



LINEAGE
CELL THERAPEUTICS

The future of cell therapy.



An Overview of OPC1 (oligodendrocyte progenitor cells) For the Treatment of Spinal Cord Injury

May 12, 2022

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A new approach to
treating patients with
Spinal Cord Injury (SCI)



OPC1: Oligodendrocyte Progenitor Cell Transplant

OPC1 Development History

Geron Corporation: 1999-2012

- IND cleared in 2009 – first ever ES-derived IND in the US
- Thoracic trial discontinued (“deprioritized”) in 2011 (N=5)

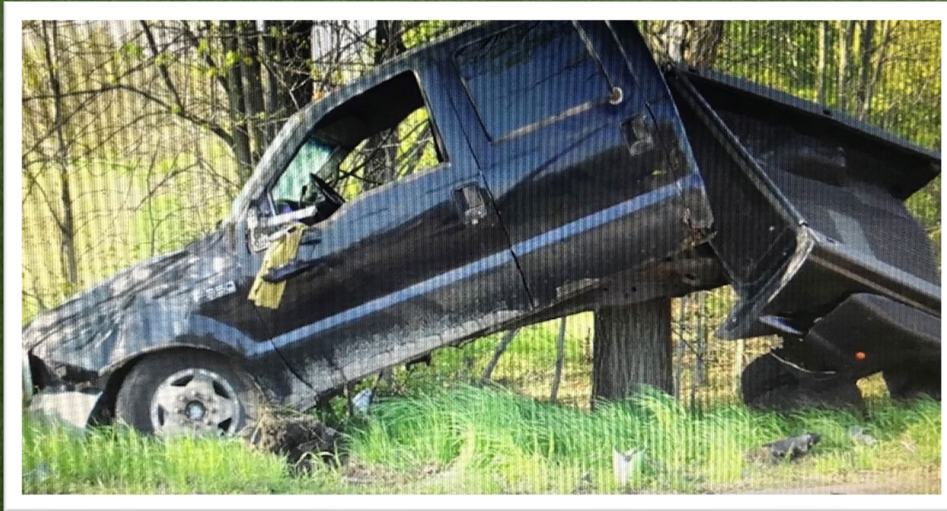
Asterias Biotherapeutics: 2013-2019

- Acquired SCI assets from Geron
- Completed cervical SCI clinical trial (N=25)

Lineage Cell Therapeutics (LCTX): 2019 – present

- Acquired Asterias in 2019
- Focused on manufacturing and surgical procedure improvements
- Anticipate testing new delivery device in 2022
- Plans to conduct larger, later-stage, multi-center trial once device safety study is complete 2023

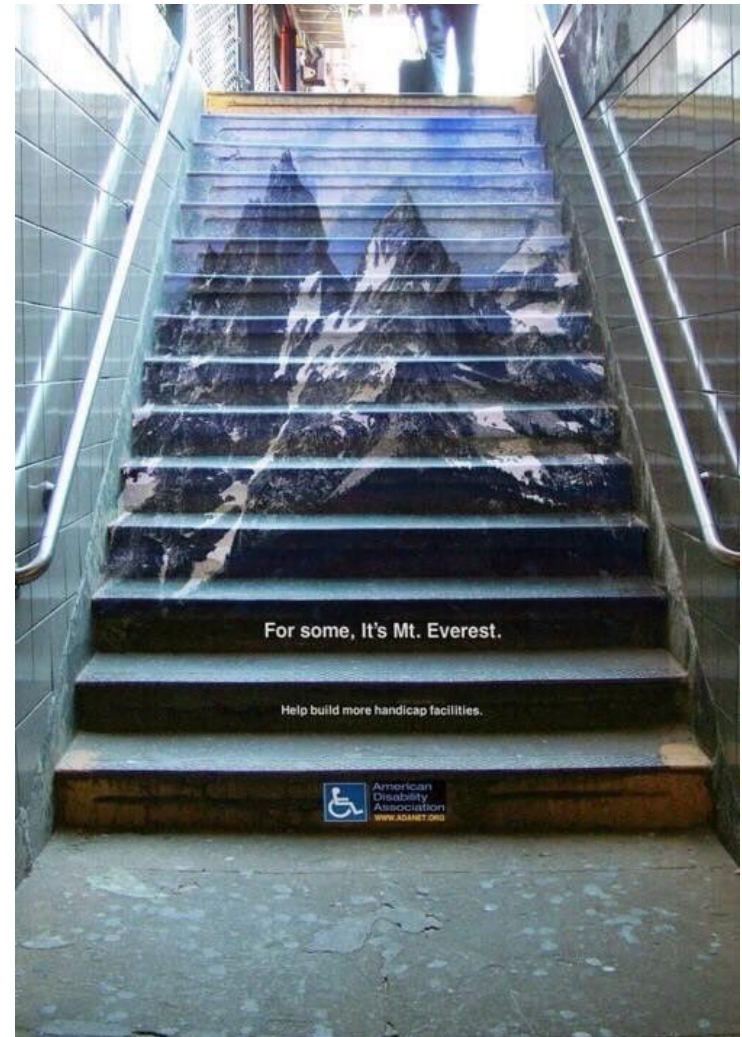
Why Spinal Cord Injury (SCI) Matters



**Lucas Linder, an OPC1 clinical trial participant, was paralyzed from the neck down.
The next year, he threw out the first pitch at a Major League Baseball game.**

SCI Burden and Unmet Needs

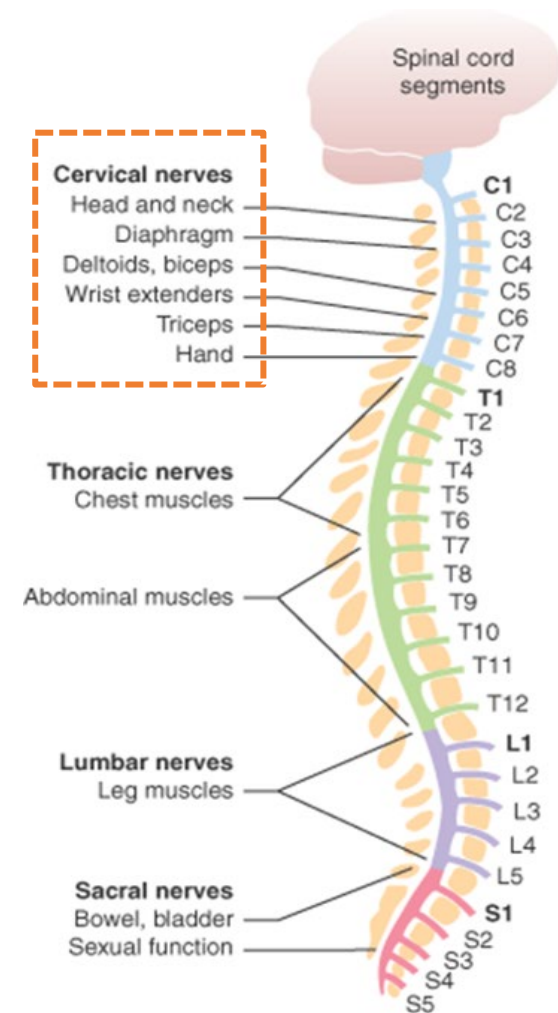
- **Approx. 18,000 cases per year (US)¹**
- **A significant burden for patients and caregivers²**
 - 67% of patients are unemployed 10 years post-injury
 - Lifetime healthcare costs can reach \$5M for one patient
- **Potential lifelong impairments**
 - Mobility (wheelchair)
 - Pain
 - Re-hospitalizations
 - Infections
 - Ventilator dependency
 - Depression
 - Shortened life expectancy



SCI Treatment Objectives

Loss of movement is the primary feature of a spinal cord injury

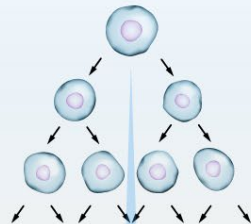
- Higher-level injuries result in more extensive impairments
- Gains in motor function, particularly in the upper extremities, can provide significant benefits in self-care and lower costs of care
- The goal of Lineage's cell therapy is to provide additional arm, hand, and finger function, increasing independence and quality of life



Lineage Technology Platform – Allogeneic Cell Transplants

Expansion

- Product development starts from a frozen vial of self-renewing stem cells
- These pluripotent cells can become any cell type in the body when provided with the correct instructions



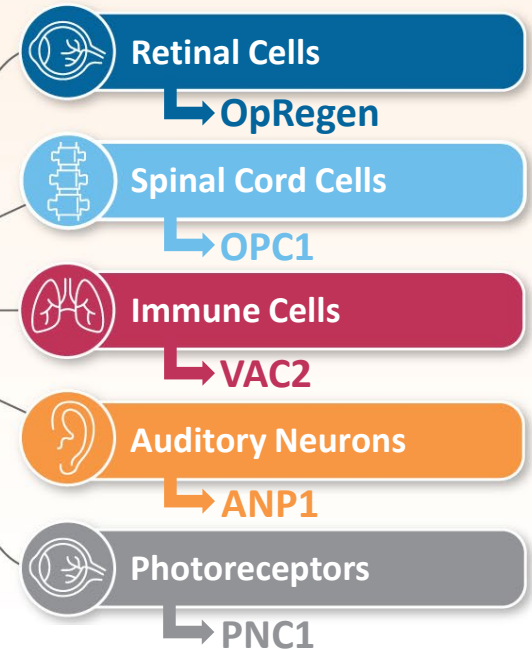
Differentiation

- Lineage’s proprietary process, honed from decades of institutional experience, creates only the cell type which is desired
- No alterations are made to the cell’s DNA
- In-house cGMP manufacturing allows for commercial-scale production from a single vial of stem cells



Development

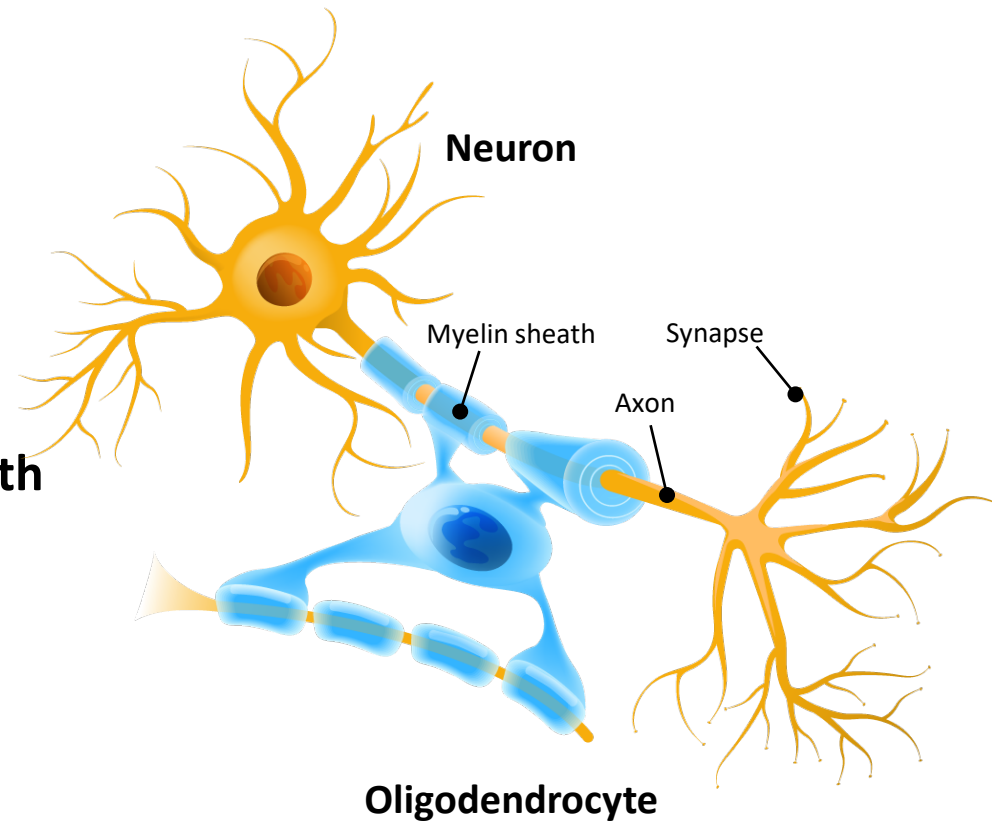
- Value is created by developing *clinically and commercially-viable* product attributes
- Expansion occurs via broadening indications or adding new cell types



OPC1 cells for Spinal Cord Injury

Transplanting oligodendrocytes may provide additional upper extremities function (arms and fingers) and improve quality of life

- **OPC1 is comprised of OPCs (oligodendrocyte progenitor cells)**
- **OPCs are precursors to oligodendrocytes, the myelinating cells of the central nervous system which provide insulation to nerve axons in the form of a myelin sheath**
- **Myelin is essential for proper function of neurons**
- **OPC1 cells are implanted into the spinal cord at the injury site**



OPC1 Asset Overview

- **OPC1 utilizes targeted cell replacement (similar approach as OpRegen)**
- **OPC1 is covered by multiple issued patents**
- **OPC1 has RMAT Designation**
- **OPC1 has Orphan Drug Designation**
- **OPC1 has received >\$14M in support from CIRM (California Institute for Regenerative Medicine)**
- **OPC1 may have application to other demyelinating conditions**



OPC1 Transplant Procedure

OPC1: hESC-Derived Oligodendrocyte Progenitor Cells (OPCs)

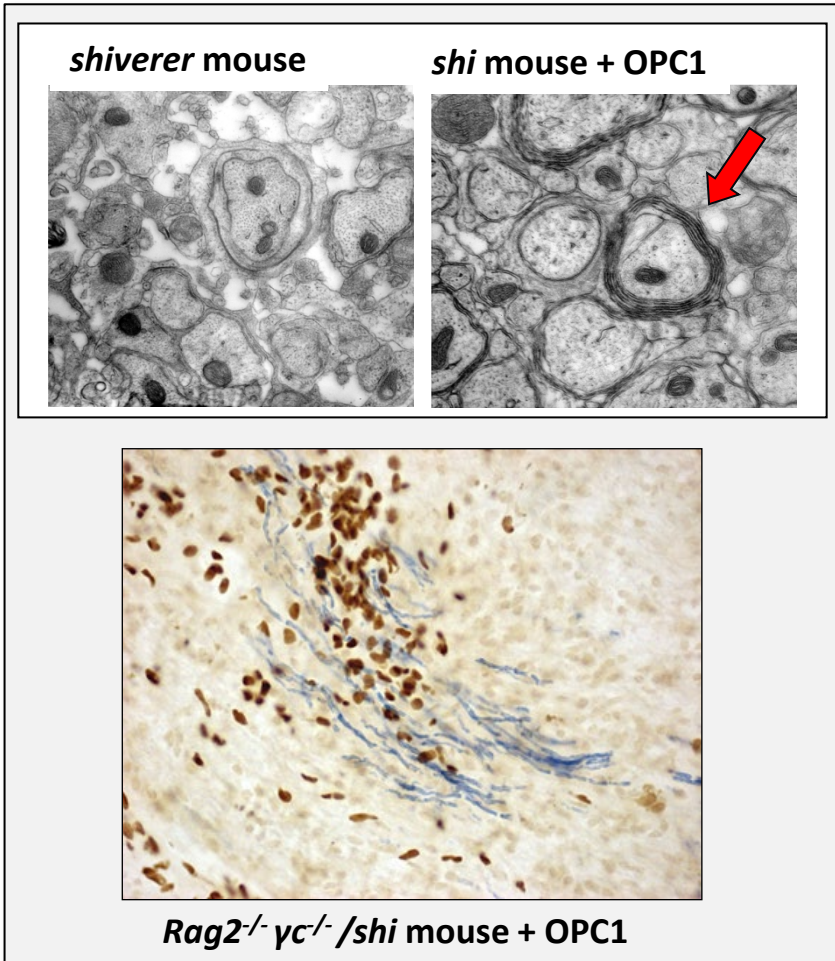


OPC1

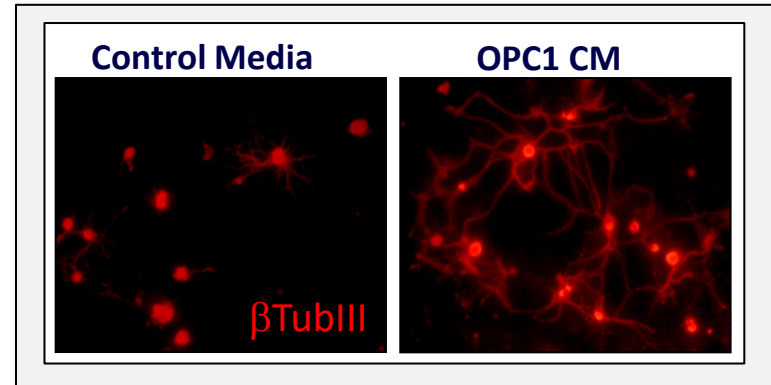
- Cryopreserved Allogeneic Cell Population
- Derived from an NIH-Registered Human Embryonic Stem Cell line (hESC)
- Characterized Composition of Cells:
 - Oligodendrocyte progenitors
 - Neural progenitors
 - Infrequent mature neural cells and
 - Rare other characterized cell types
- Three identified functions
 - Produces neurotrophic factors
 - Induces remyelination
 - Induces vascularization
- “Off the shelf” administration introduced by Lineage
- First indication: spinal cord injury
- Potential line extensions in other neurodegenerative diseases

OPC1: Three Major Physiologically Relevant Functional Activities

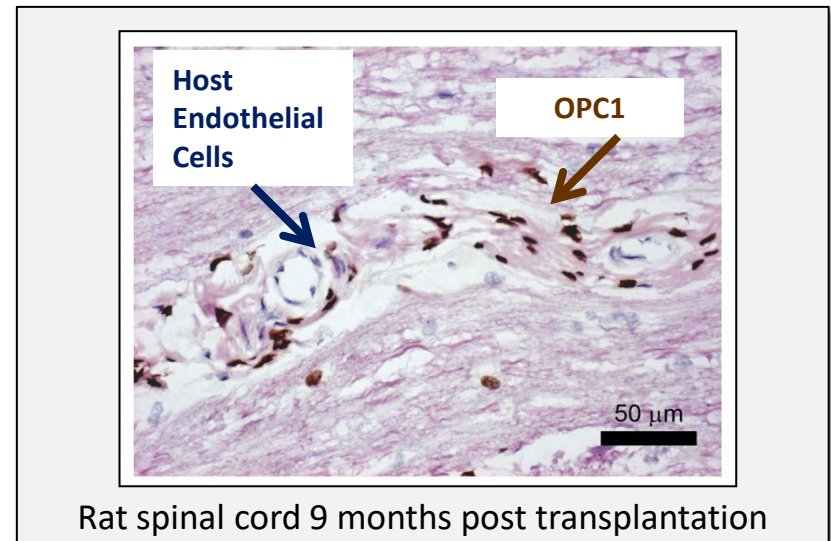
1. Wraps host neurons and forms compact myelin sheaths*



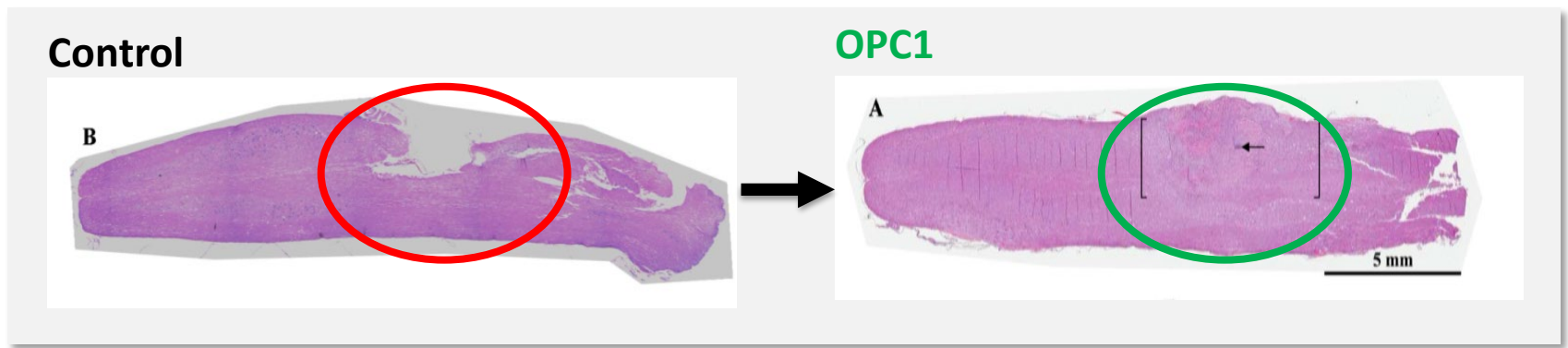
2. Produces neurotrophic factors and stimulates neurite outgrowth**



3. Stimulates neovascularization*



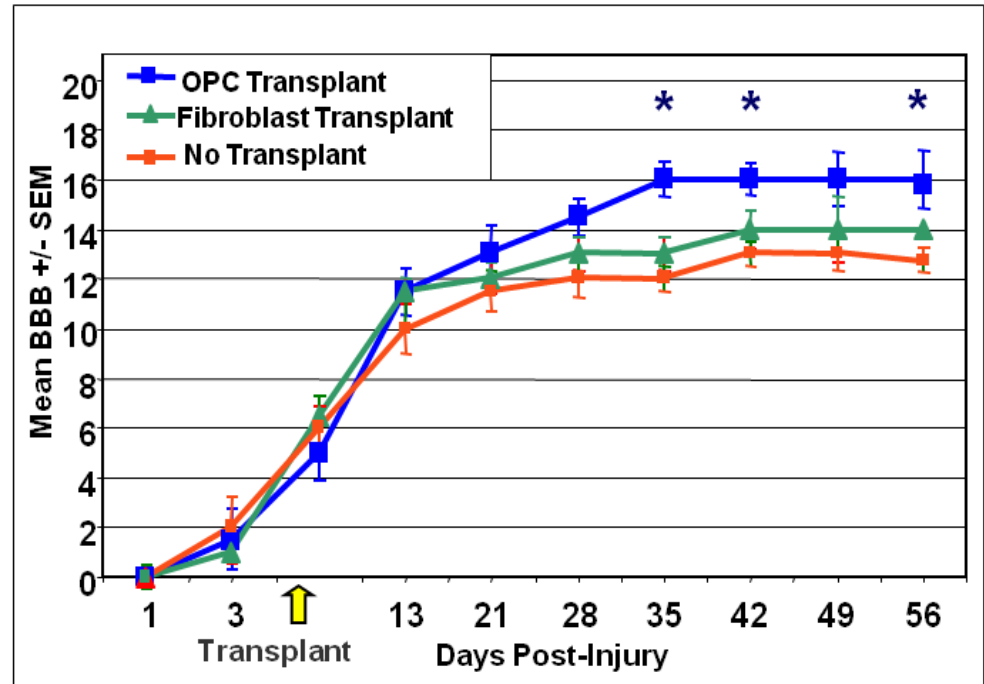
Prevention of Cavitation



OPC1 Improved Motor Function in Preclinical Animal Models

Locomotor Improvement in Thoracic SCI

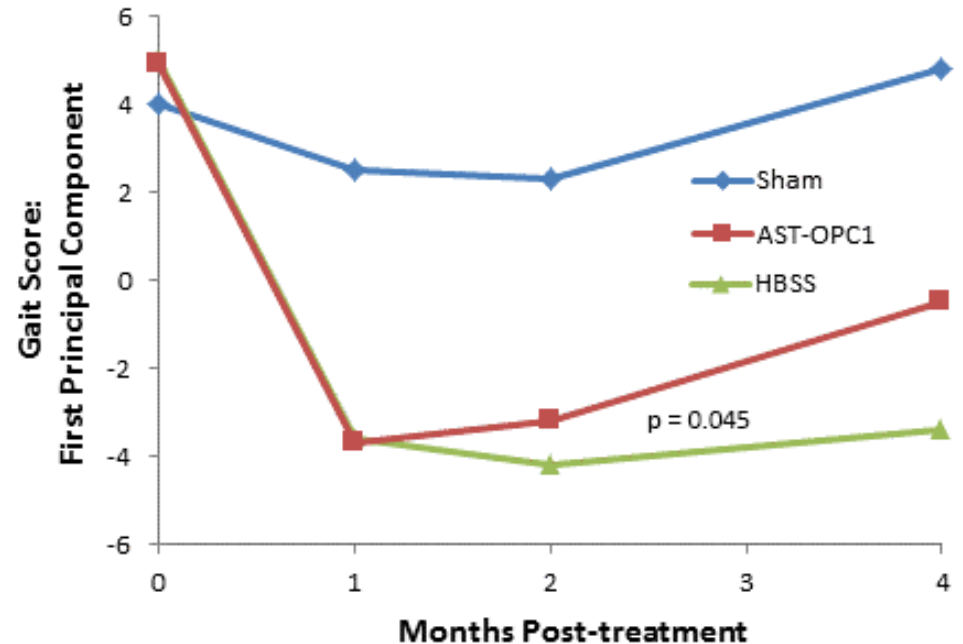
- Increased weight bearing
- Improved hindlimb-forelimb coordination
- Improved hind paw clearance
- Improved trunk stability
- Decreased tail drag



OPC1 Improved Motor Function in Preclinical Animal Models

Locomotor Improvement in Cervical SCI

- Increased running speed
- Increased right forelimb stride length
- Increased right forelimb maximal longitudinal deviation
- Increased right rear stride frequency



Thoracic Trial

AST-OPC1: Phase 1 Safety Study in Complete Thoracic SCI

- Open Label Trial
- Multi-Center (7 sites)
- 8-10 Subjects
- Subacute, Neurologically Complete T3-T11 Lesions
- 2×10^6 Cells
- Transplant 7-14 Days Post Injury
- Temporary Immunosuppression

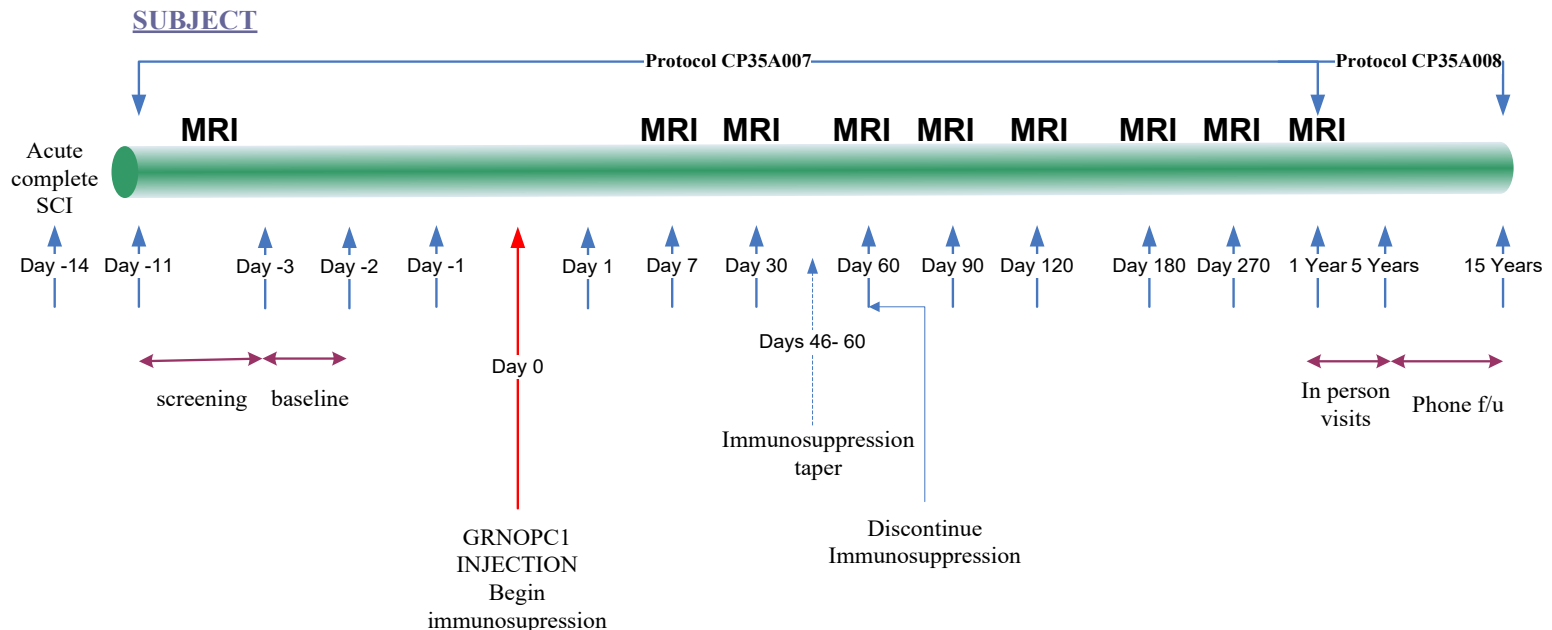


Primary Assessment:

Safety as related to OPC1 injection, the injection procedure, and/or the concomitant immunosuppression administered

Secondary Assessment:

Neurological function as measured by sensory scores and lower extremity motor scores as measured by the ISNCSCI examinations



RIGHT

MOTOR KEY MUSCLES

SENSORY KEY SENSORY POINTS Light Touch (LT) Pin Prick (PP)

C2		
C3		
C4		
C5		
C6		
C7		
C8		
T1		
T2		
T3		
T4		
T5		
T6		
T7		
T8		
T9		
T10		
T11		
T12		
L1		
L2		
L3		
L4		
L5		
S1		
S2		
S3		
S4-5		
RIGHT TOTALS		

UER
(Upper Extremity Right)

- Elbow flexors C5
- Wrist extensors C6
- Elbow extensors C7
- Finger flexors C8
- Finger abductors (little finger) T1

Comments (Non-key Muscle? Reason for NT? Pain?):

LER
(Lower Extremity Right)

- Hip flexors L2
- Knee extensors L3
- Ankle dorsiflexors L4
- Long toe extensors L5
- Ankle plantar flexors S1

(VAC) Voluntary anal contraction (Yes/No)

RIGHT TOTALS (MAXIMUM)

MOTOR SUBSCORES

UER + UEL = UEMS TOTAL
MAX (25) (25) (50)

LER + LEL = LEMS TOTAL
MAX (25) (25) (50)

3. NEUROLOGICAL LEVEL OF INJURY (NLI)

4. COMPLETE OR INCOMPLETE?
Incomplete = Any sensory or motor function in S4-5

5. ASIA IMPAIRMENT SCALE (AIS)

(In complete injuries only)
ZONE OF PARTIAL PRESERVATION
Most caudal level with any innervation

SENSORY
MOTOR

LEFT

MOTOR KEY MUSCLES

SENSORY KEY SENSORY POINTS Light Touch (LT) Pin Prick (PP)

C2		
C3		
C4		
C5		
C6		
C7		
C8		
T1		
T2		
T3		
T4		
T5		
T6		
T7		
T8		
T9		
T10		
T11		
T12		
L1		
L2		
L3		
L4		
L5		
S1		
S2		
S3		
S4-5		
LEFT TOTALS		

UEL
(Upper Extremity Left)

- Elbow flexors C5
- Wrist extensors C6
- Elbow extensors C7
- Finger flexors C8
- Finger abductors (little finger) T1

MOTOR (SCORING ON REVERSE SIDE)

- 0 = total paralysis
- 1 = palpable or visible contraction
- 2 = active movement, gravity eliminated
- 3 = active movement, against gravity
- 4 = active movement, against some resistance
- 5 = active movement, against full resistance
- 5* = normal corrected for pain/disease
- NT = not testable

SENSORY (SCORING ON REVERSE SIDE)

- 0 = absent
- 1 = altered
- 2 = normal
- NT = not testable

LEL
(Lower Extremity Left)

- Hip flexors L2
- Knee extensors L3
- Ankle dorsiflexors L4
- Long toe extensors L5
- Ankle plantar flexors S1

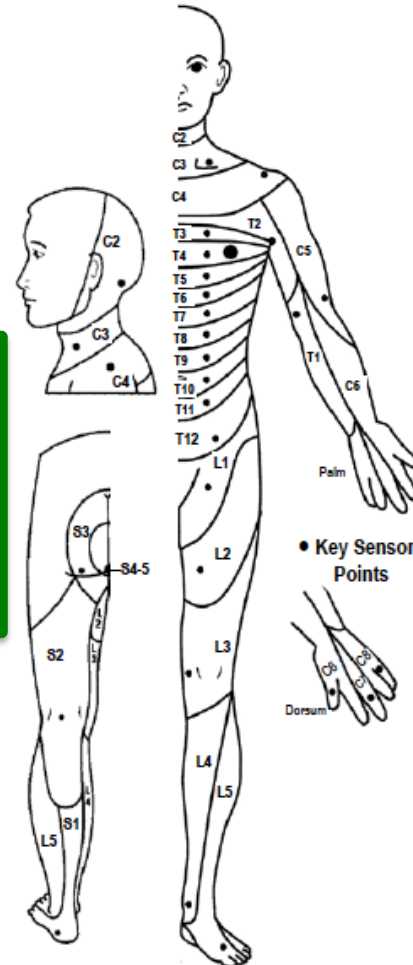
(DAP) Deep anal pressure (Yes/No)

LEFT TOTALS (MAXIMUM)

SENSORY SUBSCORES

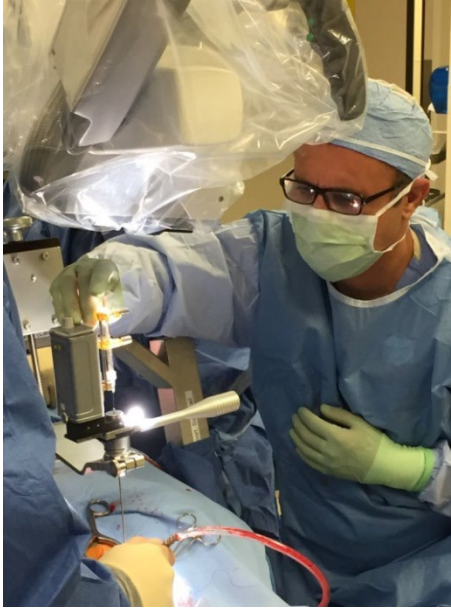
RLT + LLT = LT TOTAL
MAX (56) (56) (112)

RPP + LPP = PP TOTAL
MAX (56) (56) (112)

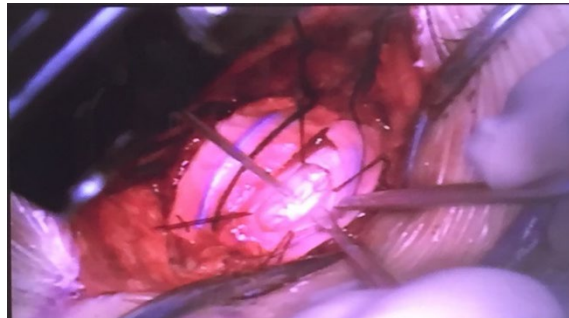


OPC1 Injection Procedure

Shepherd Center



Rush University



- Injections performed using a table-mounted syringe positioning device (SPD)
- Direct intraparenchymal injection into the spinal cord lesion
- Single 50 μ L injection, for both the 2M & 10M doses; Two injections for the 20M dose
- No intraoperative complications

OPC-1 Subject Demographics

Demographic and Baseline Disease Characteristics – All Treated Subjects				
Age (years)	Sex	Level of Injury	Cause of Injury	
21	Male	T6	Motor vehicle accident	
23	Male	T8	Restrained driver in rollover motor vehicle collision with ejection	
32	Male	T6	Motorcross	
31	Male	T7	Fell 30 feet down rock embankment	
23	Female	T3	Car accident	

Enrolling Sites



Dr. David Apple

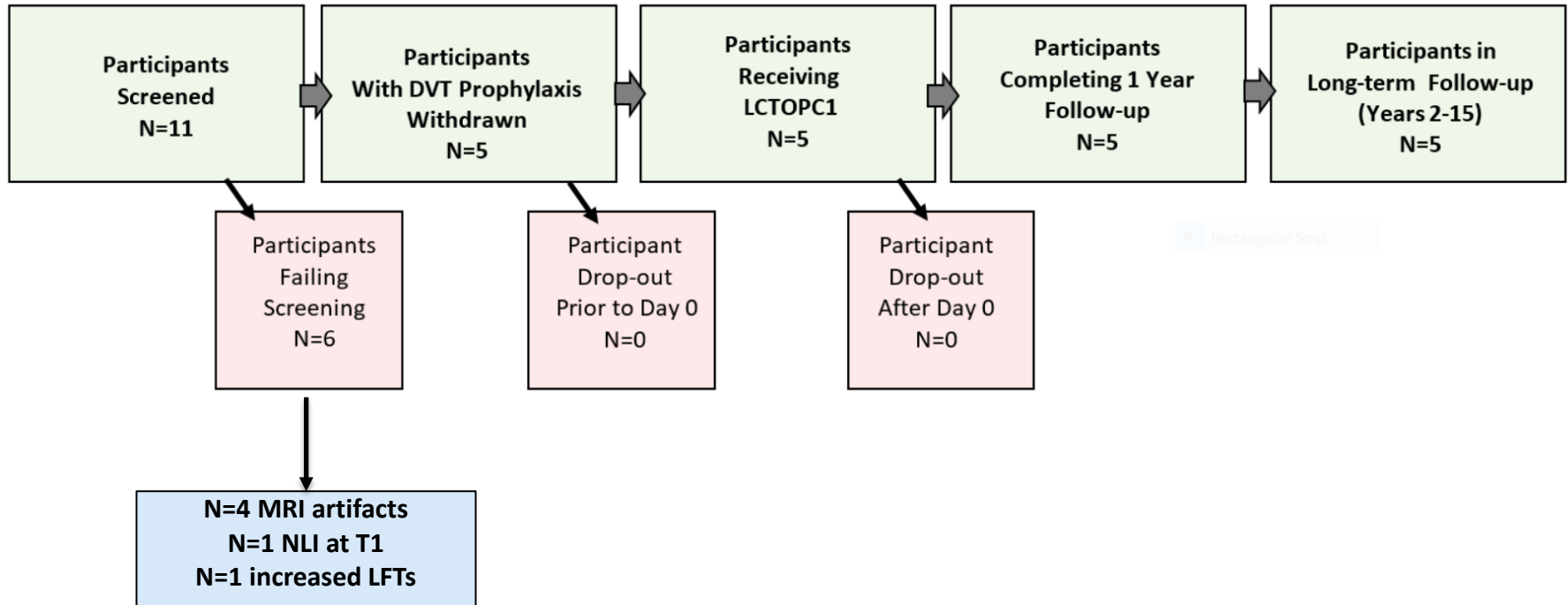


Dr. Richard Fessler
Dr. David Chen



Dr. Gary Steinberg
Dr. Steve McKenna

OPC-1 CONSORT Diagram



Thoracic Trial Adverse Events and Serious Adverse Events

Adverse Events and Serious Adverse Events	Total (N = 5)	
	Number of Events	n (%)
All events	174	
Nervous system disorders	19	4 (80.0)
Eye disorders	2	2 (40.0)
Gastrointestinal disorders	16	5 (100)
General disorders and administration site conditions	8	3 (60.0)
Immune system disorders	2	2 (40.0)
Infections and infestations	42	5 (100)
Injury, poisoning, and procedural complications	10	5 (100)
Investigations	5	3 (60.0)
Metabolism and nutrition disorders	3	2 (40.0)
Musculoskeletal and connective tissue disorders	33	5 (100)
Psychiatric disorders	8	2 (40.0)
Renal and urinary disorders	7	4 (80.0)
Reproductive system and breast disorders	1	1 (20.0)
Respiratory, thoracic, and mediastinal disorders	2	2 (40.0)
Skin and subcutaneous tissue disorders	11	3 (60.0)
Surgical and medical procedures	2	2 (40.0)
Vascular disorders	3	2 (40.0)

N = number of participants in safety population or number of participants with respective event category; n = number of participants in respective category; %= n • 100/ N.

25 possibly related AEs

Cell implant = 0

Injection procedure = 9
(pain, fever, UTI)

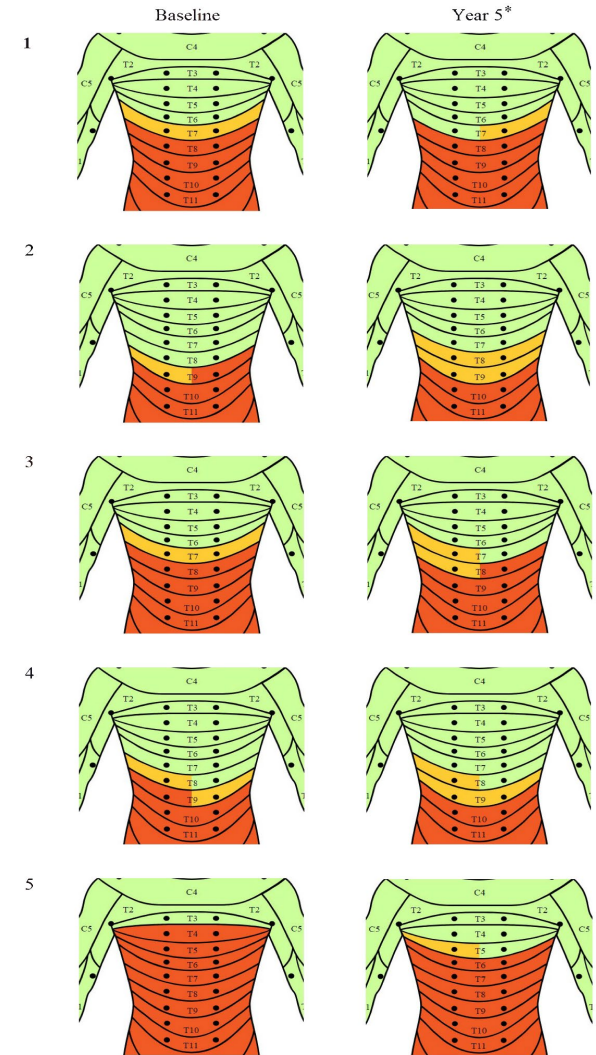
Immunosuppression = 16
(nausea, low magnesium, infections)

Thoracic Trial Serious Adverse Events

Description of Serious Adverse Events						
Event	Onset post Treatment (days)	Duration (days)	AE Serious	AE Severity	Outcome	Relatedness to: OPC1, surgical delivery of OPC1, or immuno-suppression
Pyelonephritis	215	12	Yes	Grade 2	Hospitalized, Resolved	Unrelated
Urinary Tract Infection	325	16	Yes	Grade 3	Hospitalized, Resolved	Unrelated
Increased autonomic dysreflexia	720	2	Yes	Grade 3	Resolved without Sequelae	Unrelated
Psychiatric disorder (Mood Disorder)	1610	2	Yes	Grade 3	Resolved with Sequelae	Unrelated

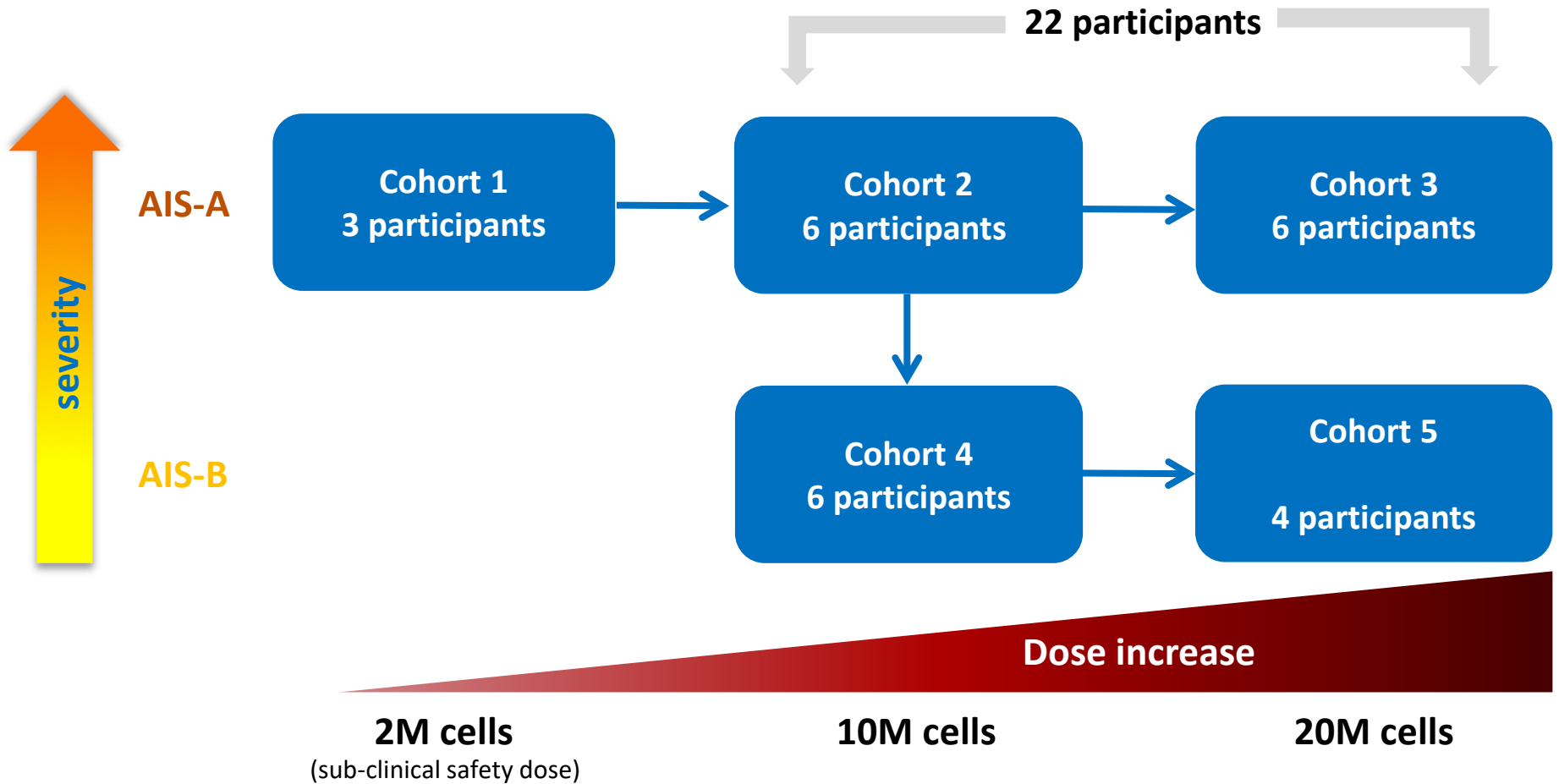
Thoracic Trial Outcomes at 5 years post OPC1

- Sensory:
 - Diagrammatic representation of sensory function of each patient at baseline and at 5 years
- Motor:
 - No changes in upper (50) or lower (0) extremity motor scores
- American Spinal Injury Association Impairment Scale
 - No changes, AIS A
- Neurological Level of Injury
 - N=2 no change
 - N=2 one level improvement
 - N=1 one level loss



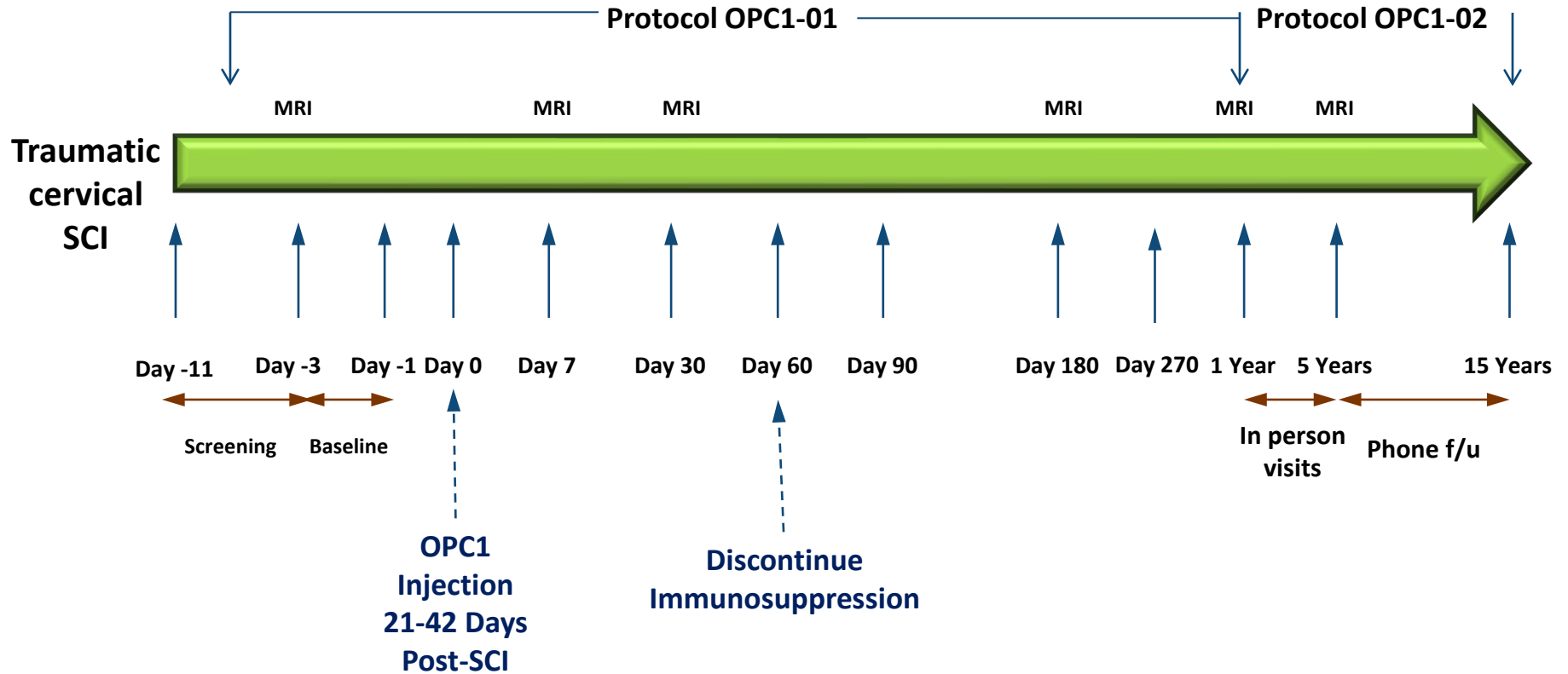
Cervical Trial: The SCiStar Study

Cervical Clinical Trial Study Design



Cervical Trial Schema

- Open Label Trial
- 21-42 days post SCI
- Traumatic SCI (C4-C7)
- Ages 18-69
- AIS A or B



RIGHT

MOTOR KEY MUSCLES

SENSORY KEY SENSORY POINTS
Light Touch (LT) Pin Prick (PP)

C2		
C3		
C4		
C5		
C6		
C7		
C8		
T1		
T2		
T3		
T4		
T5		
T6		
T7		
T8		
T9		
T10		
T11		
T12		
L1		
L2		
L3		
L4		
L5		
S1		
S2		
S3		
S4-5		
RIGHT TOTALS		
(MAXIMUM)	(50)	(56)

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(Upper Extremity Right)

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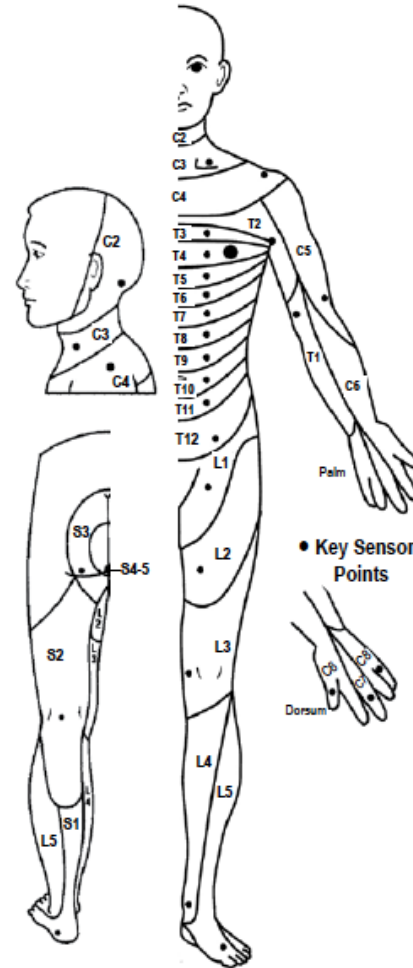
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MOTOR SUBSCORES

UER + UEL = UEMS TOTAL MAX (25) (25) (50)
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SENSORY

KEY SENSORY POINTS
Light Touch (LT) Pin Prick (PP)

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T7		
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T9		
T10		
T11		
T12		
L1		
L2		
L3		
L4		
L5		
S1		
S2		
S3		
S4-5		
RIGHT TOTALS		
(MAXIMUM)	(56)	(56)

SENSORY SUBSCORES

RLT + LLT = LT TOTAL MAX (56) (56) (112)
RPP + LPP = PP TOTAL MAX (56) (56) (112)

MOTOR KEY MUSCLES

LEFT

C2		
C3		
C4		
C5		
C6		
C7		
C8		
T1		
T2		
T3		
T4		
T5		
T6		
T7		
T8		
T9		
T10		
T11		
T12		
L1		
L2		
L3		
L4		
L5		
S1		
S2		
S3		
S4-5		
LEFT TOTALS		
(MAXIMUM)	(50)	(56)

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- Long toe extensors L5
- Ankle plantar flexors S1

(DAP) Deep anal pressure (Yes/No)

NEUROLOGICAL LEVELS

1. SENSORY

R	L
<input type="checkbox"/>	<input type="checkbox"/>

2. MOTOR

R	L
<input type="checkbox"/>	<input type="checkbox"/>

3. NEUROLOGICAL LEVEL OF INJURY (NLI)

4. COMPLETE OR INCOMPLETE?
Incomplete = Any sensory or motor function in S4-5

5. ASIA IMPAIRMENT SCALE (AIS)

(In complete injuries only)
ZONE OF PARTIAL PRESERVATION
Most caudal level with any innervation

SENSORY

R	L
<input type="checkbox"/>	<input type="checkbox"/>

MOTOR

R	L
<input type="checkbox"/>	<input type="checkbox"/>

Year 1 Follow-Up Status for Cervical Trial

Cohort	# Participants Administered OPC1	# Participants with 12 Months Follow-Up
Safety Cohort 1 AIS-A 2x10 ⁶ Dose	3	3
Safety and Efficacy Cohort 2 AIS-A 1x10 ⁷ Dose	6	6
Safety and Efficacy Cohort 3 AIS-A 2x10 ⁷ Dose	6 ^a	6
Safety and Efficacy Cohort 4 AIS-B 1x10 ⁷ Dose	6	6
Safety and Efficacy Cohort 5 AIS-B 2x10 ⁷ Dose	4 ^b	4

^a One participant enrolled in Cohort 3 received only the 1 x 10⁷ dose due to an error during dose preparation

^b One participant enrolled in Cohort 5 received only the 1 x 10⁷ dose due to a very small spinal cord lesion

Cervical Trial Summary of Adverse Events

- Majority of Cervical Trial adverse events were mild to moderate in severity

All treated participants (n=25)	AEs	SAEs
Total	534	29
Mild (Grade 1)	343	0
Moderate (Grade 2)	161	15
Severe (Grade 3)	30	14
Life threatening (Grade 4)	0	0
Death (Grade 5)	0	0
Related to OPC1	1*	0
Related to Injection Procedure	20	1**
Related to Tacrolimus	11	1***

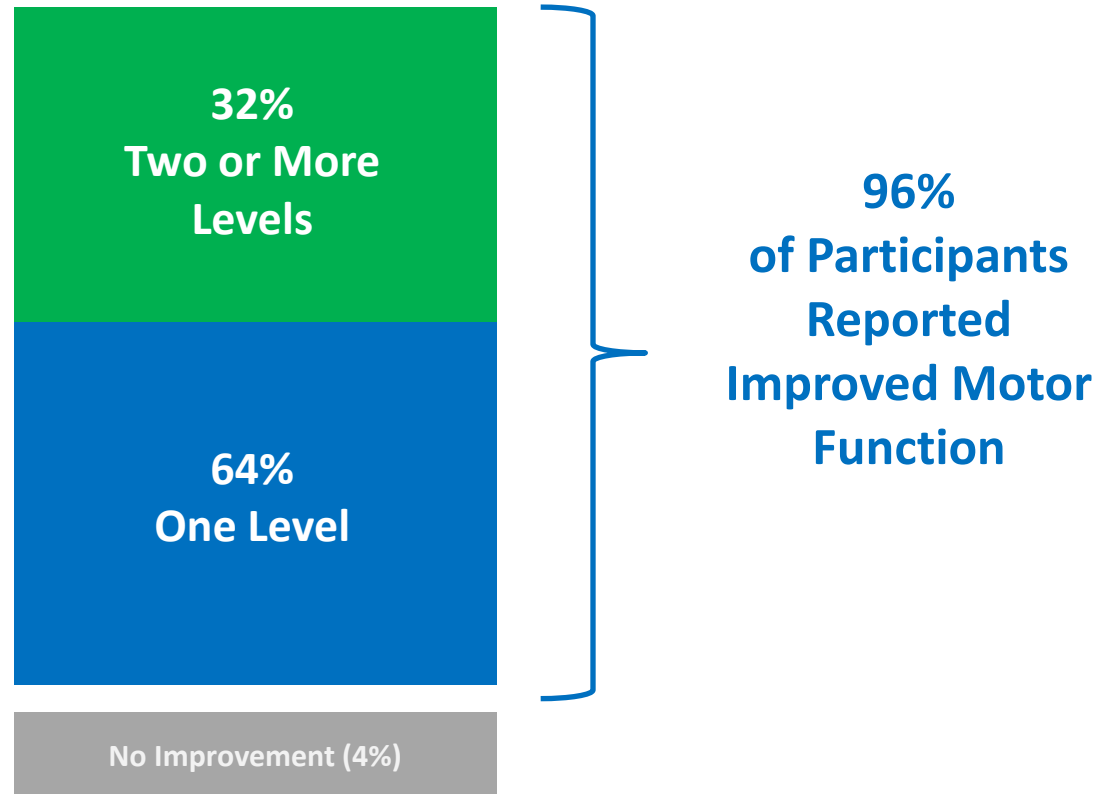
* AE possibly related to OPC1, Grade 2 dysesthesia began POD 47 and resolved by Year 2 follow-up

** CSF leak reported on POD 7 and resolved with CSF drain

*** Urosepsis reported on POD 30 and resolved with antibiotics

Cervical Trial - Motor Function Gains


22 Patients at 12 months




Real-World Benefit from a 2 Motor Level Improvement

Motor level gains translate into clinically meaningful improvements in self-care and reductions in cost of care


Function	Cervical Injury Level				
	C1-C3	C4	C5	C6	C7-C8
Bowel	Red	Red	Red	Yellow	Green
Bladder	Red	Red	Red	Yellow	Green
Bed Mobility	Red	Red	Yellow	Green	Green
Transfers	Red	Red	Red	Green	Green
Pressure Relief	Red	Red	Yellow	Green	Green
Eating	Red	Red	Yellow	Green	Green
Dressing	Red	Red	Yellow	Green	Green
Grooming	Red	Red	Yellow	Green	Green
Bathing	Red	Red	Red	Green	Green
Wheelchair	Red	Red	Red	Yellow	Green
Car transport	Red	Red	Red	Yellow	Green
Daily Home Care	24 hr attendant	18-24 hr attendant	6-12 hr assistance	4 hr housework	1 hr housework



Total Assist



Partial Assist



Independent

Cervical Trial Evaluation of Change in UEMS (12 Months Post-Injection Versus Key Variables)

Key Variable	Correlation with UEMS Change from Baseline to 12 months
Age	$p = 0.95$
Gender	$P = 0.86$
Baseline AIS Grade	$P = 0.02$ (Better for AIS-A due to Cohort 2)
Baseline NLI (C5-C7)	C5: $P = 0.22$ C6: $p = 0.39$ C7: $p = 0.13$
Dose (10M or 20M cells)	$P = 0.94$
Number of days from SCI to OPC1 injection	$P = 0.25$
Manufacturing Lot of OPC1 (21 of 22 received cells from Lot A or Lot B)	Lot A (n=7): $P = 0.41$ Lot B (n=14): $P = 0.76$

- Analysis performed for all 22 participants in Cohorts 2-5 (except for Baseline NLI, which was only analyzed for participants with a baseline NLI of C5, C6 or C7)

Cervical Trial - Analysis of Patients with Least UEMS Recovery

C4 or cord compressions occurred in 5 of the 7 worst patient outcomes and both issues can be addressed in the next trial

Subject	UEMS Change at 12 mo.	Cord Compression After OPC1 Injection?	NLI Baseline	Baseline AIS	Cohort	Dose	Age	Injection Days Post Injury
23	7	N	C4	B	5	20 M	62	37
14	6	N	C6	A	3	20 M	45	31
15	6	N	C4	A	3	10 M	19	20
21	5	N	C6	B	4	10 M	21	25
18	4	N	C4	B	4	10 M	55	38
23	4	Y	C5	B	5	10 M	19	38
17	3	Y	C6	B	4	10 M	22	35

- Two patients had cord compression after OPC1 injection (17 and 23 at Day 30 and Day 7)
- Patients 15, 23, 18 had a C4 (highest/most severe) injury level at baseline
- Patient 15 also had a hematoma in the spinal cord at baseline & a failed graft

Some Injuries May Be Too Severe for Cell Survival (Hematoma case)

Subject 15 (Cohort 3): Hematoma in Spinal Cord

Pre-Injection Baseline



Day 365 Post-Injection



Failed
graft
(single
case out
of 25
patients)
with
lesion
cavity
formation

- Large hematoma in spinal cord
- Most severe lesion at baseline
- Least favorable environment for survival of OPC1 cells

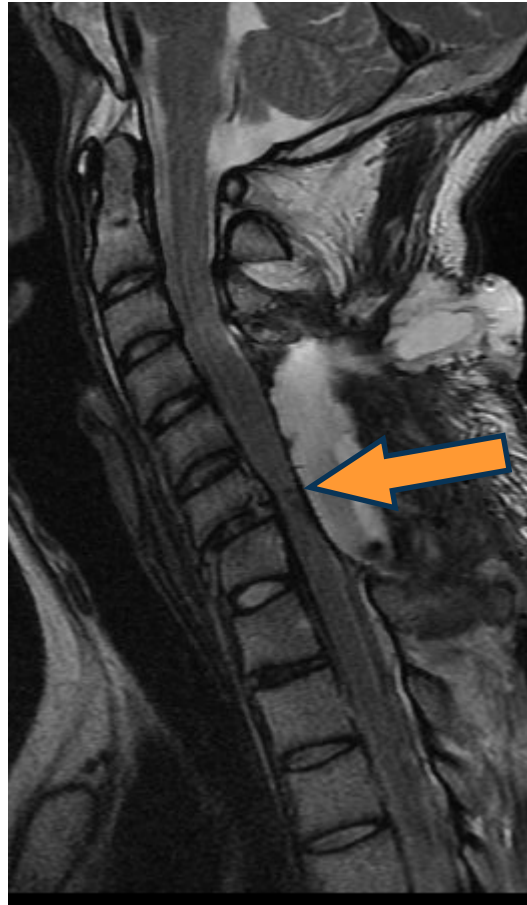
Cervical Trial – Cord Compression

Subject 17 (Cohort 4): Cord Compression at Day 30

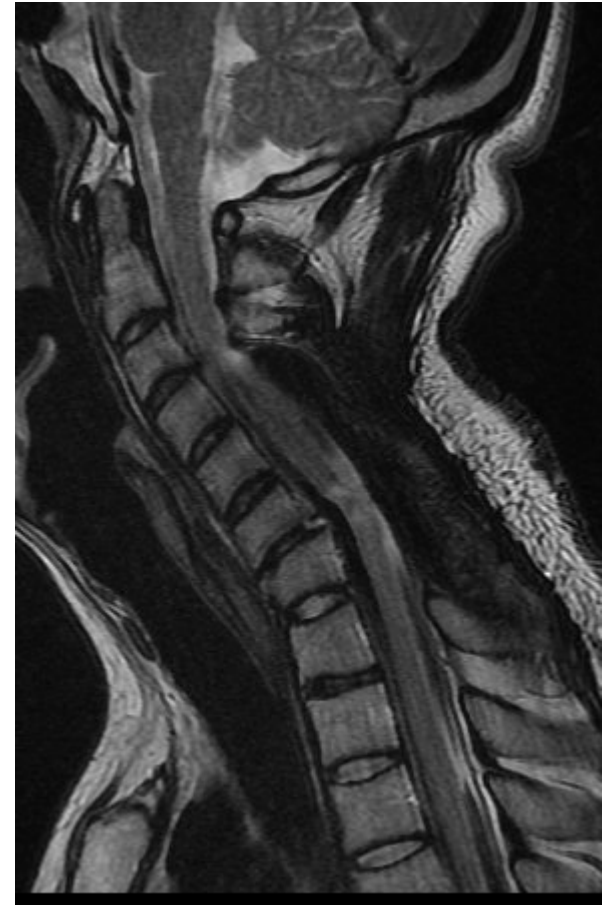
Baseline



Day 30



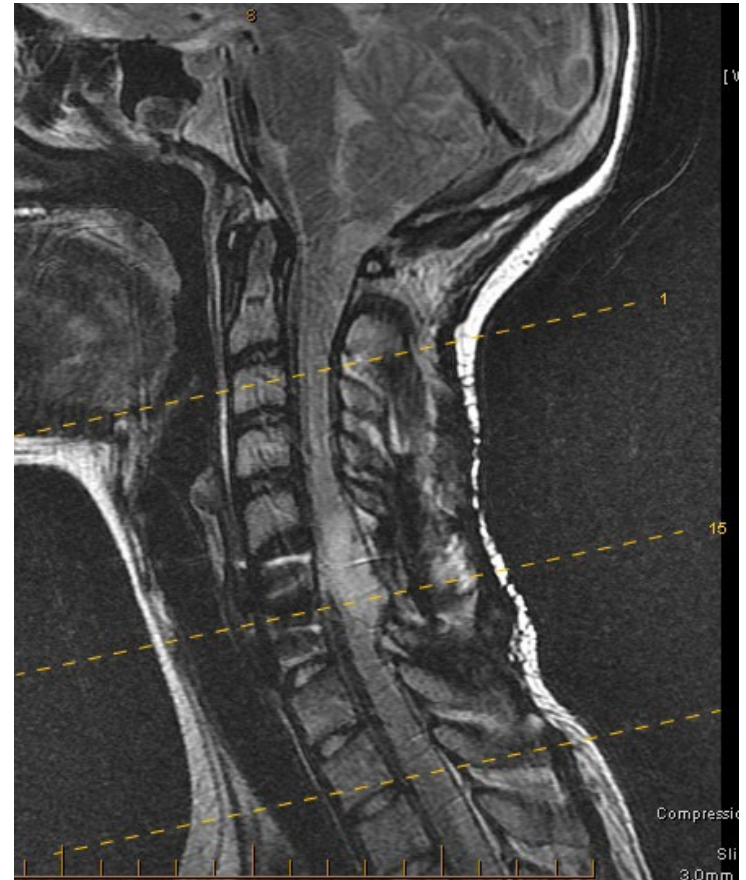
Day 365



MRI Results Support Durable Engraftment of OPC1 Cells

12- and 24-Month MRI Scans Indicate Durable Engraftment

- **Cystic cavitation (syringomyelia) occurs in ~80% of SCI cases**
- **MRI results suggest formation of a tissue matrix at the injury site, indicating that OPC1 cells have durably engrafted and helped prevent syringomyelia**
- **96% (24/25) of OPC1 patients had serial MRI scans that indicated no sign of a lesion cavity at 12 months (or 24 months for 22 scans available)**



Weighted sagittal MRI

Cervical Trial Summary – One Year Results

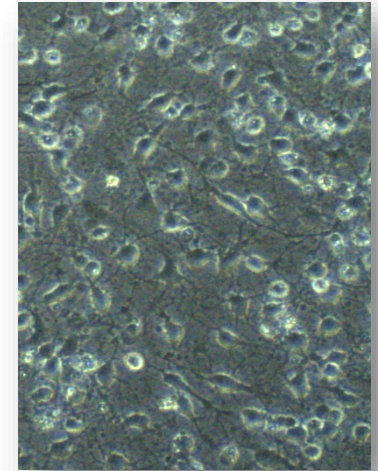
- **The overall safety profile of OPC1 was excellent, and immunosuppression with tacrolimus was well-tolerated**
- **MRI scans consistent with a very high rate (96%) of durable engraftment through 1 year post-injection**
- **Majority of participants who received 10M or 20M OPC1 cells exhibited motor recovery in the upper extremities**
 - **21/22 participants in Cohorts 2-5 improved at least 1 motor level on at least 1 side**
 - **7/22 participants in Cohorts 2-5 improved at least 2 motor level on at least 1 side**
- **Two issues (C4 NLI; postop cord compression) that may negatively impact motor recovery are believed to be addressable in future studies**
- **These encouraging engraftment & motor recovery data warranted further evaluation in studies incorporating a period of rehabilitation utilizing novel strategies designed to augment the potential of hESC base therapies to promote functional recovery**
- **Data from the Cervical Trial will help inform the design of future randomized studies with respect to inclusion/exclusion criteria, dose, and timing of administration**

OPC1 Program Enhancements

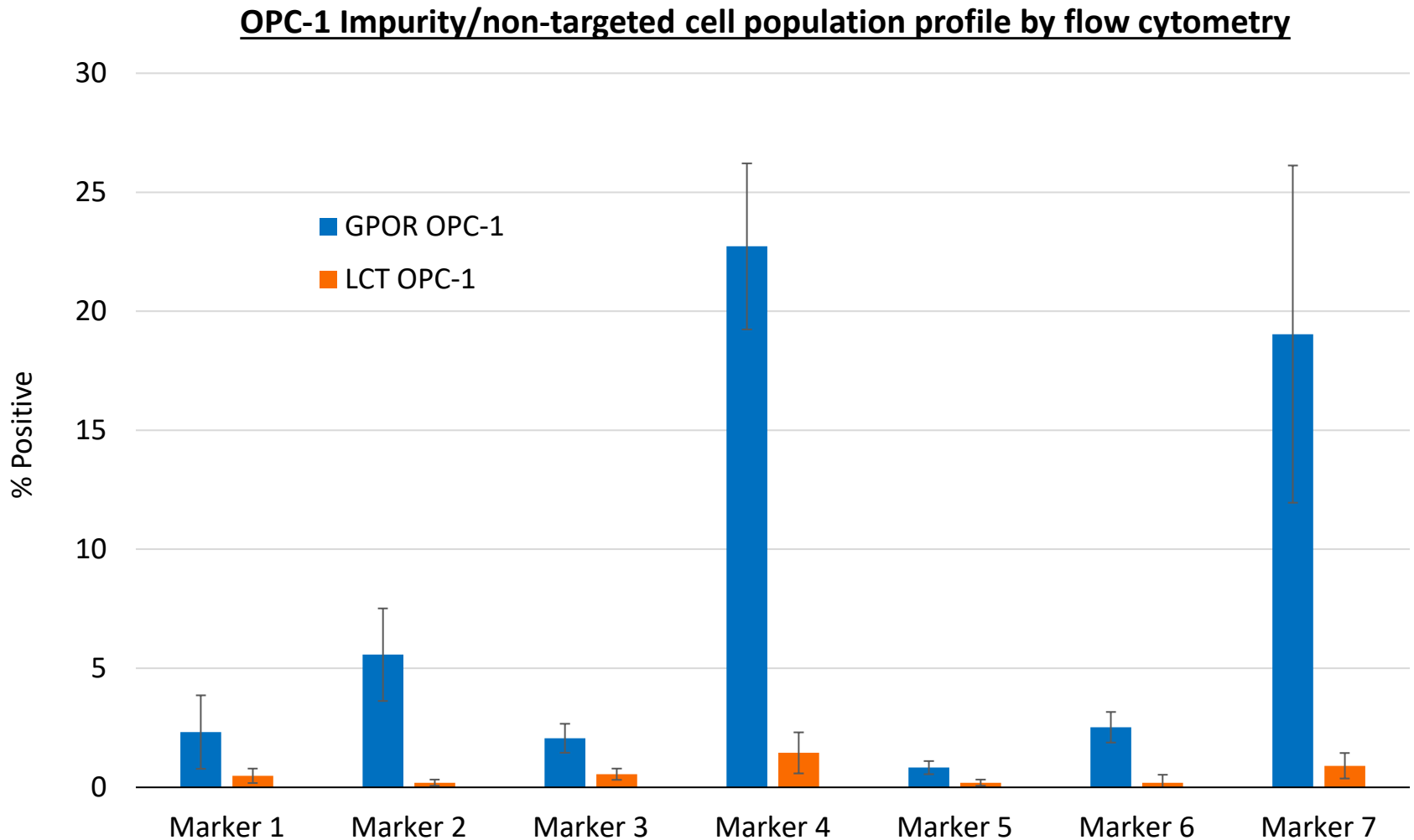
OPC1 Manufacturing Improvements Following FIM Study

Lineage has made major improvements in production and quality of OPC1

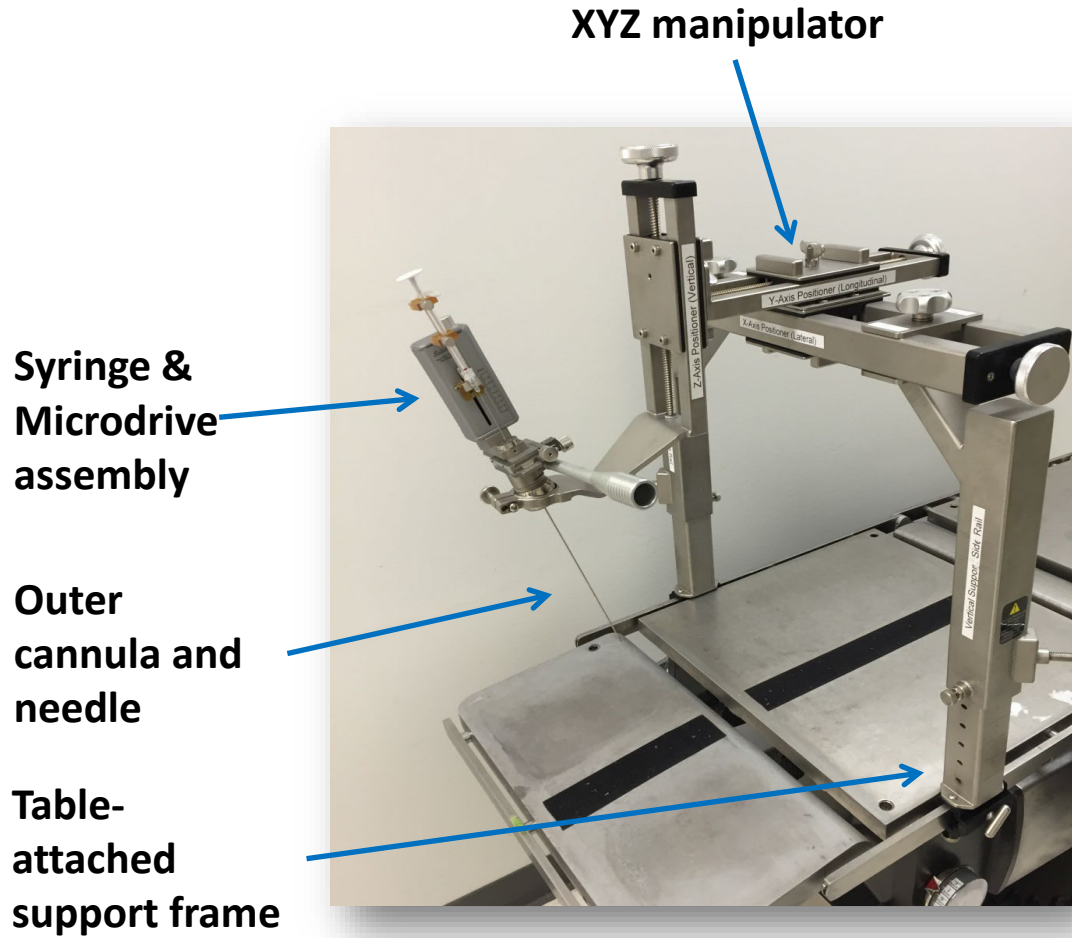
- **A new ready-to-inject formulation was developed**
- **Elimination of dose preparation achieved**
- **10- to 20-fold increase in production scale**
- **Significant reduction in impurities**
- **No reduction in functional activity**
- **12 new analytical and functional methods developed**
- **Elimination of all animal-based production reagents**
- **Estimated expiration dates of pending patent applications range from 2036 to 2040**



OPC1 Manufacturing Improvements: Lower Impurities



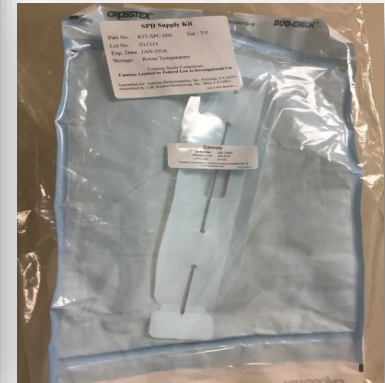
Cervical Trial - Original Syringe Positioning Device



Storage trays

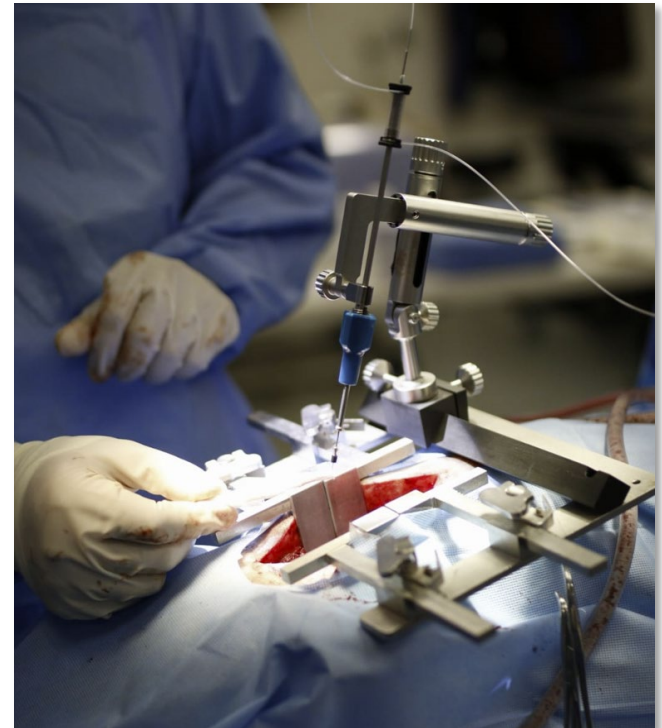


Supply Kits



New Spinal Cord Delivery System – Clinical Testing in 2022

- **Better stability and control**
 - Eliminates motion between platform/XYZ manipulator/needle
- **Enhanced usability and safety: no cessation of ventilation**
 - Attaches directly to the patient, compatible with breathing motion
- **Improved user experience**
 - Smaller and fewer components
 - Single hand operation
- **Animal testing ongoing**
- **Device clinical trial in sub-acute and chronic patients planned**



Next Steps

OPC1 Next Steps

Lineage has focused on CMC and delivery to prepare for late-stage clinical testing of OPC1

- **Initial data is supportive of further development, but enhancements to the program can increase the probability of success and conduct of future trials**
- **Major improvements have been made to the OPC1 process, scale, and quality**
 - Similar efforts led to a \$670M big pharma alliance for a related, Phase 1/2a RPE program
- **Ongoing efforts intended to validate a superior delivery system**
 - FDA supportive of enrolling subacute and chronic patients in small safety study
- **Data from above will support the design and conduct of a larger, later-stage, multi-center trial in sub-acute cervical SCI patients**
 - Upcoming regulatory engagements will inform size, design, and timing of next clinical study

Patients Are An Inspiration

View their stories at lineagecell.com/media/#patients

OPC1 SCiStar Clinical Trial Participants



Lucas Lindner

“There’s no reason to not look forward in the same way now that I had before all of this happened. I’m looking forward to driving again... it’s a bright future.”



Kris Boesen

“I couldn’t drink, couldn’t feed myself, couldn’t text or pretty much do anything, I was basically just existing. I wasn’t living my life, I was existing.”



Jake Javier

“Even though it’s a completely different perspective, I can still lead that way. I can just try to be the best I can and to persevere the best I can.”

Diablo Magazine, Feb. 16, 2017

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