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The future of cell therapy.



Oligodendrocyte Cell Transplants to Improve Outcomes Following Spinal Cord Injury (OPC1)

February 22, 2021

Agenda

Welcome	Jason McCarthy, Ph.D. Senior Managing Director, Maxim Group
Technology Overview	Brian Culley, CEO Lineage Cell Therapeutics
OPC1 Mechanism of Action	Ed Wirth, M.D., Ph.D. Former OPC1 Study Head
OPC1 Clinical Results	Ed Wirth, M.D., Ph.D. Former OPC1 Study Head
Manufacturing and Next Steps	Brian Culley, CEO Lineage Cell Therapeutics
Q&A Session	Jason McCarthy, Ph.D. Senior Managing Director, Maxim Group

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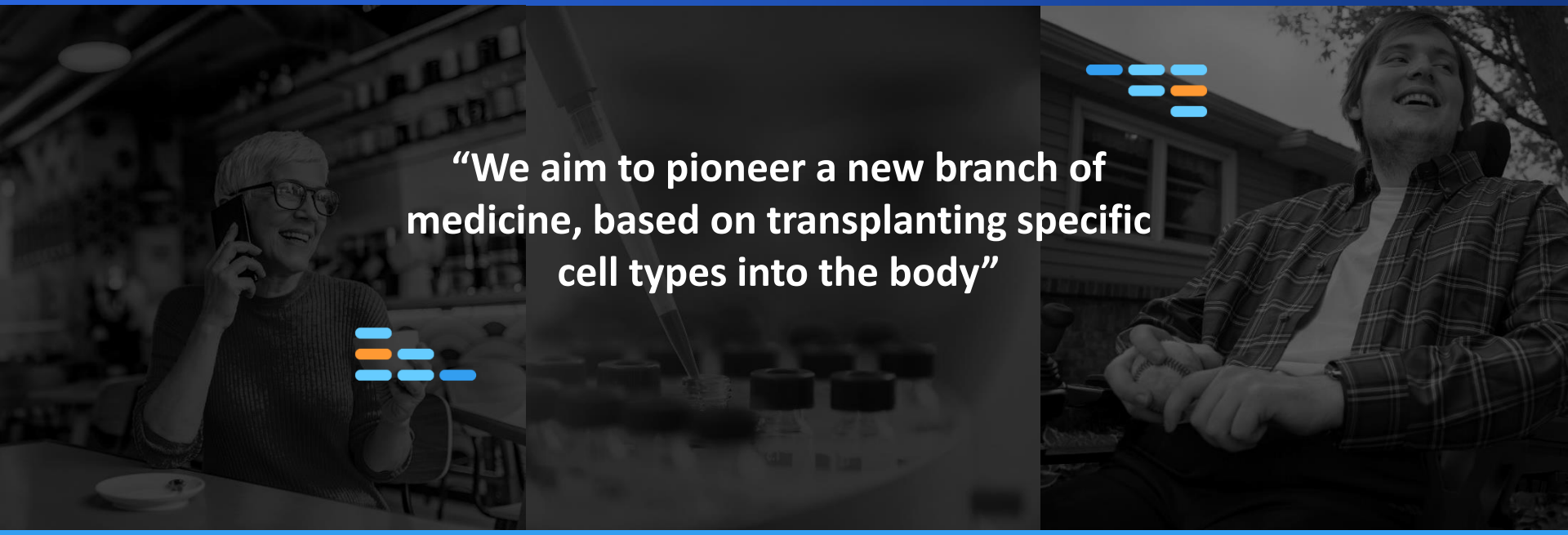

Technology Overview

Brian Culley, CEO

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.

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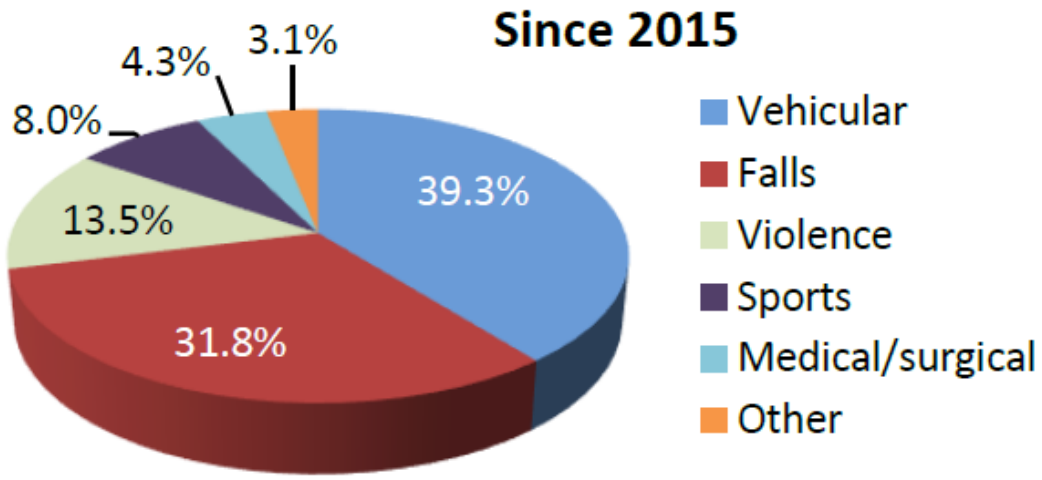
Spinal Cord Injury (SCI) Overview

Lifetime care for an SCI patient can cost nearly $5 million

- **Incidence**
  - Approximately 18,000 new cases each year
- **Prevalence**
  - Between 249,000 and 363,000 people in the US
- **Causes**



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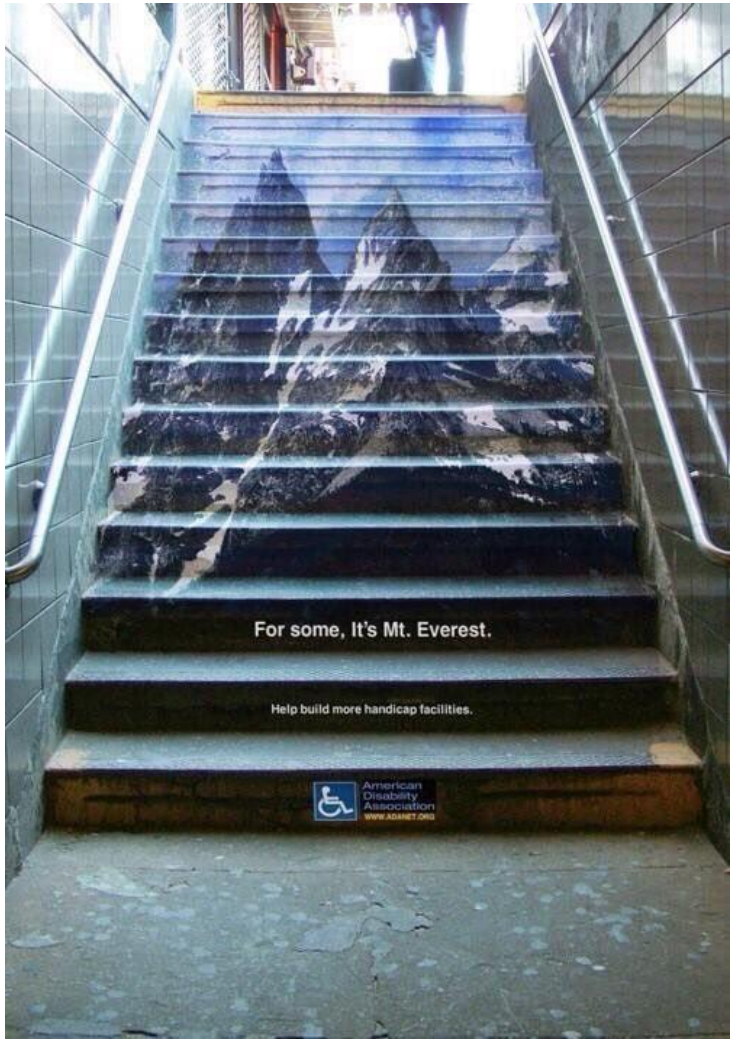
Source: National Spinal Cord Injury Statistical Center

SCI Burden and Unmet Needs

- **A significant burden for patients and caregivers***
  - 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



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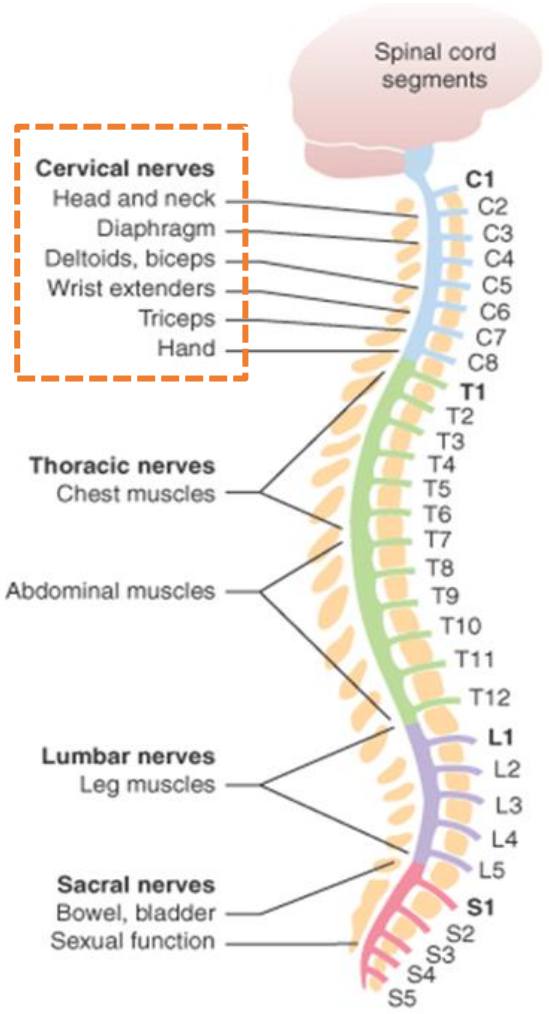
(*) National SCI Statistical Center, 2019 SCI Data Sheet.

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 activity, 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**
- **Emphasis on cervical (C4-C7) injuries**



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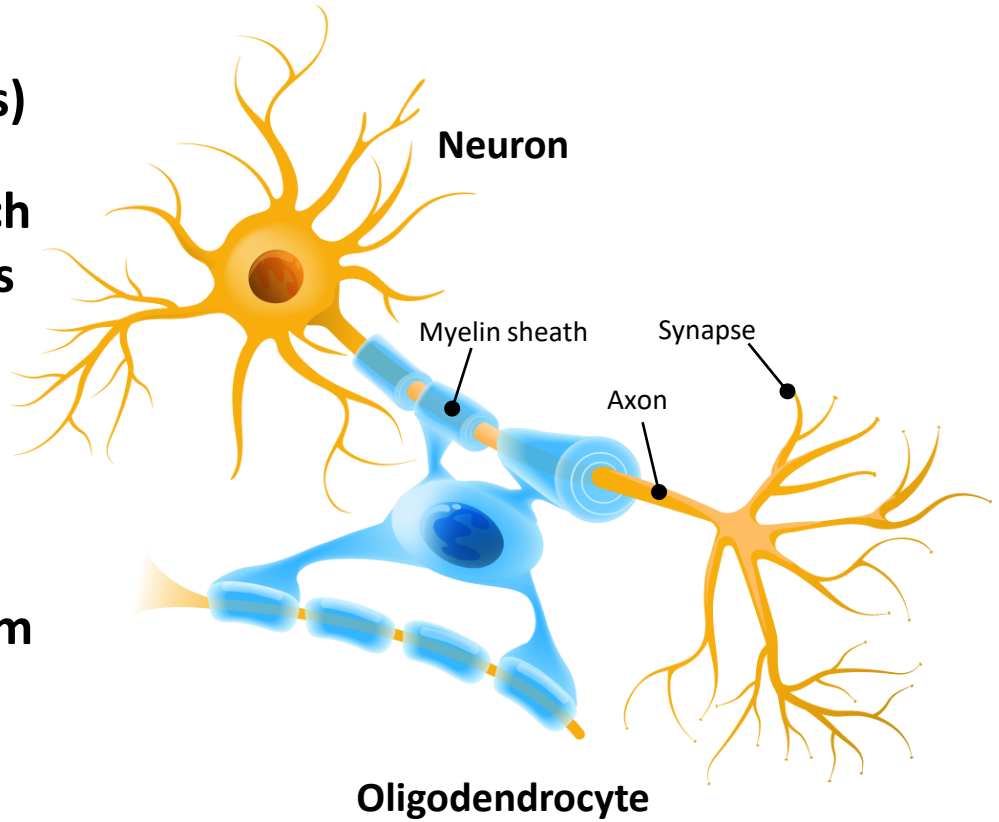
(*) National SCI Statistical Center, 2019 SCI Data Sheet.

Lineage's **OPC1 cells** for Spinal Cord Injury

Replacing oligodendrocytes may provide additional upper limb and finger function and improve the quality of life for patients

- **OPC1 is comprised of OPCs (oligodendrocyte progenitor cells)**
- **OPCs are precursors to cells which provide insulation to nerve axons in the form of a myelin sheath**
- **Myelin is necessary for proper function of neurons**
- **OPC1 cells are manufactured from a cell line and injected into the spinal cord**



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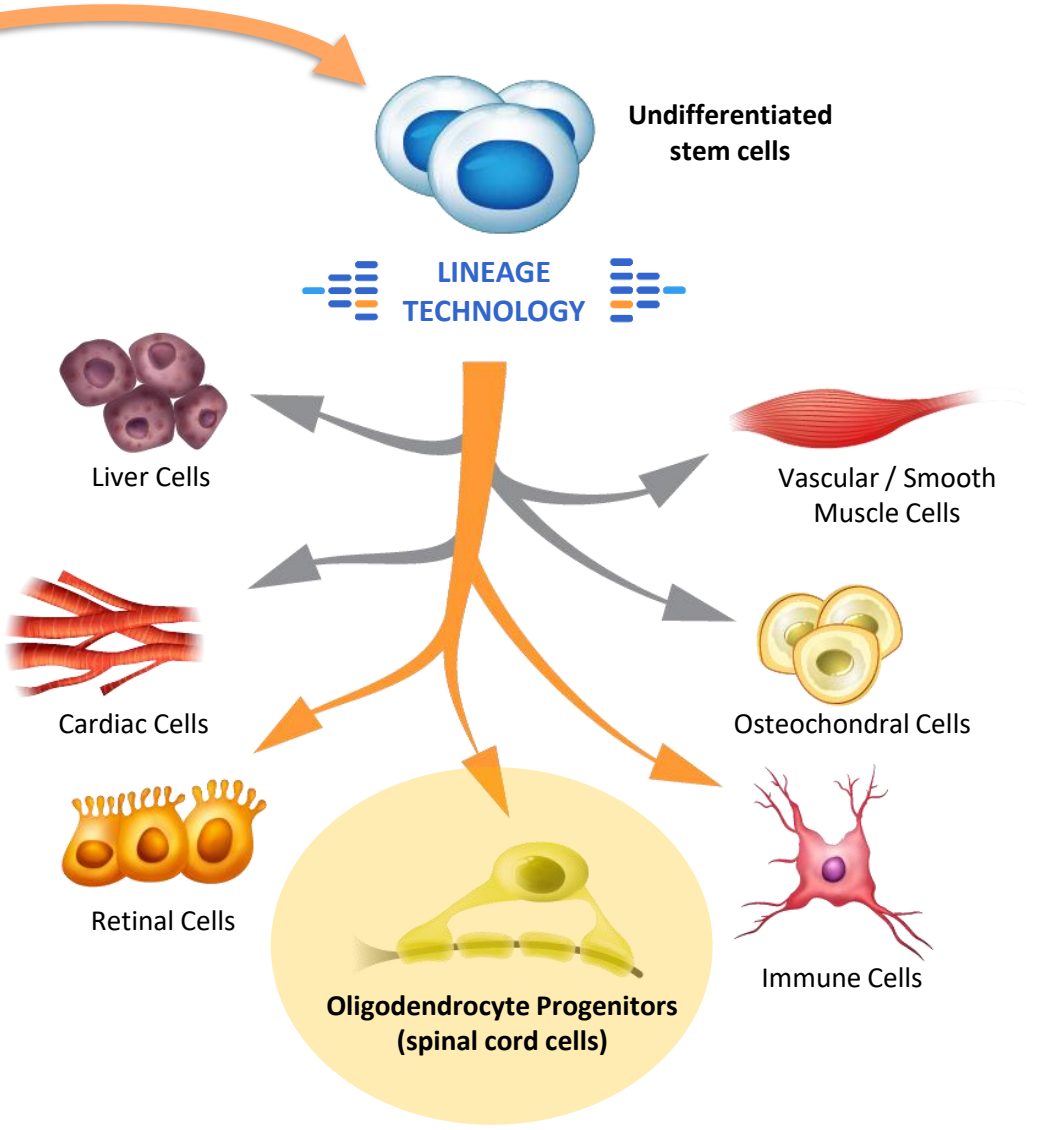
(*) National SCI Statistical Center, 2019 SCI Data Sheet.

Lineage Technology Platform – Allogeneic Cell Transplants

- **The Lineage Platform starts with a frozen vial of *self-renewing stem cells***
- **These unique cells can become *any* cell type in the body**
- **Lineage's proprietary processes create *only* the cell type which is desired**
- **No alterations are made to the cell's DNA**
- **Commercial-scale production occurs from a single vial of cells**



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OPC1 Program Overview

- **OPC1 cells are manufactured from a single cell line**
- **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 could have application to other demyelinating conditions**

OPC1 Transplant Procedure

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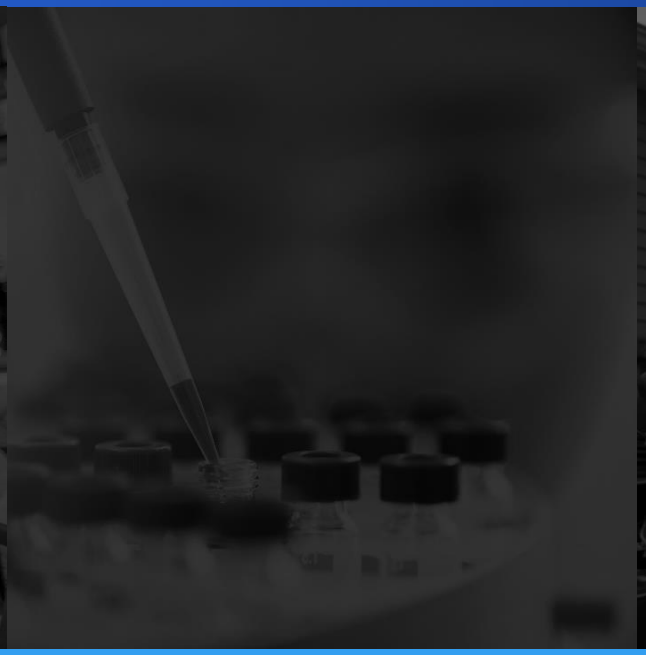
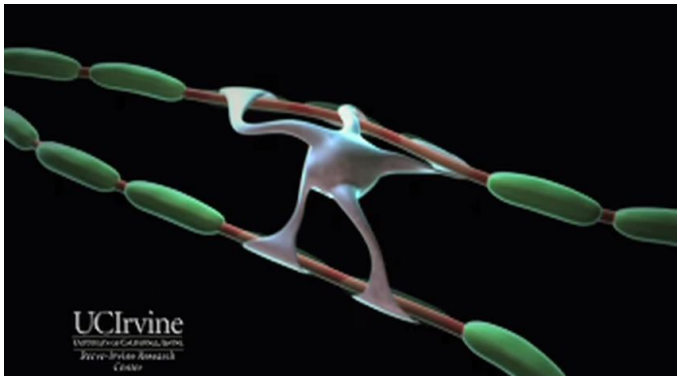



Oligodendrocyte Progenitor Cell Transplants (OPC1)

Ed Wirth, M.D., Ph.D.

OPC1 Addresses the Complex Pathology of SCI

OPC1 is a cellular therapy involving the transplant of oligodendrocyte progenitor cells (OPCs) derived from a pluripotent stem cell line

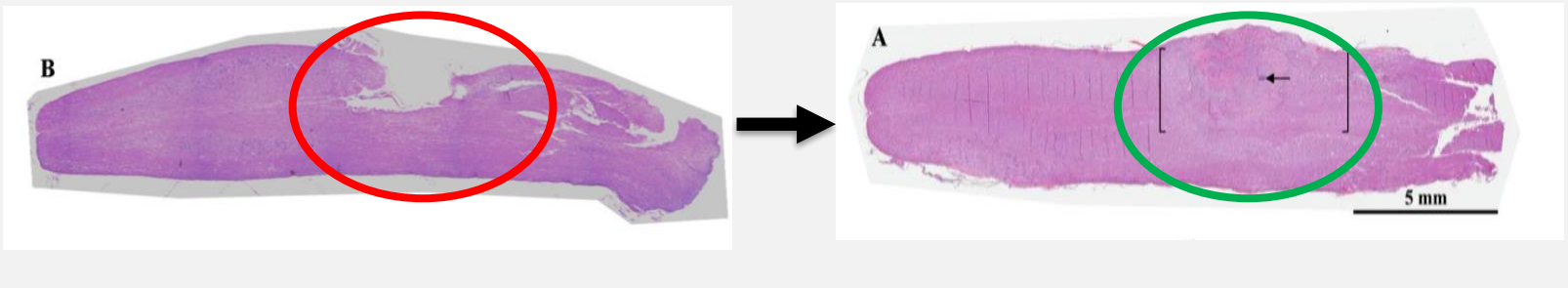


- **OPCs, which function to support and myelinate neurons, can be damaged and lost due to inflammatory response post injury**

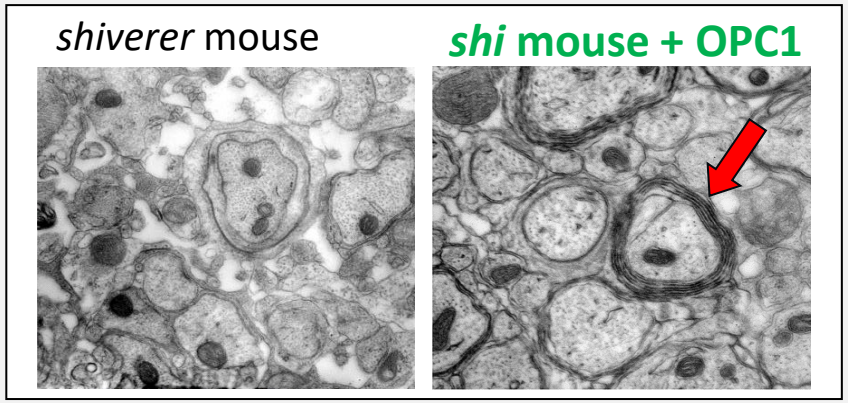
- **OPC1 has been shown to**
  - Remyelinate axons
  - Tissue remodeling: neovascularization, cavitation prevention
  - Promote neurite growth
  - Improve motor function

OPC1 Mechanisms of Action

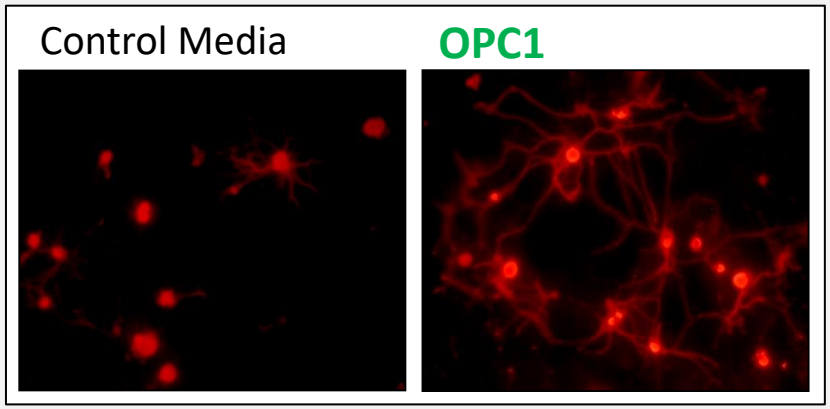
Prevention of Cavitation



Myelination of axons



Secretion of neurotrophic factors



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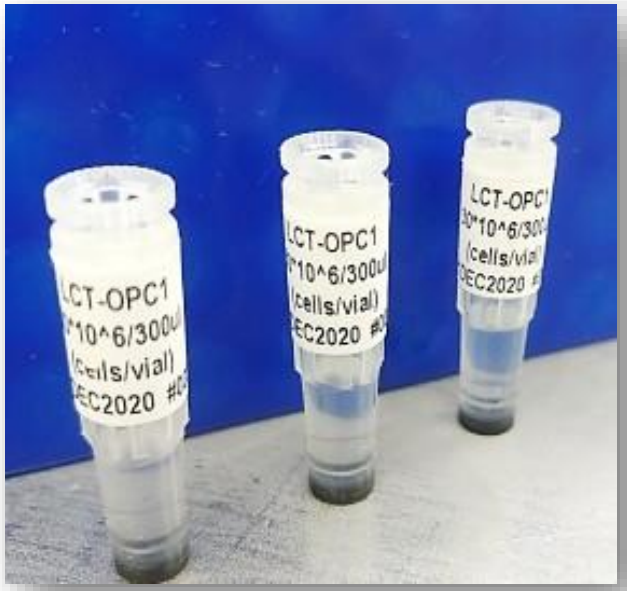
OPC1 for Spinal Cord Injury

- **Lineage's cells are derived from an NIH-registered cell line**
- **The cells are allogeneic ("off the shelf") and not taken from the patient**
- **Treatment for SCI occurs 3-6 weeks post-injury and includes short-course (60-day) immunosuppression**
- **The cells are cryopreserved for "thaw and inject" use**



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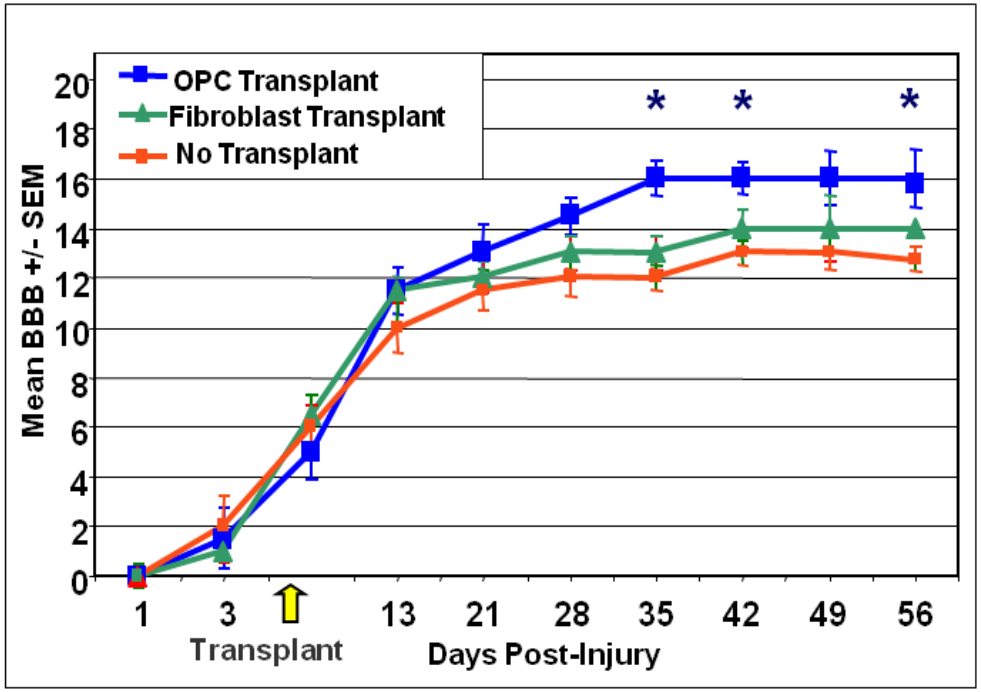
OPC1 Improved Motor Function in Preclinical Animal Models

Locomotor Improvement in Thoracic SCI

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



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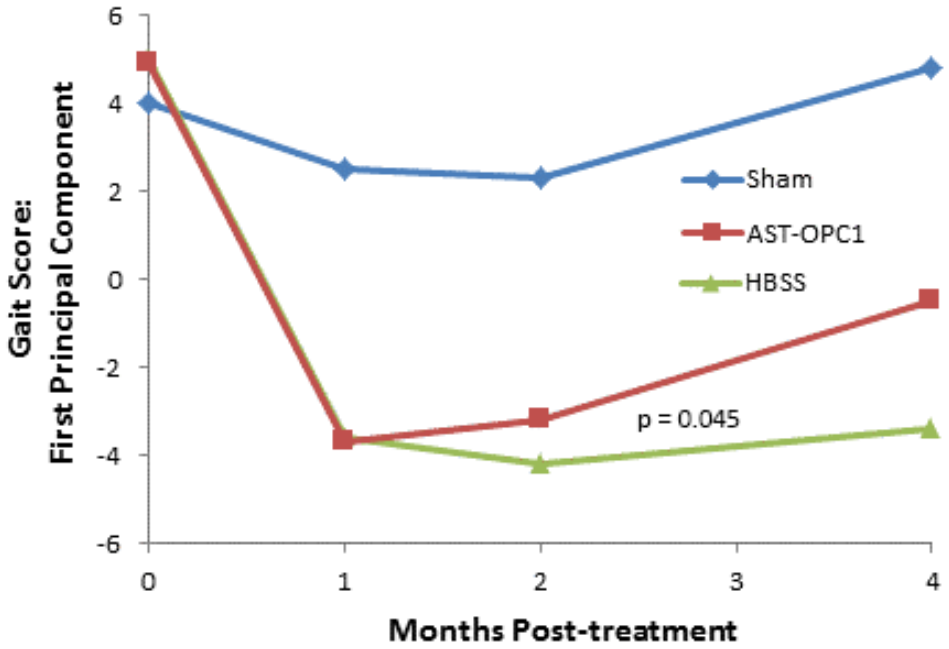
Keirstead et al, J Neuroscience, 2005
Manley et al, Stem Cells Trans Med, 2017

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**



LINEAGE CELL THERAPEUTICS

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Phase 1/2a "SCiStar" Clinical Trial (enrollment complete)

Safety and Dose Escalation

- **Open Label (n=25)**
- **More severe (AIS A) or less severe (AIS B)**
- **Dose Range**
  - 2M *sub-clinical* safety dose (n=3)
  - 10M low dose (n=12)
  - 20M high dose (n=10)

Efficacy analysis population (n=22)

- **Traumatic cervical injury level C4-C7**
- **Treated 21-42 days post-injury**
- **Ages 18-69**
- **Clinical Assessments**
  - Primary Assessment: Safety
  - Secondary Assessment: Neurological Function (ISNCSCI exams)
  - Exploratory Functional Assessments: SCIM, GRASSP

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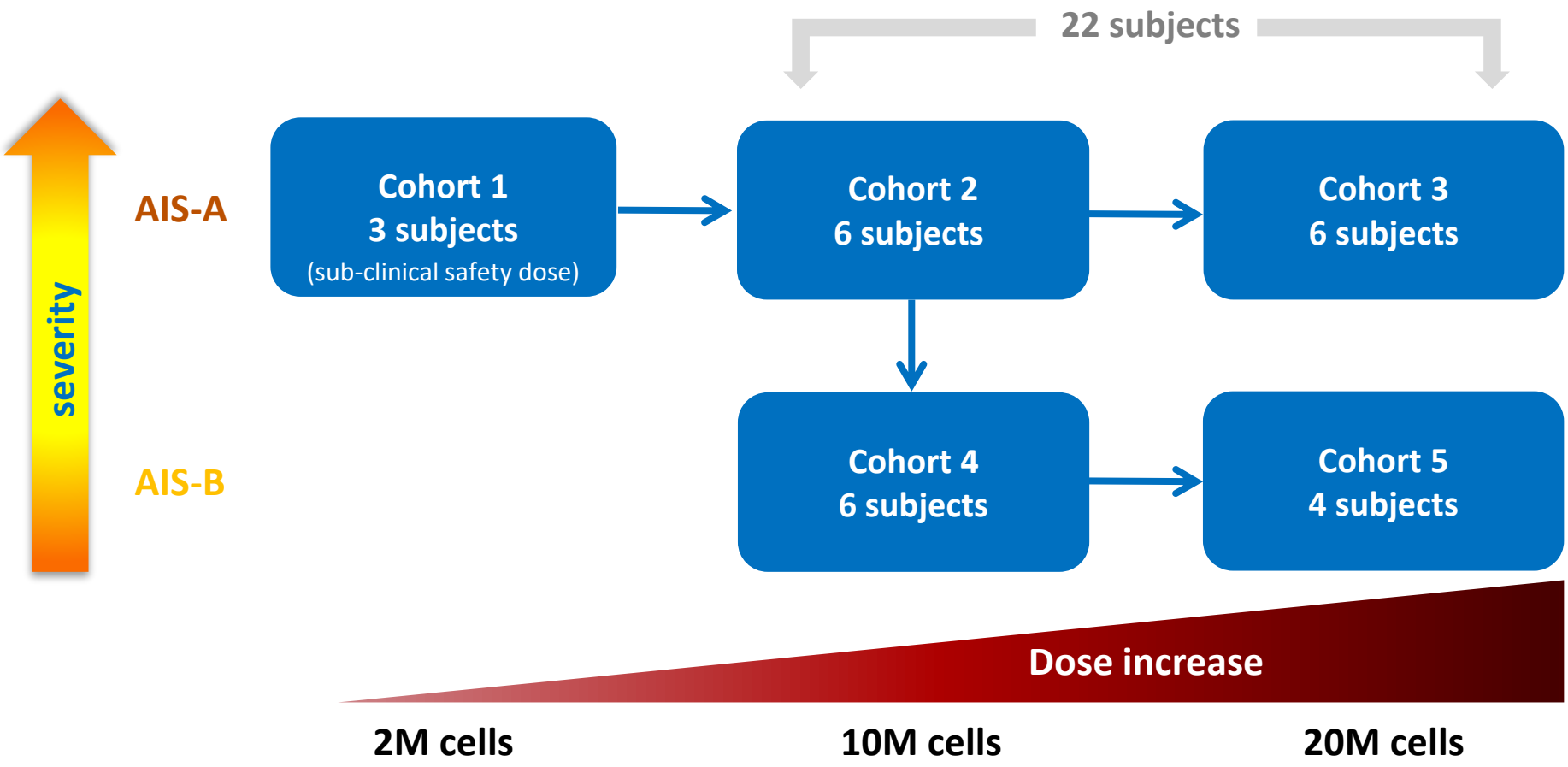
SCiStar Clinical Trial Study Design



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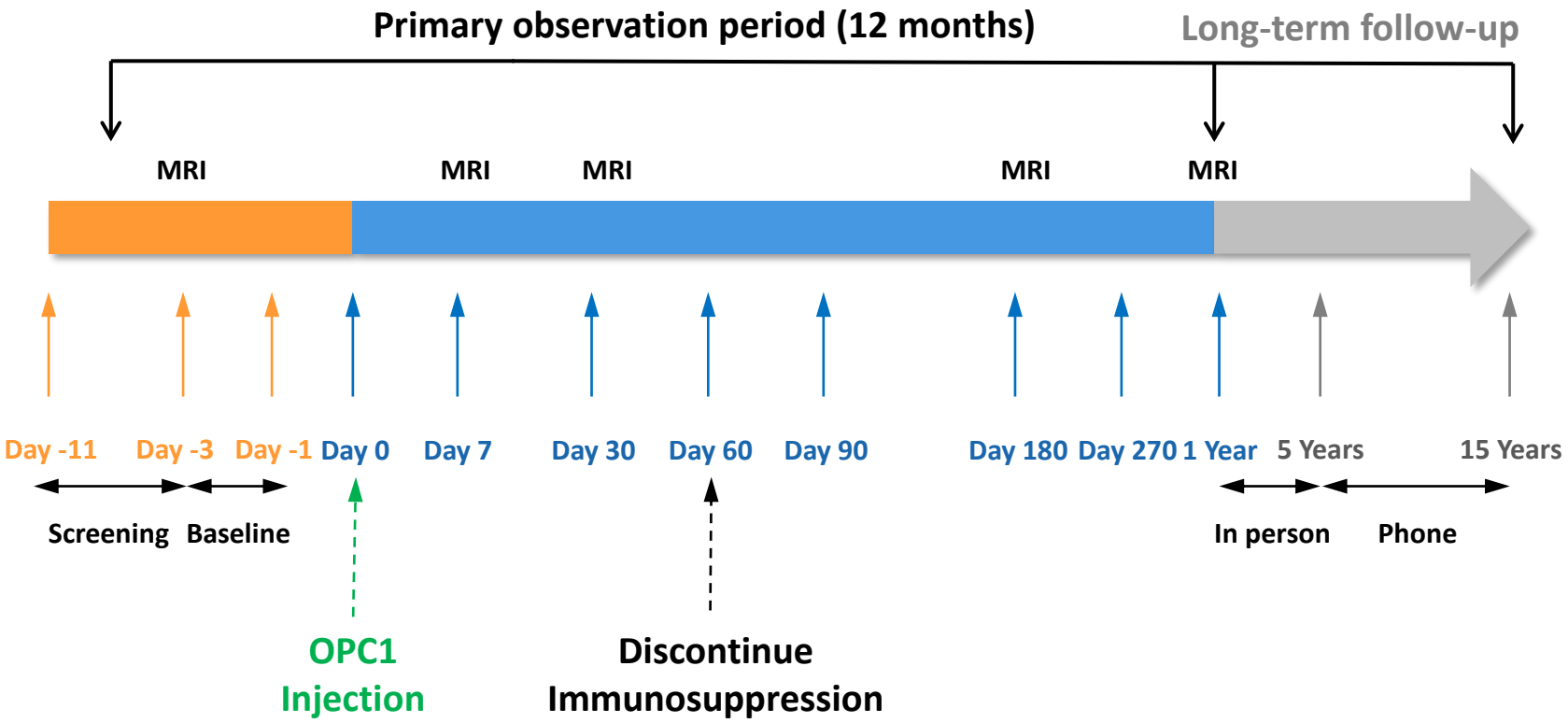
SCiStar Clinical Trial Study Schema



SCiStar Clinical Trial Results Overview

Clinical Insights (n=25)	
Safety	✓
Engraftment / Cavitation	✓
Efficacy / Motor Activity	✓
Notable Findings	✓

SCiStar Clinical Trial - Summary of Adverse Events

Majority of adverse events were mild to moderate in severity

All Treated Subjects (n=25)	AEs	SAEs
Total	534	29
Related to OPC1	1*	0
Related to Injection Procedure	20	1
Related to Tacrolimus	11	1

To date, there have been no serious adverse events related to the OPC1 cells
Safety data is available for 2 to 5 years on all 25 patients

**One AE possibly related to OPC1 was a Grade 2 dysesthesia that began 47 days post-injection but had resolved by the Year 2 follow-up visit*

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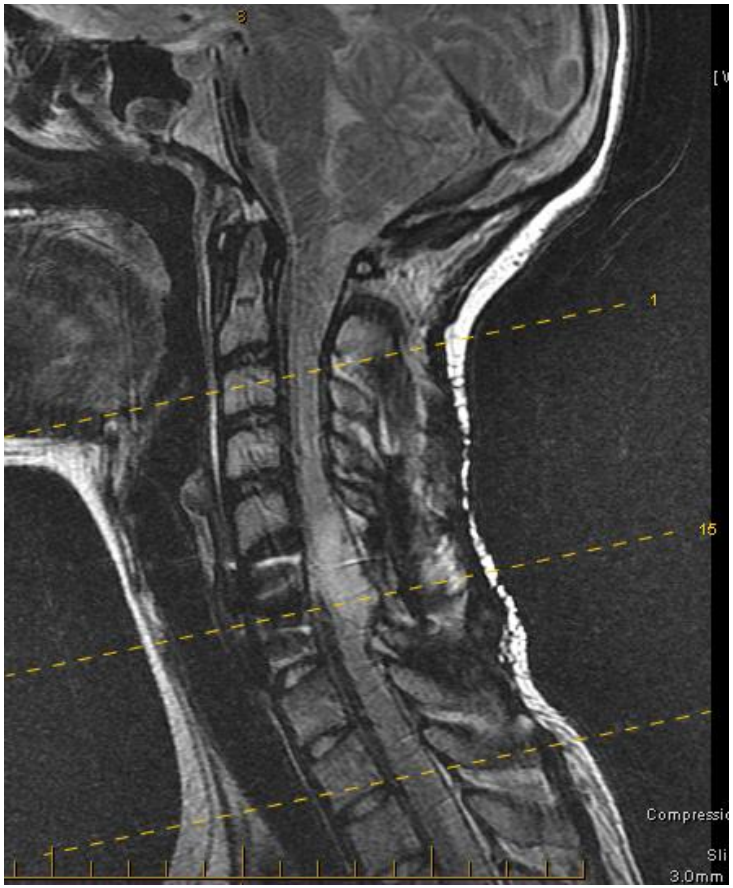
SCiStar Clinical Trial - Cell Engraftment

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 cavitation**
- **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

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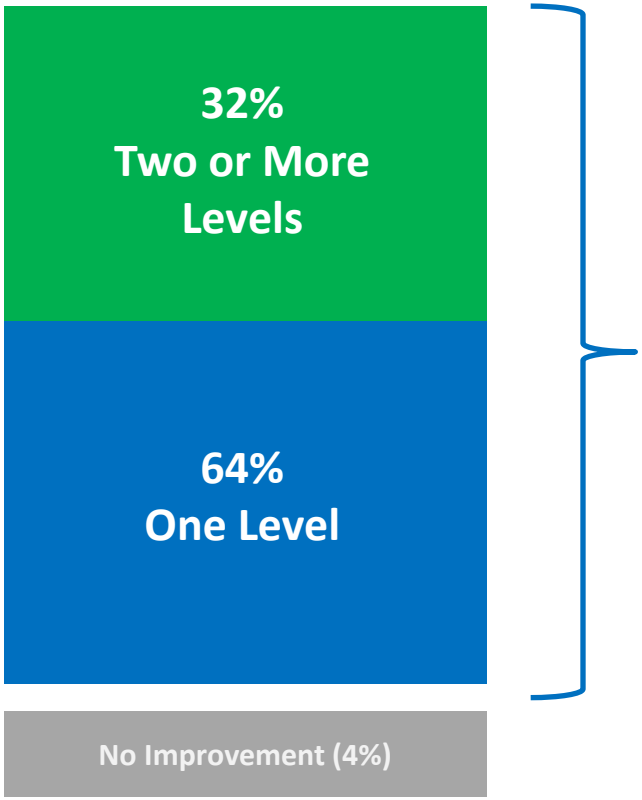
SCiStar Clinical Trial - Motor Function Gains

22 Patients at 12 months



96% of Subjects Reported Improved Motor Function

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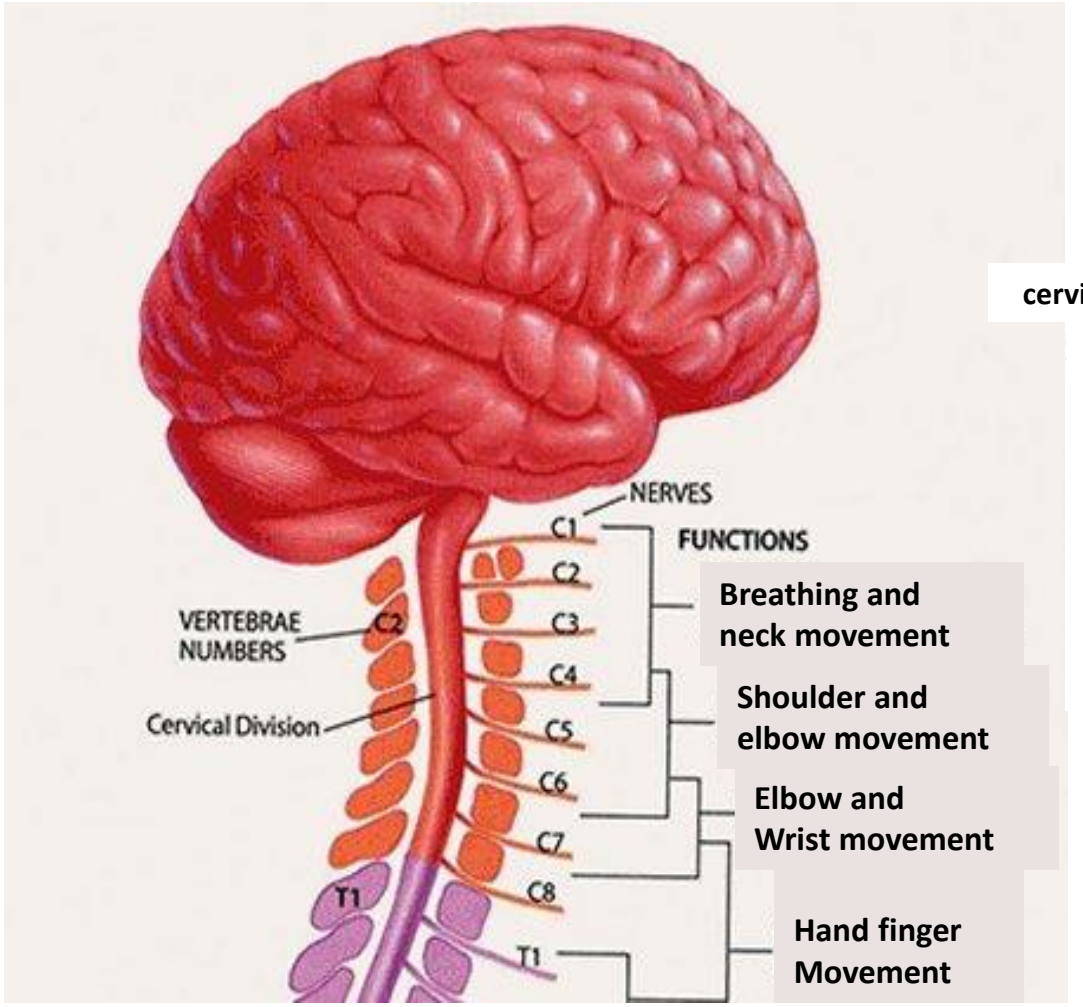
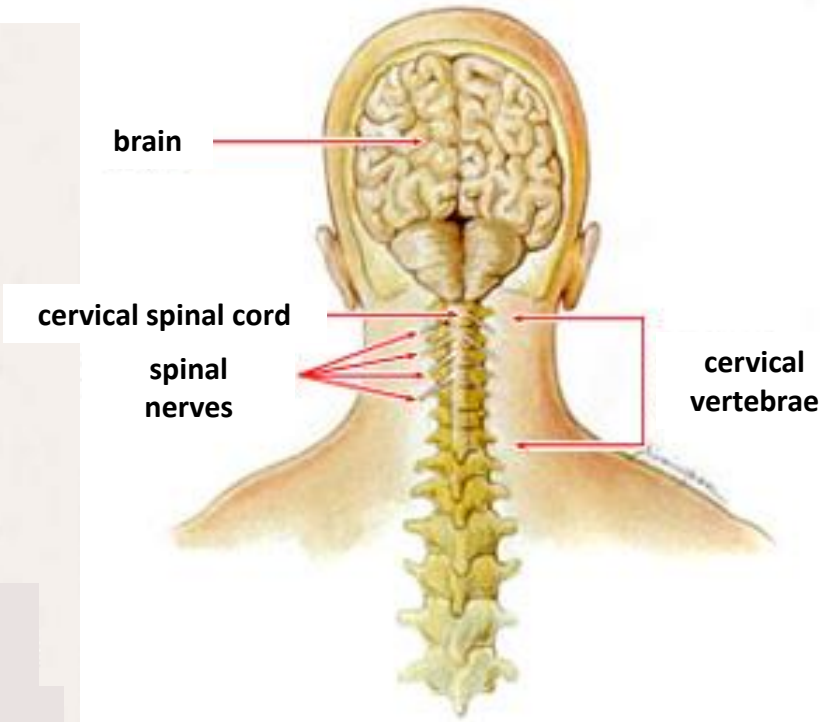
N=22 because 3 patients from Cohort 1 received a sub-clinical "safety" dose of only 2M cells (the clinical dose is 10-20M cells)

Understanding Motor Function in Cervical SCI Patients





C5 – elbow flexors

C6 – wrist extensors

C7 – elbow extensors

C8 – hand finger flexors

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Functional Recovery Requires Return of *Motor* Activity

- **The ISNCSCI motor score evaluates strength of contraction by key muscles**
- **Upper Extremity Motor Score (UEMS)**
  - 5 muscles x max. strength score of 5 x 2 sides = maximum 50 points
- **Motor Level Score**
  - Defined by the lowest key muscle function that has a grade of at least 3, providing the key muscle functions represented by segments above that level are judged to be intact (graded as a 5)
- **Additional Assessment Tools Used in the Field:**
  - SCAR Spinal Cord Ability Ruler
  - SCIM Spinal Cord Independence Measure
  - Capabilities of Upper Extremities Test (CUE-T) – new
  - Spinal Cord Injury Functional Index (SCI-FI) – new

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INTERNATIONAL STANDARDS FOR NEUROLOGICAL CLASSIFICATION OF SPINAL CORD INJURY (ISNCSCI)

ASIA American Spinal Injury Association — ISCOS International Spinal Cord Society

Patient Name _____ Date/Time of Exam _____

Examiner Name _____ Signature _____

RIGHT

LEFT

	MOTOR KEY MUSCLES	SENSORY KEY SENSORY POINTS Light Touch (LT)	SENSORY KEY SENSORY POINTS Pin Prick (PP)
C2			
C3			
C4			
C5	Elbow flexors		
C6	Wrist extensors		
C7	Elbow extensors		
C8	Finger flexors		
T1	Finger abductors (little finger)		
T2			
T3			
T4			
T5			
T6			
T7			
T8			
T9			
T10			
T11			
T12			
L1			
L2	Hip flexors		
L3	Knee extensors		
L4	Ankle dorsiflexors		
L5	Long toe extensors		
S1	Ankle plantar flexors		
S2			
S3			
S4-5			
RIGHT TOTALS (MAXIMUM)		(50)	(56) (56)

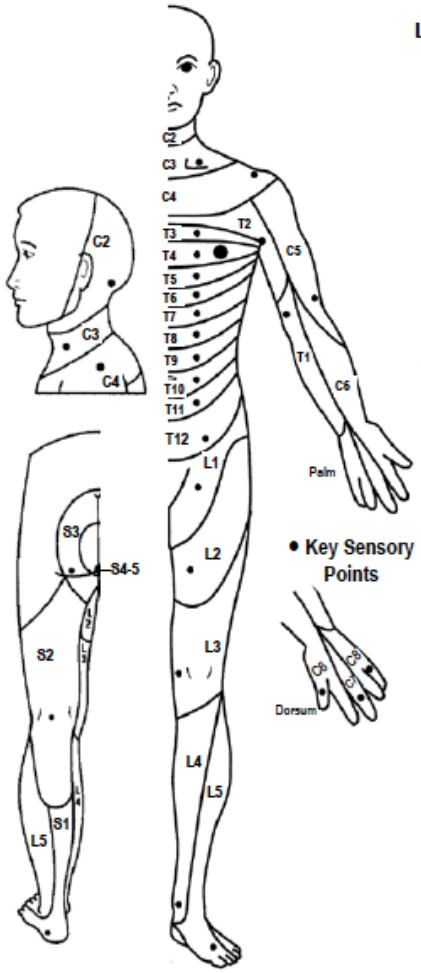
UER (Upper Extremity Right): Elbow flexors C5; Wrist extensors C6; Elbow extensors C7; Finger flexors C8; Finger abductors (little finger) T1

UEL (Upper Extremity Left): C5 Elbow flexors; C6 Wrist extensors; C7 Elbow extensors; C8 Finger flexors; T1 Finger abductors (little finger)

LER (Lower Extremity Right): Hip flexors L2; Knee extensors L3; Ankle dorsiflexors L4; Long toe extensors L5; Ankle plantar flexors S1

LEL (Lower Extremity Left): L2 Hip flexors; L3 Knee extensors; L4 Ankle dorsiflexors; L5 Long toe extensors; S1 Ankle plantar flexors

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



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/disuse
NT = not testable

SENSORY (SCORING ON REVERSE SIDE)

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

(VAC) Voluntary anal contraction (Yes/No) ☐

(DAP) Deep anal pressure (Yes/No) ☐

LEFT TOTALS (MAXIMUM) (50) (56) (56)

MOTOR SUBSCORES

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

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

SENSORY SUBSCORES

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

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

NEUROLOGICAL LEVELS (Steps 1-5 for classification as on reverse)

	R	L
1. SENSORY		
2. MOTOR		

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)

	R	L
SENSORY		
MOTOR		

REV 02/13

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					
Bladder					
Bed Mobility					
Transfers					
Pressure Relief					
Eating					
Dressing					
Grooming					
Bathing					
Wheelchair					
Car transport					
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**

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Activities of Daily Living across different levels of motor function after cervical complete SCI Modified from Whiteneck et al. 1999)

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

33% had +2 Level Improvement

Function	Cervical Injury Level				
	C1-C3	*C4*	*C5*	*C6*	*C7-C8*
Bowel					
Bladder					
Bed Mobility					
Transfers					
Pressure Relief					
Eating					
Dressing					
Grooming					
Bathing					
Wheelchair					
Car transport					
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**

Activities of Daily Living across different levels of motor function after cervical complete SCI Modified from Whiteneck et al. 1999)

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SCiStar Clinical Trial - Motor Recovery and Upper Extremity Motor Score (UEMS)

Motor Recovery and UEMS in Cohorts 2-5 at 12 Months

	+2 Motor Level		UEMS Improvement #	
	6 Months	12 Months	6 Months	12 Months
Cohort 2	2/6	4/6	9.7	12.3
Cohort 3	1/6	1/6	6.0	9.2
Cohort 4	1/6	1/6	5.5	6.7
Cohort 5	0/4	1/4	5.8	6.8
Cohorts 2-5	4/22	7/22	6.8	8.9 +/- 4.2

Internal analysis of European Multicenter Study of Spinal Cord Injury (EMSCI) provided historical control of 7.8 for 12-month UEMS (with support from Prof A. Curt, Balgrist Univ Hospital, Zurich)

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Cohort 1 (n=3) received 2x10^6 cells; Cohorts 2-5 (n=22) received 1x10^7 or 2x10^7 cells.

SCiStar Clinical 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
2207	7	N	C4	B	5	20 M	62	37
2203	6	N	C6	A	3	20 M	45	31
2105	6	N	C4	A	3	10 M	19	20
2004	5	N	C6	B	4	10 M	21	25
2007	4	N	C4	B	4	10 M	55	38
2307	4	Y	C5	B	5	10 M	19	38
2303	3	Y	C6	B	4	10 M	22	35

- **Two patients had cord compression after OPC1 injection (2303 and 2307 at Day 30 and Day 7)**
- **Patients 2105, 2207, 2007 had a C4 (highest/most severe) injury level at baseline**
- **Patient 2105 also had a hematoma in the spinal cord at baseline & a failed graft**

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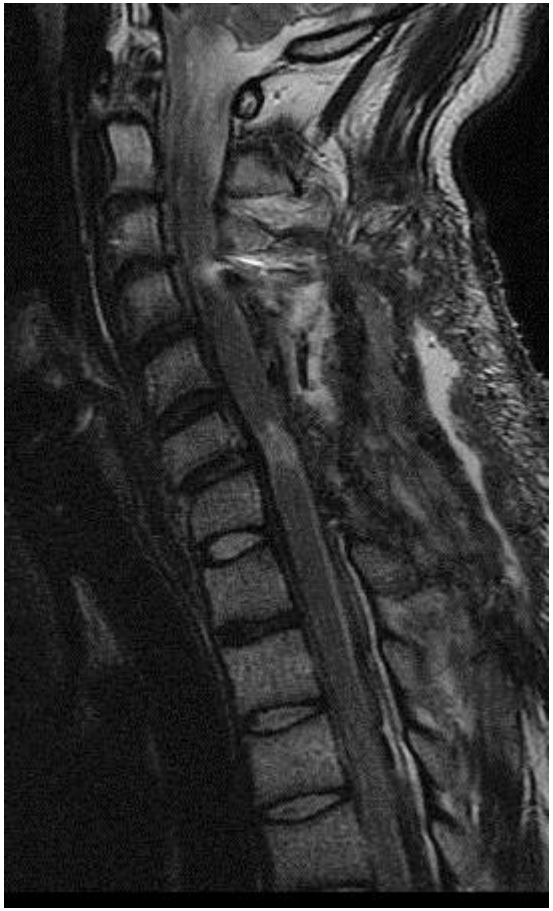
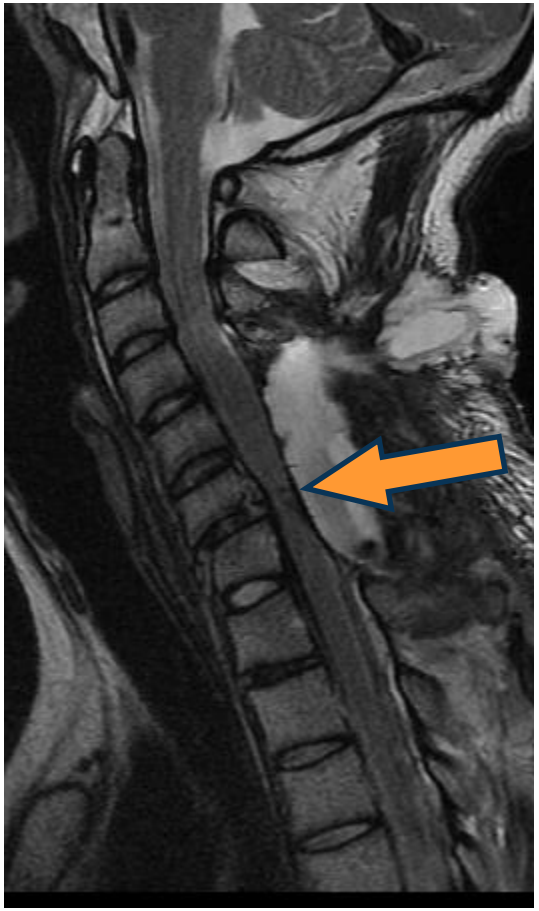
SCiStar Clinical Trial – Cord Compression

Subject 2303 (Cohort 4): Cord Compression at Day 30

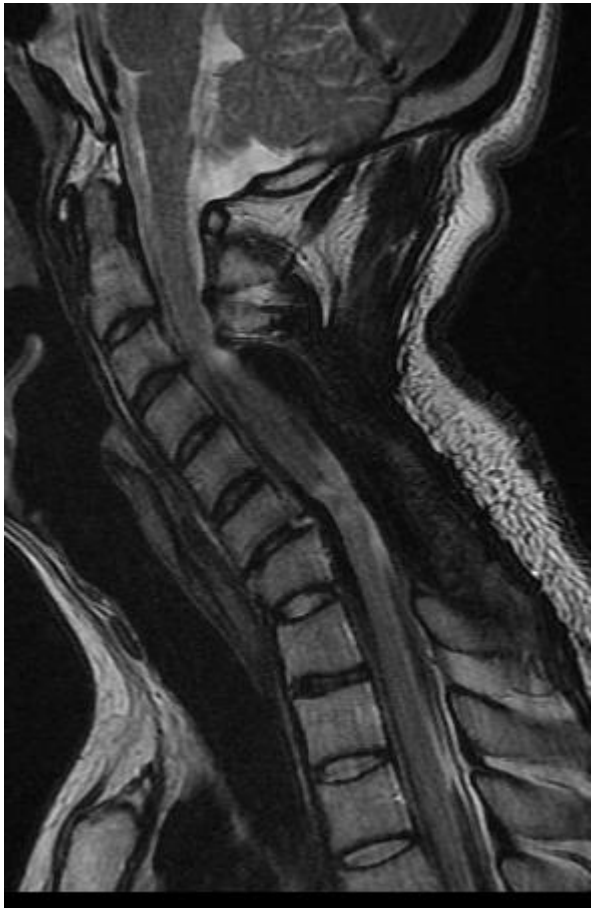
Baseline



Day 30



Day 365



LINEAGE CELL THERAPEUTICS

SCiStar Clinical Trial - Subset Analysis

Low-performing characteristics – C4 injury and cord compression - can be selected out or addressed in the next study

Cohort	N	Mean UEMS Gain	Applicable Patients
Cohort 2	6	12.3	One C4 injury level
Cohort 3	5	8.8	One C4 injury level
Cohort 4	4	8.0	One cord compression at Day 30 One C4 injury level
Cohort 5	2	8.5	One cord compression at Day 7 One C4 injury level
Targeted Patients	**17**	**10.2 +/- 3.9**	**Without C4 (higher level) injury or cord compression patients**
All Patients	22	8.9 +/- 4.2	

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SCiStar Clinical Trial - Change in UEMS Across Key Variables

Analysis performed for all 22 subjects in Cohorts 2-5

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 (AIS-A better 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
# of days from SCI to OPC1 injection	P = 0.25

SCiStar Clinical Trial Results – 2 Year Results

- **Overall safety profile of OPC1 continues to be excellent**
  - All 25 subjects evaluated for at least 2 years
  - MRI scans show no evidence of adverse changes
  - No unexpected serious adverse events related to the OPC1 cells
  - No study subjects had worsening of neurological function

- **Motor Level Improvements Have Been Durable One Patient Improved Further**
  - Cohort 1 subjects continue to be stable 2-4 years after treatment
  - 5 subjects in cohort 2 achieved at least 2 motor levels of improvement over baseline on at least one side (previously 4 of 6 at 12 months)
  - 1 subject in cohort 2 achieved 3 motor levels of improvement on one side; maintained at 3 years

SCiStar Clinical Trial – Takeaways

- **Excellent overall safety profile**
- **96% durable engraftment confirmed via MRI**
- **MRI scans through 24 months show no evidence of adverse changes**
- **No subjects had a decline in motor function from Year 1 to Year 2**
- **95% of patients exhibited motor recovery in the upper extremities at 12 months (requires at least 1 motor level gain on at least 1 side)**
- **Significant motor improvements achieved in five of six Cohort 2 subjects**
- **The two worst performing subjects had spinal cord compression (can be addressed in next trial)**
- **Results support further testing in a randomized, controlled clinical trial**

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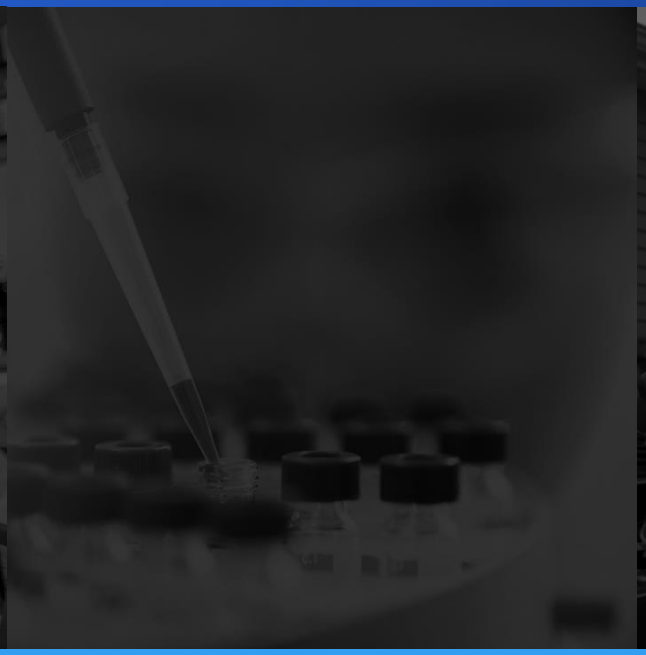
The future of cell therapy.


OPC1 Delivery

Ed Wirth, M.D., Ph.D.

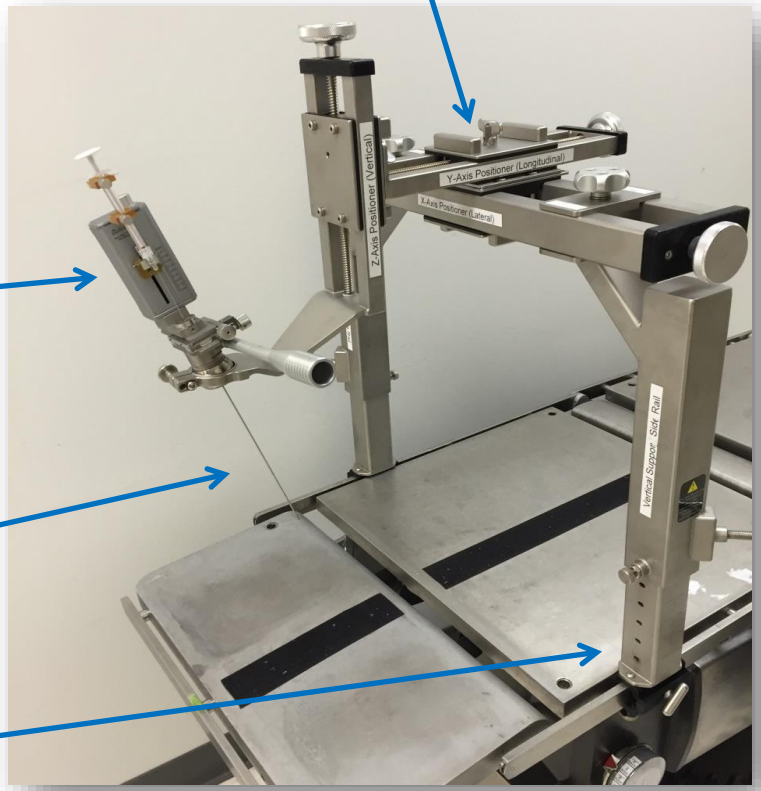
SCiStar Clinical Trial - Original Syringe Positioning Device

XYZ manipulator

Syringe & Microdrive assembly

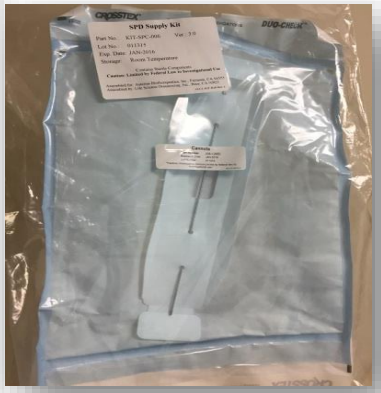
Outer cannula and needle

Table-attached support frame



Storage trays

Supply Kits



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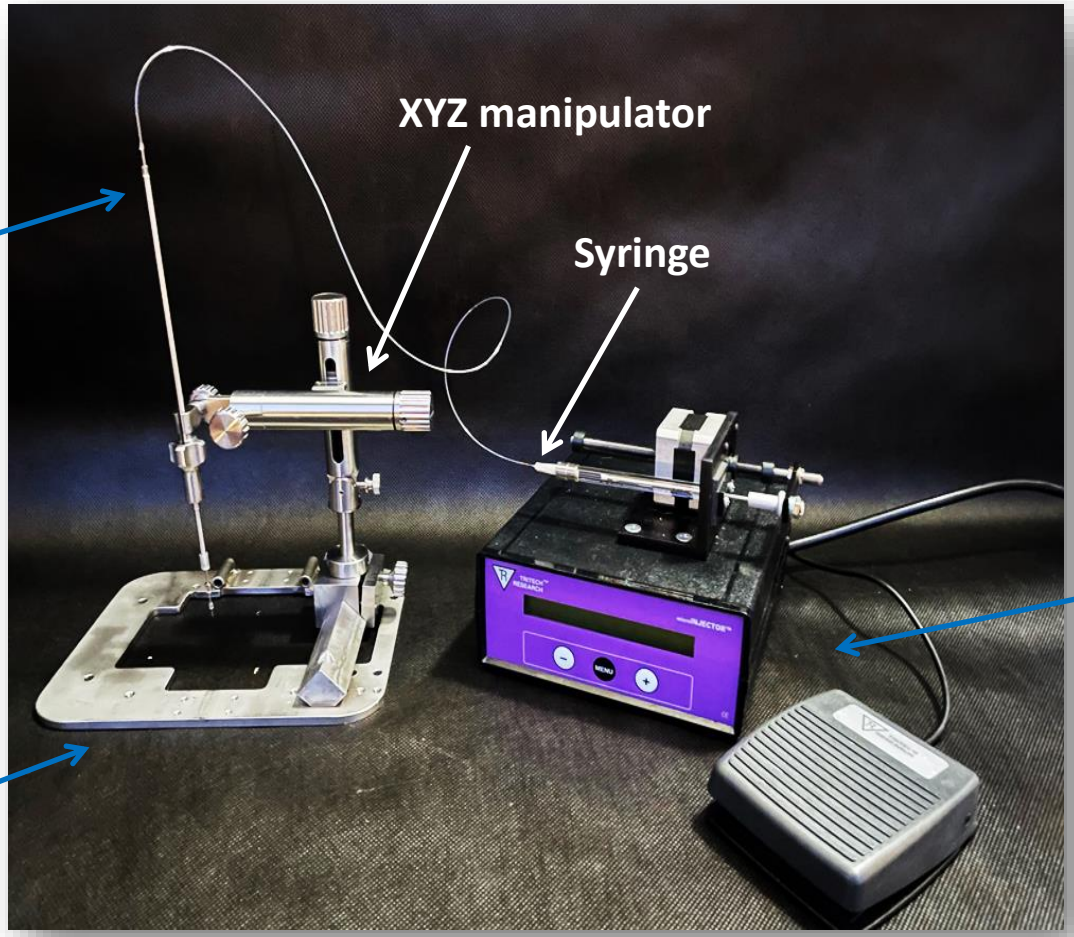
Experience with Original Syringe Positioning Device

- **5 thoracic and 25 cervical SCI patients have been treated**
- **Known logistic and technical challenges**
  - Large complex components
  - Flow variability (manual syringe)
  - Assembly requires support at sites
  - Motion between unit sections
  - Components prone to wear and tear
  - FDA requires 2 full sets at sites
- **Requires ventilator stop, limited to two minutes injection time**
- **Ventilation limit not compatible with new OPC1 thaw and inject (TAI) formulation**

Overview of Novel Parenchymal Delivery Injection (PDI) System



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Benefits of New Parenchymal Delivery Injection (PDI) System

- **Device offers stability and control**
  - Eliminates motion between platform/XYZ manipulator/injection needle
  - Pump and needle not in sterile field: programmed accurate dose rate
- **Device requires no cessation of ventilation**
  - Attaches directly to the patient, syncs with patient breathing motion
  - Magnetic needle provides stabilization from micromotion due to heartbeats
- **Device is easier to use in clinical setting**
  - Smaller and uses fewer components
  - Easily assembled prior to surgery
  - Single hand operation for XYZ positioning
  - Accurate needle depth insertion
  - Straightforward cleaning and sterilization
  - Compatible with OPC1 TAI formulation; eliminates prior-day dose prep
- **Device adaptation and compatibility with OPC1 is ongoing**

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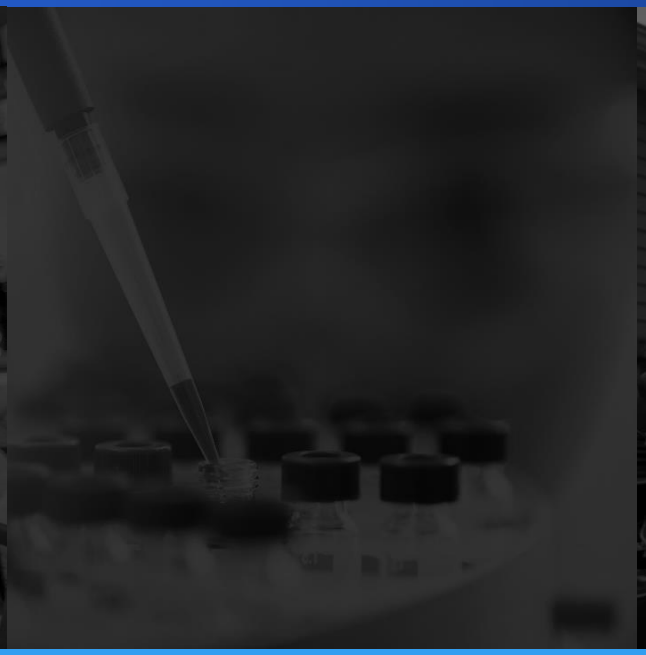
The future of cell therapy.

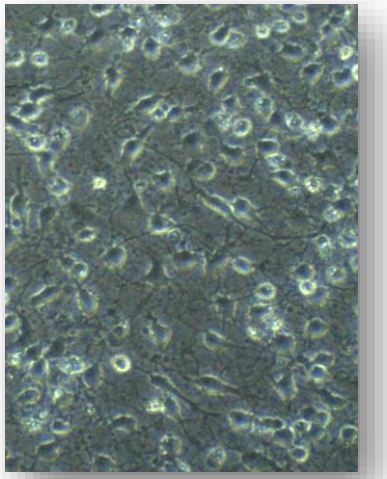

OPC1 Manufacturing Improvements

Brian Culley, CEO

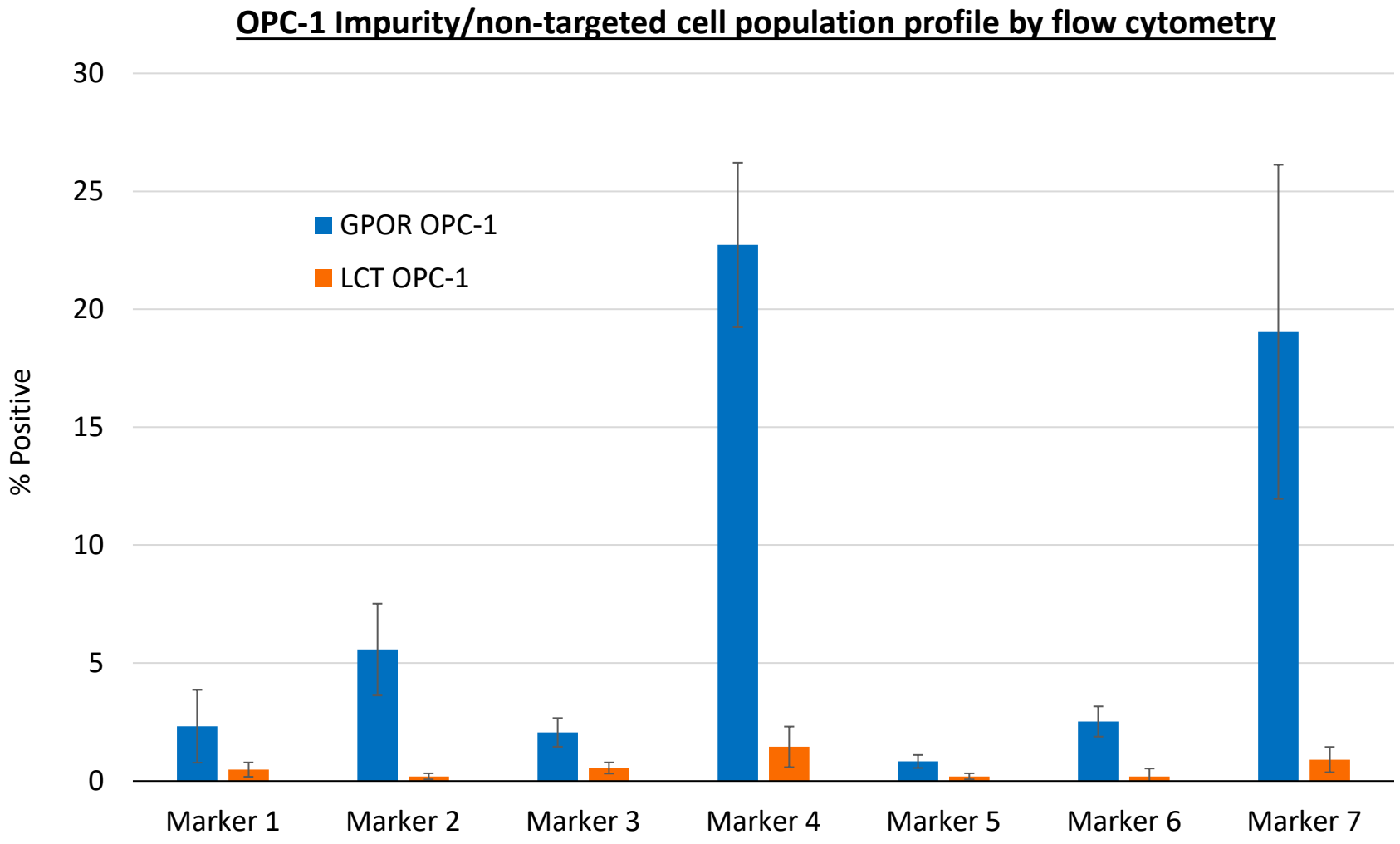
OPC1 Manufacturing (December 2020 Update)

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 product impurities**
- **Improvements in functional activity**
- **12 new analytical and functional methods developed**
- **Elimination of all animal-based production reagents**
- **Patent applications recently filed on the process and product which if allowed, will have expiration dates of 2039 and 2040**

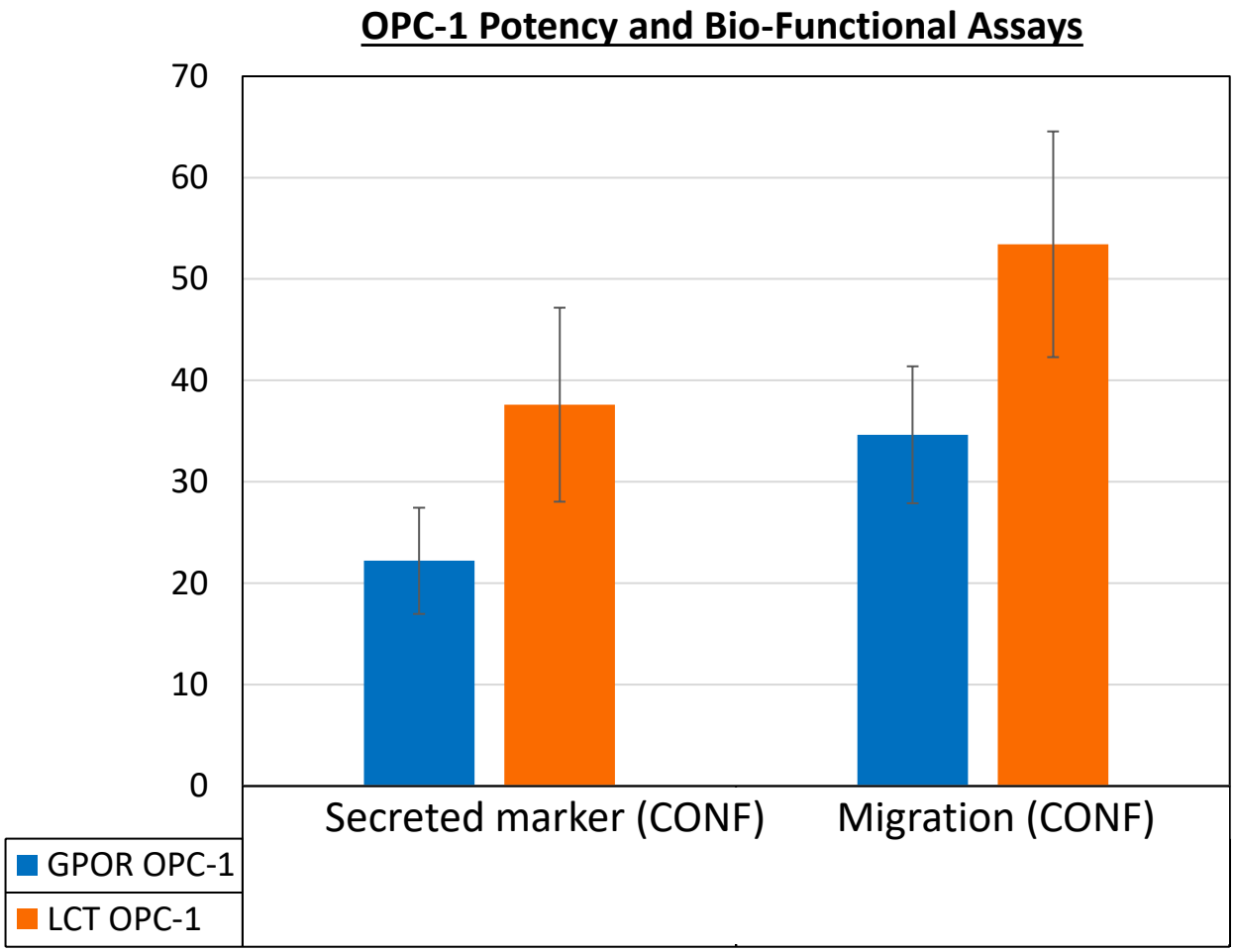


OPC1 Manufacturing Improvements: Lower Impurities



LINEAGE CELL THERAPEUTICS

OPC1 Manufacturing Improvements: Higher Function



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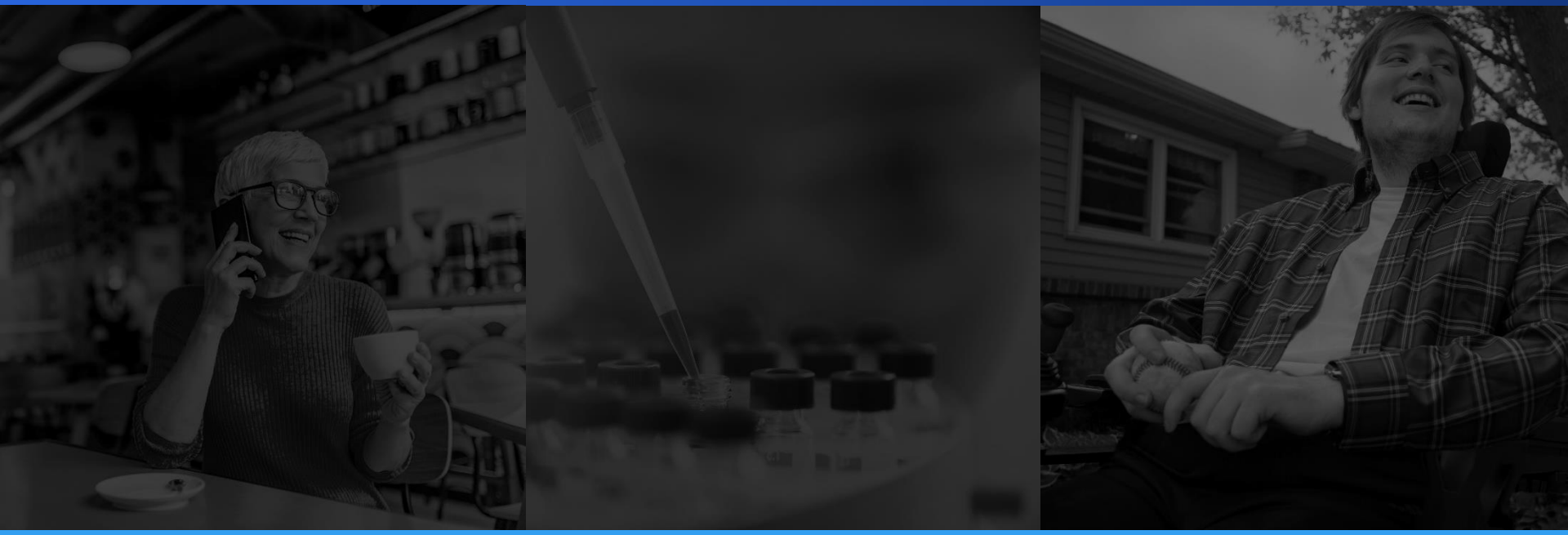


Competition

Brian Culley, CEO

Competition

	OPC1	HC106	KP-100IT	ES135	Elezamumab
Company	**Lineage Cell Therapeutics**	Histocell	Kringle Pharma	Eusol Biotech	Abbvie
Approach	**Cell transplant**	Cell transplant	Molecule	Molecule	mAb
Description	**Oligodendrocyte progenitor cells**	Mesenchymal (adipose) stem cells	Recombinant human hepatocyte growth factor	Recombinant human fibroblast growth factor 1	Anti-RGMa
Delivery route	**Direct intraparenchymal**	Direct intraparenchymal	Intrathecal	Intrathecal	IV infusion
Treatment window	**3-6 weeks post-injury**	48-120 hrs	72 hrs	Acute	<24 hrs + monthly
Proposed therapeutic mechanism(s)	**Lesion suppression, nerve regeneration, neovascularization, oligodendrocyte replacement**	Anti-inflammatory, trophic support	Neuronal protection, axon extension	Neurite outgrowth and repair	Axonal outgrowth/neural regeneration
Status	**Phase 1/2a enrollment complete**	Phase 1/2 enrolling	Phase 1/2 completed	Phase 2 data available; Phase 3 ongoing in Taiwan	Phase 2 enrolling

OPC1 Program Key Considerations

- **OPC1 offers a compelling opportunity to deploy next-generation cell transplant technology against a high unmet need with low competition**
  - Clinical data supports moving to later-stage clinical development
  - Manufacturing issues: being addressed by Lineage in-house
  - Delivery issues: being addressed by Lineage through device alliance
- **Next steps include collecting data to support FDA discussion of comparability plan (for new process and new delivery) and the regulatory path for a comparative trial**
- **New opportunities for regional and/or global partnership opportunities**
- **New opportunities for additional settings of demyelination**

Patients Are Our Inspiration

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

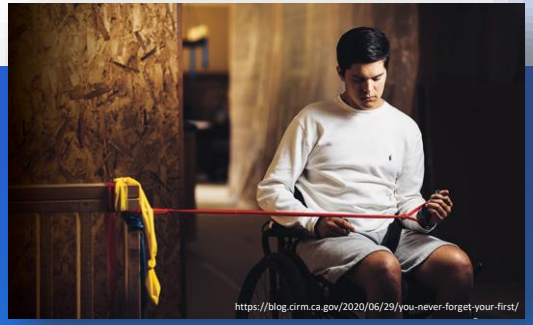
OPC1 SCiStar Clinical Trial Participants

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

OPC1 was supported in part by a valuable alliance with CIRM CALIFORNIA'S STEM CELL AGENCY