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Top-line 12-month Results from the SCiStar Study - A Phase 1/2a Trial of Human Embryonic Stem Cell-Derived Oligodendrocyte Progenitor Cells (OPC1) in Patients with Subacute Cervical Spinal Cord Injury

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ASNTR 26th Annual Conference

April 26, 2019

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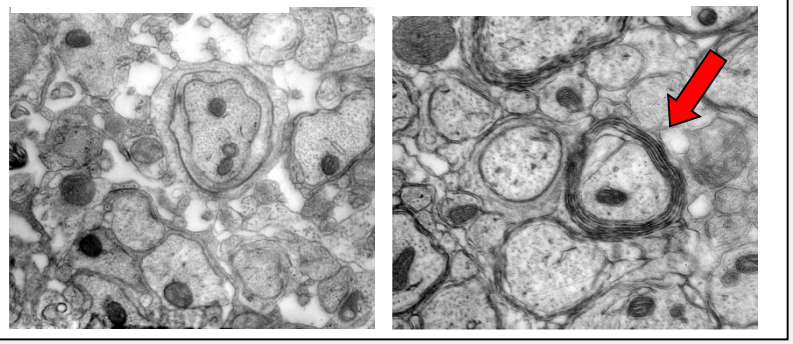
OPC1: hESC-Derived Oligodendrocyte Progenitor Cells (OPCs)

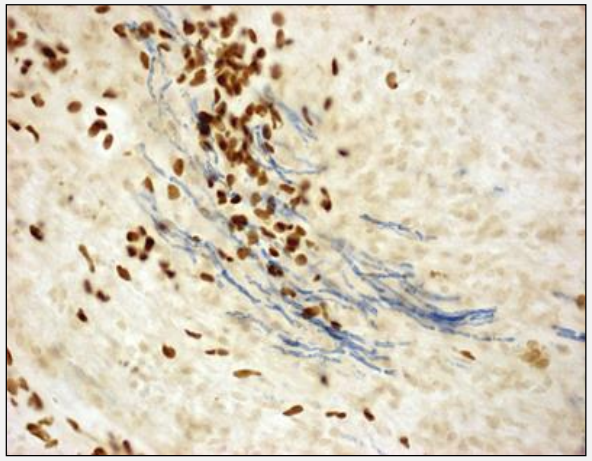
OPC1

- 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
- First indication: spinal cord injury
- Potential line extensions in other neurodegenerative diseases

OPC1: Three Major Physiologically Relevant Functional Activities

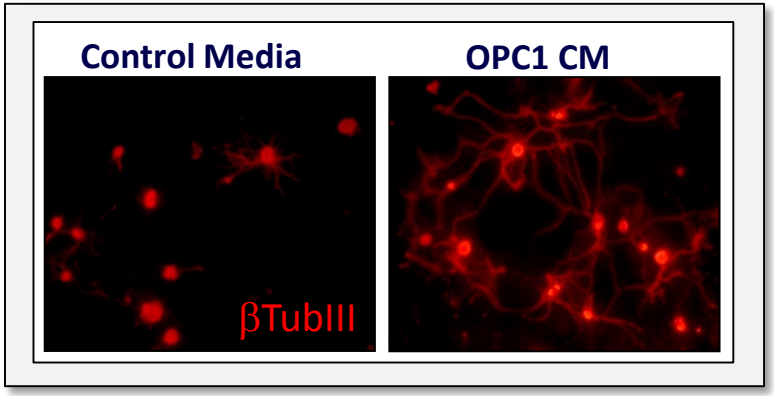
1. Wraps host neurons and forms compact myelin sheaths*



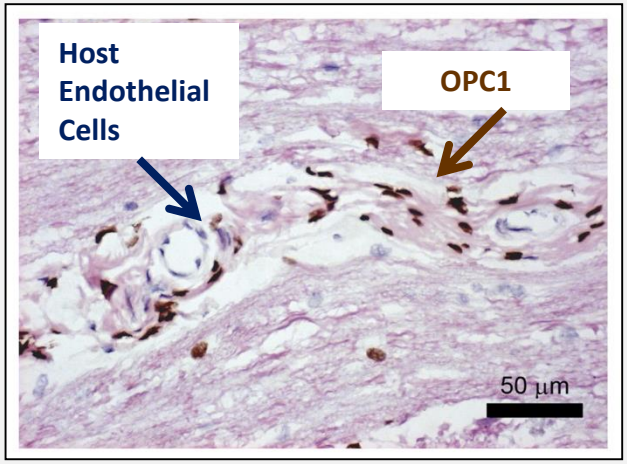


***Rag2*$^{-/-}$ γc$^{-/-}$ /*shi* mouse + OPC1**

2. Produces neurotrophic factors and stimulates neurite outgrowth**



3. Stimulates neovascularization*



Rat spinal cord 9 months post transplantation

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**Priest et al. Regen Med (2015); **Zhang et al Stem Cells and Development (2006)*

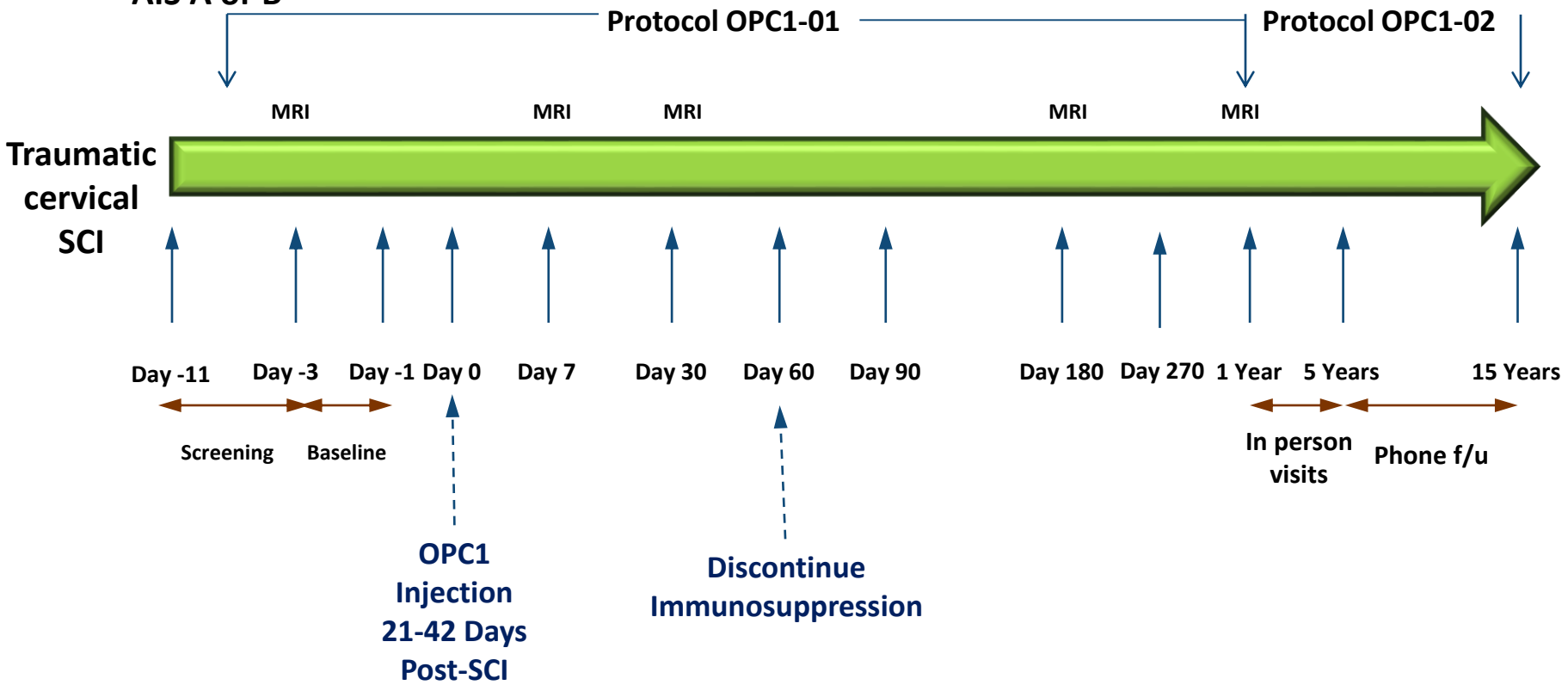
SCiStar Study Schema

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

Primary Assessment: Safety

Secondary Assessment: Neurological Function (ISNCSCI exams)

Exploratory Assessments: SCIM, GRASSP



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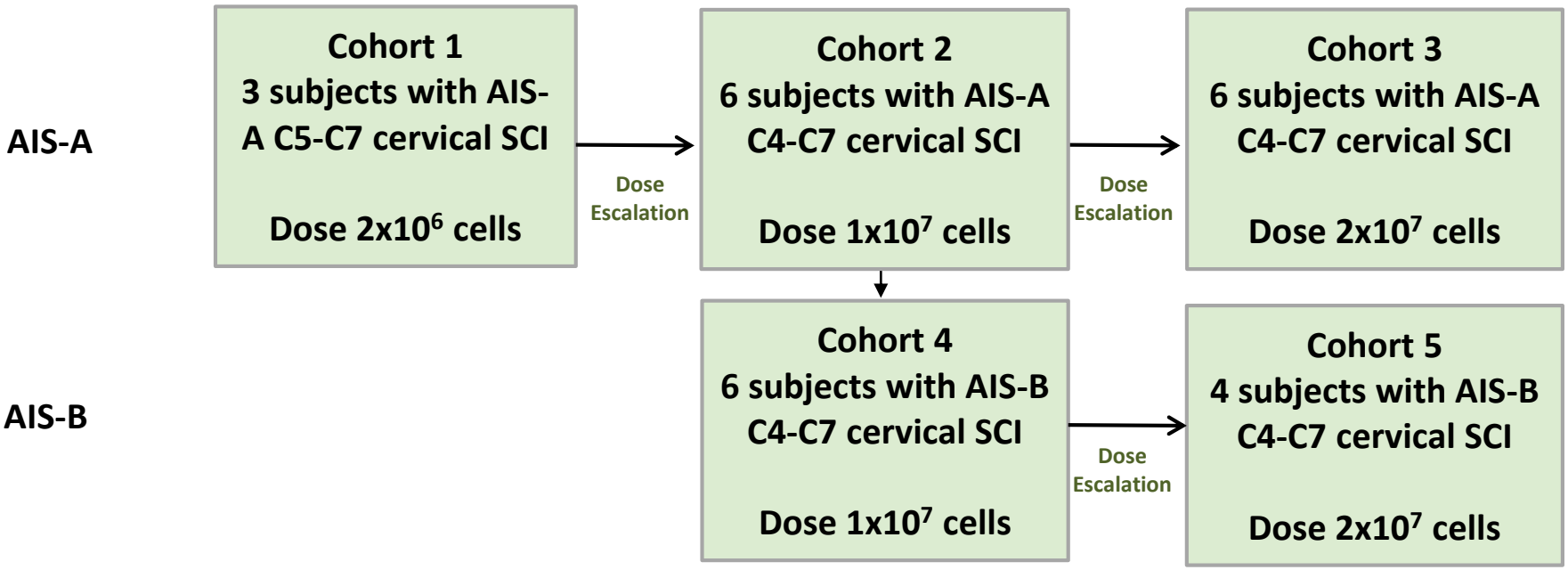
SCiStar Study Enrollment & Cohort Progression



Follow-Up Status for SCiStar Study

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

[a] One subject enrolled in Cohort 3 received only the 1 x 10^7 dose due to an error during dose preparation

[b] One subject enrolled in Cohort 5 received only the 1 x 10^7 dose due to a very small spinal cord lesion

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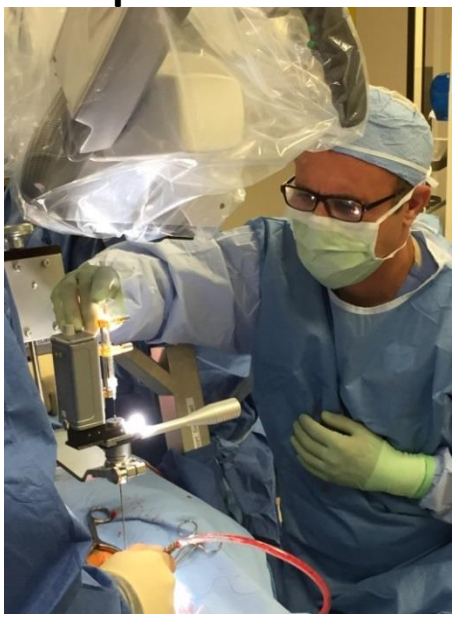
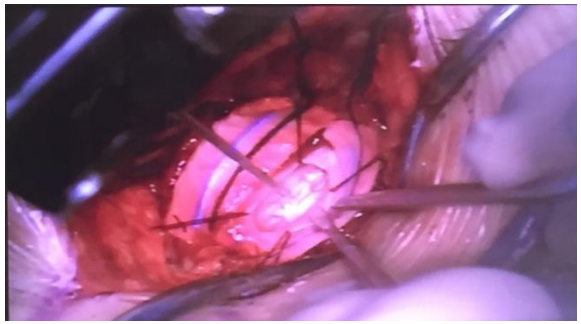
OPC1 Injection Procedure

Shepherd Center



Rush University

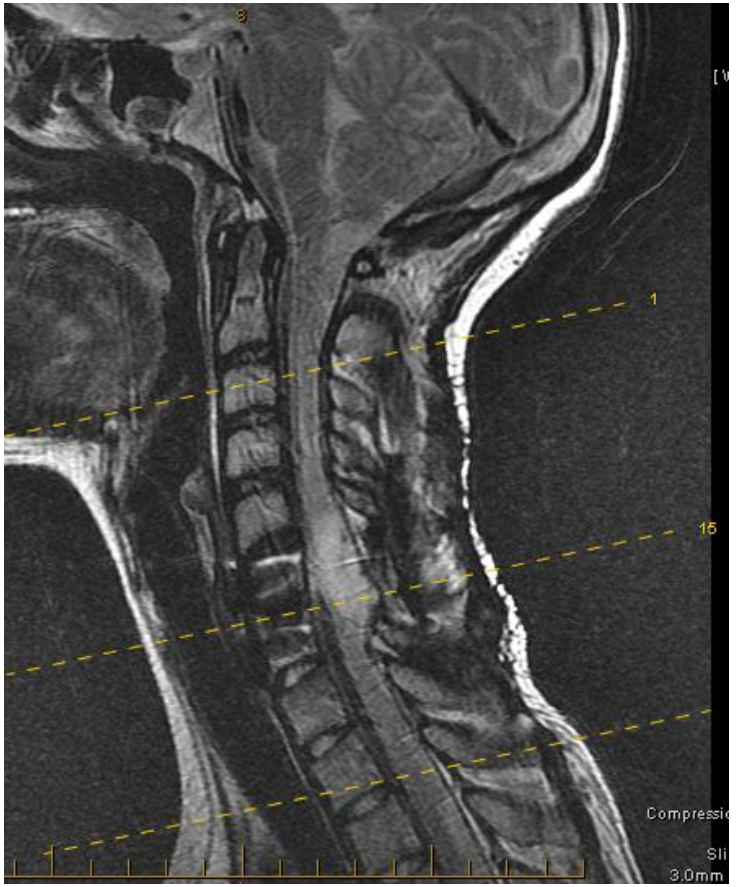


- **Injections performed using a table-mounted syringe positioning device (SPD)**
- **Direct intra-parenchymal injection into the spinal cord lesion**
- **Single 50µL injection for both the 2M & 10M doses; Two injections for the 20M dose**
- **No intraoperative complications**

12 Month MRI Results Support Durable Engraftment of OPC1 Cells

- Cavitation is estimated to occur in ~80% of spinal cord injury patients meeting SCiStar Study inclusion criteria
- 96% (24/25) of subjects had serial MRI scans at 12 months that indicated no sign of a lesion cavity
- The MRI results are consistent with formation of a tissue matrix at injury site, which we believe is supportive evidence showing that OPC1 cells have durably engrafted to help prevent cavitation at the injury site[(1)]

Cohort 2 subject
365 Day T2 –weighted sagittal MRI



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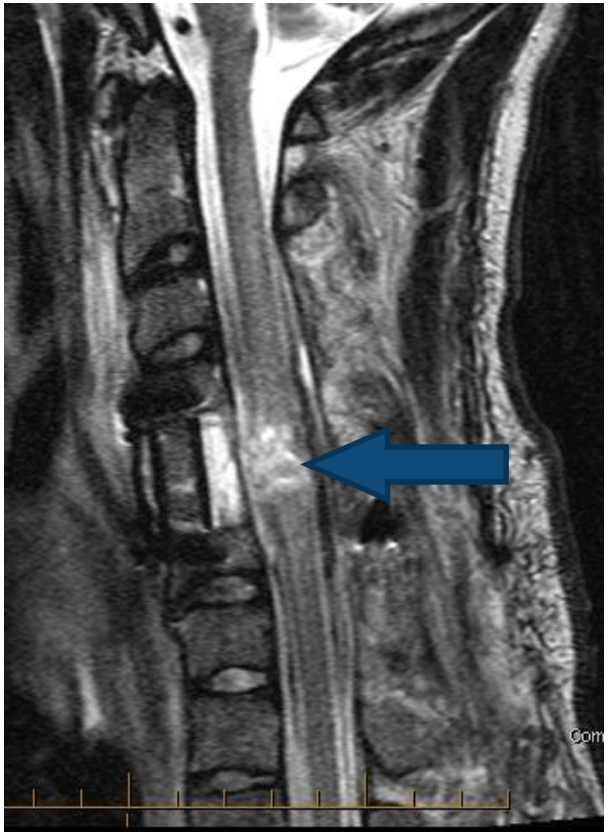
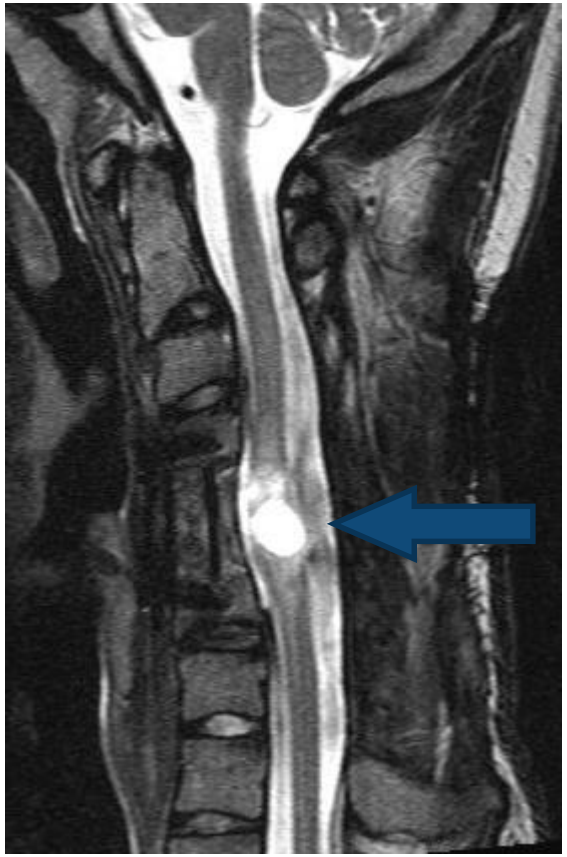
(1) Wirth et al, Exp Neurology 1995

Some Lesions May Be Too Severe for OPC1 Cell Survival

Pre-Injection Baseline



Day 365 Post-Injection



Failed graft with lesion cavity formation

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

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SCiStar Study Primary Endpoint: Safety

Tolerability Also Assessed

- **SCiStar Study primary endpoint was met:**
  - **Safety assessed by the frequency and severity of adverse events (AE) related to OPC1, the injection procedure, and immunosuppression with short-term, low-dose tacrolimus**
- **No concerning safety issues have been noted**
- **No intraoperative complications**
- **Immunosuppression with tacrolimus was well-tolerated**
- **No serious adverse events (SAEs) related to OPC1**
- **No subjects had worsening of neurological function post-injection**
- **No adverse findings on follow-up MRI scans**

SCiStar Study Summary of Adverse Events

- **Majority of SCiStar Study adverse events were mild to moderate in severity**

All Treated Subjects (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

* The AE that was possibly related to OPC1 was a Grade 2 dysesthesia (unpleasant, abnormal sensation) that began 47 days post-injection and resolved by the Year 2 follow-up visit

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SCiStar Study Most Common SAEs

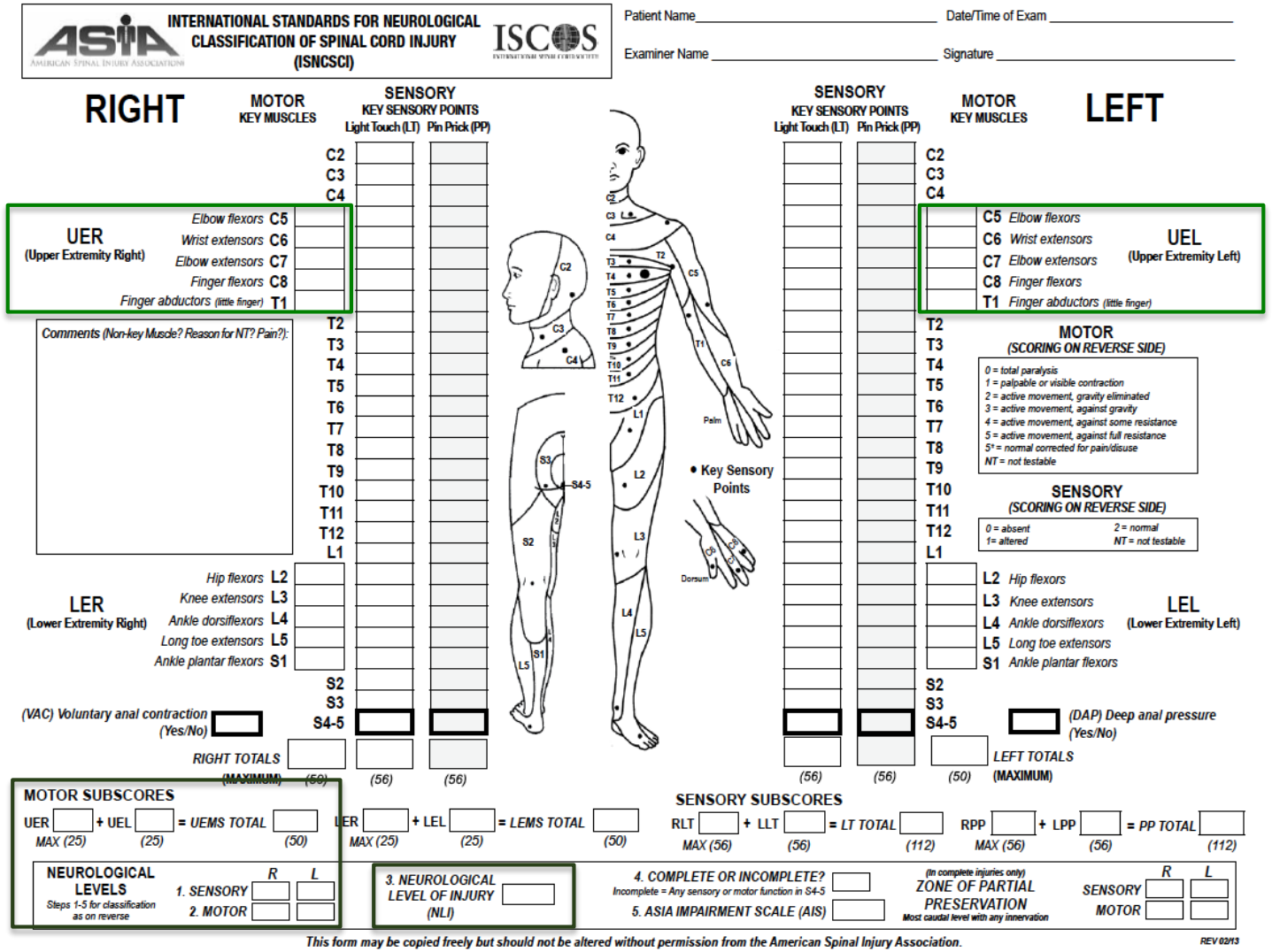
All Treated Subjects (N=25)	SAE #	Causality
Total	29	27 not related
UTI	7	Not related
Urinary Sepsis	2	Not related
Pulmonary Embolus	2	Not related
Mental Status Changes	2	Not related
CSF Fluid Leak	1	Related to Injection Procedure
Infected Epidural Fluid	1	Related to Tacrolimus

SCiStar Study Top 5 Most Common AEs

All Treated Subjects (N=25)	AE #	Causality*
Total	**534**	402 not related AEs
UTI	60	60 not related
Decubitus Ulcer	37	37 not related
Hypokalemia	24	24 not related
Hypomagnesemia	16	8 related to tacrolimus
Headache	15	2 related to injection procedure

- *Related to either OPC1 or injection procedure or tacrolimus
- Majority of AEs were mild to moderate in severity

Neurological Function Assessment: International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI)



Upper Extremity Motor Score (UEMS) Recovery in Cohorts 2-5

	+2 Motor Levels		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

- Next step was to look all 22 subjects ranked by UEMS improvement

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

Subjects with the Least Motor Recovery (Cohorts 2-5)

Subject	UEMS Change from Baseline to 12 mo	2 Motor level Gain Y/N	Cohort	Dose	Lot	Age	Injection Date Days from Injury	Baseline AIS	NLI Baseline
2207	7	N	5	20 million	M22	62	37	B	C4
2203	6	N	3	20 million	M25	45	31	A	C6
2105	6	N	3*	10 million	M25	19	20	A	C4
2004	5	N	4	10 million	M25	21	25	B	C6
2007	4	N	4	10 million	M22	55	38	B	C4
2307	4	N	5*	10 million	M22	19	38	B	C5
2303	3	N	4	10 million	M25	22	35	B	C6

- * As previously noted on Slide 7, these two subjects received 10 million cells rather than the planned 20 million cells for cohorts 3 and 5
- Two subjects had cord compression after OPC1 injection (Subject 2307 at Day 7; Subject 2303 at Day 30)
- Subjects 2207, 2105, & 2007 had a C4 NLI (lowest intact neurological level) at Baseline
- Subject 2105 also had hematoma in spinal cord at baseline & failed OPC1 graft
- Subject 2004 focused on lower extremity rehab; regained normal bowel function

SCiStar Study Preliminary Subset Analysis

Cohort	N	2 ML Gain	Mean UEMS Gain	Comments
Cohort 2	6	4	12.3	
Cohort 3	5	1	8.8	2105 had C4 NLI*, severe lesion and failed graft
Cohort 4	4	1	8.0	2303 had cord compression at Day 30 2007 had C4 NLI
Cohort 5	2	1	8.5	2307 had cord compression at Day 7 2207 had C4 NLI
Total	17	7	10.2 +/- 3.9	Mean is still 10.2 even if 2103 (C4 NLI in Cohort 2) is excluded

* Neurological Level of Injury (NLI) is the lowest level with intact motor and sensory function

SCiStar Study Evaluation of Change in UEMS (12 Months Post-Injection Versus Key Variables)

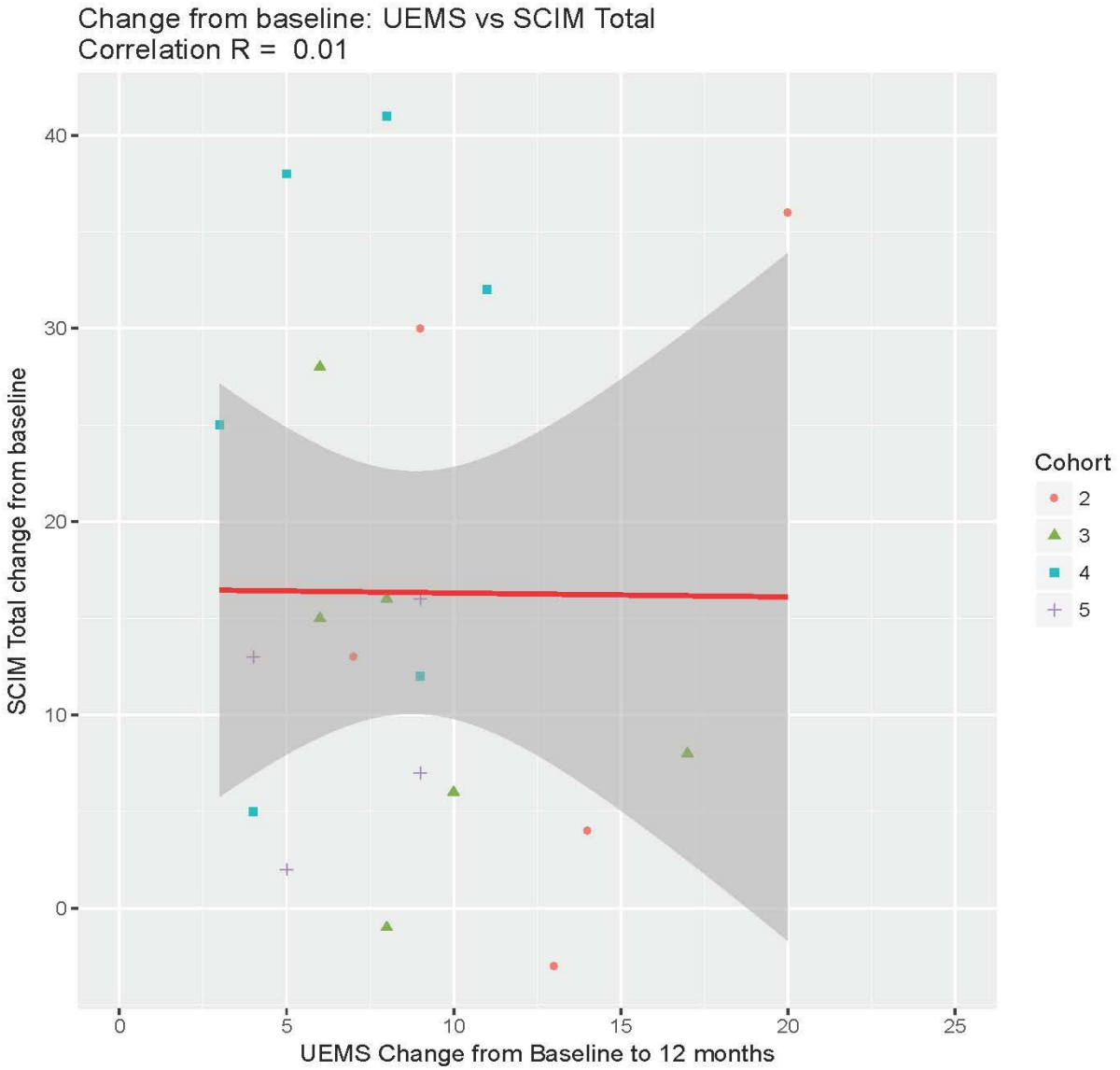
- **Analysis performed for all 22 subjects in Cohorts 2-5 (except for Baseline NLI, which was only analyzed for subjects with a baseline NLI of C5, C6 or C7)**

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 subjects received cells from Lot A or Lot B)	Lot A (n=7): P = 0.41 Lot B (n=14): P = 0.76

Exploratory Assessment: Spinal Cord Independence Measure (SCIM)

- **SCIM is a "global" functional activities exam within the activity/function domain (does not cover pain, spasticity, or autonomic functions)**
- **Maximum score of 100 comes from 3 sub-scales within SCIM (self-care = 20 points, respiration and sphincter management = 40, mobility = 20)**
- **SCIM Self-care sub-score focuses on upper extremity activities and is therefore linked to assessments of cervical SCI**
  - **Feeding (3 pts)**
  - **Bathing: Upper body (3 pts), Lower body (3 pts)**
  - **Dressing: Upper body (4 pts), Lower body (4 pts)**
  - **Grooming (3 pts)**

Change in SCIM Total Score did not correlate with UEMS



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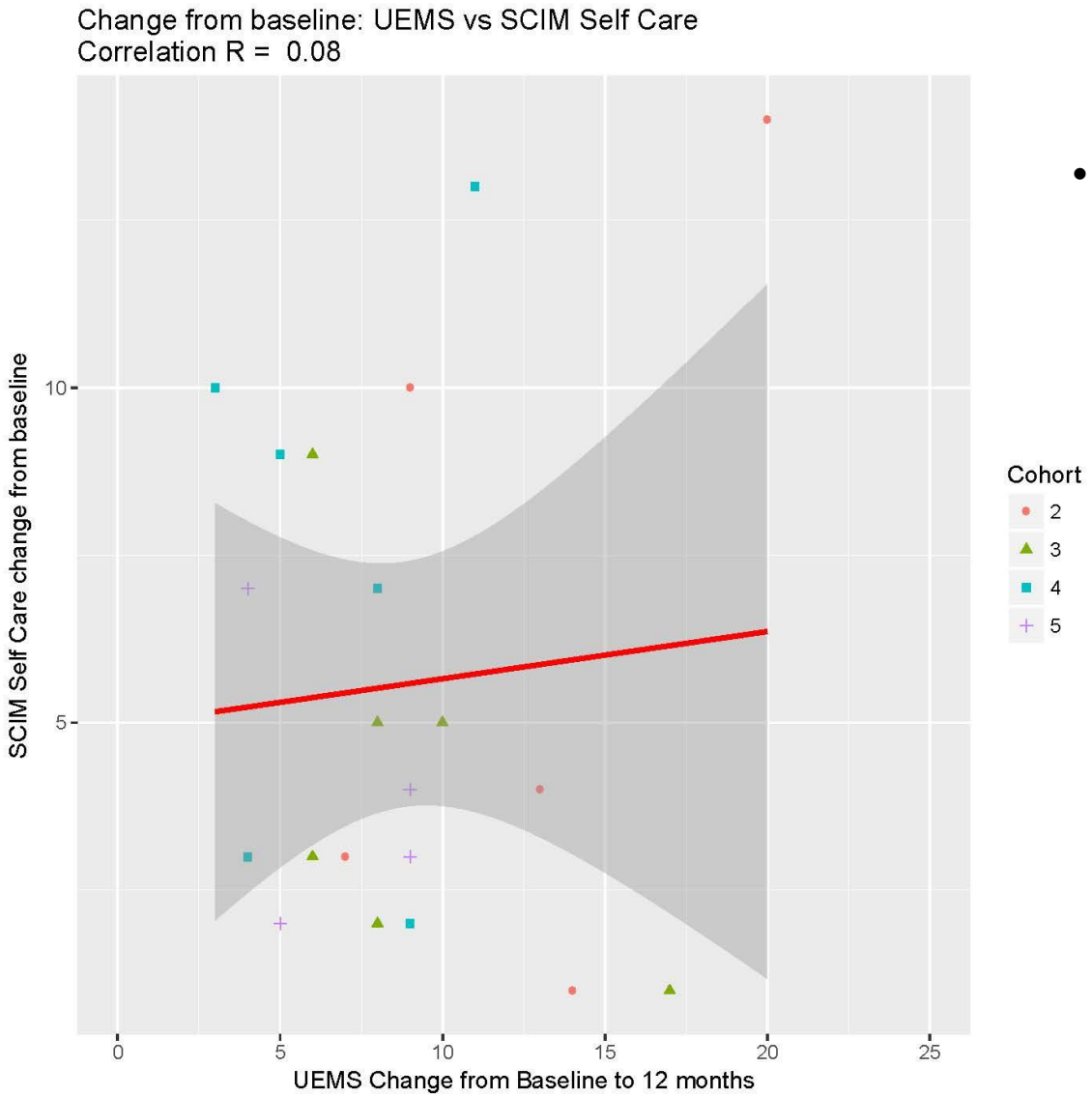
Change in SCIM Self-Care Subscore is Poorly Correlated with UEMS



- **Will review with reordered SCIM data per the Rasch analysis used to develop the Spinal Cord Ability Ruler (SCAR)* outcome measure to assess utility of SCIM in subsequent trials**

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*Reed et al., Spinal Cord, 2017 Aug;55(8):730-738.

Summary

- **The overall safety profile of OPC1 to date is excellent, and immunosuppression with tacrolimus was well-tolerated**
- **MRI scans are consistent with a very high rate (96%) of durable engraftment through 1 year post-injection**
- **Majority of subjects who received 10M or 20M OPC1 cells exhibited robust motor recovery in the upper extremities**
  - **In addition, 21/22 (95%) of subjects in Cohorts 2-5 improved at least 1 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 warrant further evaluation in randomized, controlled studies**
- **Data from the SCiStar Study will help inform the design of future randomized studies with respect to inclusion/exclusion criteria, dose, and timing of administration**

Acknowledgments

Asterias*

Jane Lebkowski
Katy Spink
Susy Chen
Maria Schaefer
Sherin Halfon
Oliver Tilk
Rekha Nair
Maggie Morysewicz
Kevin Nishimoto
Naomi Kautz
OPC1 Team

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Steve McKenna
Gary Steinberg
Marco Lee
Charles Liu
Eric Horn
Shekar Kurpad

Funding

CIRM
CALIFORNIA'S STEM CELL AGENCY

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** Asterias was acquired by BioTime on March 8, 2019.*

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