Hope Center for Biomedicine and Genetics will produce clinical supplies**

2017 Calendar



Senior Management

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President and CEO

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COO and CMO

Uri Yablonka
Exec. VP, Chief Business Officer

Mary Kay Turner
VP, Patient Advocacy and Government Affairs

Yael Gothelf PhD.
VP, Scientific and Regulatory Affairs

Yossef Levy PhD.
VP, Cell Production

Revital Aricha PhD.
VP, R&D