

# ONLINE ONLY **Supplemental material**

A phase 1/2a dose-escalation study of oligodendrocyte progenitor cells in individuals with subacute cervical spinal cord injury

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#### SUPPLEMENTAL MATERIALS

#### STAGGERED ENROLLMENT WITHIN EACH COHORT

Enrollment in Cohort 1 was staggered such that there were at least 10 days between administration of LCTOPC1 to each participant. Enrollment within Cohorts 2 through 5 were staggered after the initial participant in each cohort was dosed, with at least 8 days between administration of LCTOPC1 to the first and second participants. If the first 2 participants were successfully dosed with no serious adverse events (SAEs) that would trigger study suspension (per the study Suspension Rules), then the remaining participants in that cohort were dosed without further staggering. An additional staggering rule for Cohorts 2 through 5 required that a minimum of 14 days must elapse between the dosing of any 2 consecutive participants who both had a C4 NLI. This 14-day stagger for consecutive C4 NLI participants applied throughout each of these cohorts and superseded the 8-day stagger rule noted above if the first two participants in any cohort both had a C4 NLI.

#### **RULES FOR ADVANCEMENT TO COHORTS 2-5**

Enrollment in Cohort 2 commenced after all 3 participants in Cohort 1 had completed 30 days of follow up after LCTOPC1 administration AND the safety data for Cohort 1 had been reviewed by the Data and Safety Monitoring Board (DSMB). Enrollment in Cohort 3 commenced after at least 5 participants in Cohort 2 completed 30 days of follow up after LCTOPC1 administration and the safety data from Cohorts 1 and 2 had been reviewed by the DSMB.

Enrollment in Cohort 4 commenced after at least 2 participants in Cohort 2 had completed 30

days of follow up after LCTOPC1 administration AND if there were no SAEs that would trigger study suspension.

Enrollment in Cohort 5 commenced after at least 2 participants in Cohort 3 AND at least 5 participants in Cohort 4 had completed 30 days of follow up after LCTOPC1 administration AND if there were no SAEs that would trigger study suspension. The DSMB reviewed enrollment to each cohort as noted above and had the ability to recommend whether enrollment of the next dose cohort could commence or whether additional follow up was needed.

#### RATIONALE BEHIND TIME FRAME AND TIME FRAME SHIFT

The original dosing window of 14-30 days for the current Phase 1/2a study was selected to avoid the early hemorrhage and inflammation that occurs following SCI, as well as the scar tissue formation that occurs in the chronic phase of SCI. This window was also based on the preclinical data available prior to the initiation of this clinical study. However, Asterias completed an additional non-GLP preclinical study to further evaluate the appropriate dosing window for OPC1, and the findings from this study suggest that the optimal dosing window in human subjects may extend to at least 60 days post-SCI.

Asterias reviewed these new preclinical data with the current study investigators and several SCI experts to determine whether the dosing window should be adjusted. Consideration was also given to the planned inclusion of patients with a C4 NLI. Based on these reviews, it was determined that a dosing window of 21-42 days post-SCI would still be squarely within the

subacute period but would also allow more time for patients to be medically stable prior to undergoing elective surgery for OPC1 administration.

#### STUDY OVERSIGHT AND MONITORING

In addition to FDA review, the protocol and study design were reviewed by a steering committee. Due to the nature of the study product, the protocol was also reviewed by an overall study Embryonic Stem Cell Research Oversight (ESCRO) committee as well as individual site ESCRO committees where required. As noted above, safety monitoring occurred via an External Medical Monitor, Sponsor Medical Monitor, and DSMB.

#### **INFORMED CONSENT**

A written informed consent form, in compliance with the Declaration of Helsinki, ICH-E6 Section 4.8, 21 Code of Federal Regulations (CFR) Part 50.20, and other applicable local regulations, was obtained for each participant prior to entering the participant into the study. According to 21 CFR Part 50.20, no Investigator could involve a human being as a participant in research covered by these regulations unless the Investigator had obtained the legally effective informed consent of the participant or the participant's legally authorized representative. An Investigator sought such consent only under circumstances that provided the prospective participant or the participant's legally authorized representative sufficient opportunity to consider whether or not to participate and that minimized the possibility of coercion or undue influence. The information that was given to the participant or the representative was in language understandable to the participant or the representative.

The Investigator was provided with a study-specific template for the informed consent form. State and local laws and/or institutional requirements may have required the disclosure of additional information in the consent form. The proposed consent form was submitted to the Sponsor or the Sponsor's designee prior to submission to the IRB or IEC to ensure that it met Sponsor's standards for informed consent forms.

The IRB or IEC had to approve the informed consent form. A copy of the approved consent form was submitted to the Sponsor or the Sponsor's designee prior to participant screening.

Prior to the initiation of any procedures relating to the study, informed consent was documented via a written consent form approved by the IRB/IEC and signed and dated by the participant or the participant's legally authorized representative at the time of consent. A copy of the signed informed consent form was given to the person signing the form. The Investigator kept each participant's signed consent form on file for inspection by authorized representatives of the Sponsor, the IRB/IEC, or a regulatory authority at any time.

Due to the potential for long term risks of human embryonic stem cells, two protocols and thus two informed consent forms were required: one for the administration of LCTOPC1 and one-year follow-up (Part I), the second covered follow-up from years 2- 15 following

product administration (Part II). Written informed consent for both protocols was obtained for all individuals prior to study enrollment.

#### SAFETY ASSESSMENT

Safety assessments included physical examination, vital signs, ISNCSCI neurological examination, pain questionnaire, electrocardiogram, MRI, laboratory tests for hematology and blood chemistry, laboratory tests for immunosuppression safety monitoring (whole blood trough levels of tacrolimus, serum levels of creatinine, potassium, magnesium, phosphate, ionized calcium, aspartate aminotransferase, alanine aminotransferase, and total bilirubin), concomitant medications.

### ADVERSE EVENT: DEFINITION, REPORTING, AND EVALUATION

An adverse event (AE) was any untoward medical event that occurred to a study participant once the participant had signed the informed consent form until the study participant's last study visit, whether or not the event was considered related to the investigational product.

A pre-existing condition was one that was present prior to or at the start of the study and was to be reported as part of the participant's medical history. It was reported as an AE only if the frequency, intensity, or the character of the condition worsened during the study. An unexpected AE was one not identified in nature, severity, or frequency in the current protocol or Investigator's Brochure.

The collection period for AEs began once the participant had signed the informed consent form and ended 365 days after receiving the study drug. Adverse events were assessed at each clinic visit and all AEs that occurred during the study period were collected and reported. All AEs, including observed problems, complaints, or symptoms, were to be recorded on the appropriate electronic CRF (eCRF) whether or not considered related to the investigational product. Documentation must have been supported by an entry in the participant's source document. Laboratory test abnormalities considered by the Investigator to be clinically relevant were to be reported on the eCRF. Each event was to be evaluated for duration, severity, and causal relationship with the investigational product or other factors.

AE severity was evaluated using the following criteria:

- Grade 1, Mild: Awareness of symptom, but easily tolerated; usually transient and required no special treatment; did not interfere with usual status or activities.
- Grade 2, Moderate: May be ameliorated by simple therapeutic measures; may interfere with usual activities.
- Grade 3, Severe: Incapacitating, inability to perform usual activities.
- Grade 4, Life-threatening/Disabling: Patient was at risk of death or significant disability at the time of the event.
- Grade 5, Fatal.

Relationship of the AEs to the investigational drug, the surgical procedure, and the immunosuppressive agent were determined by the Investigator, and were categorized as:

- Unrelated: The occurrence of the AE was not reasonably related in time, or the AE was
  considered unlikely to be related to use of LCTOPC1, the injection procedure used to
  administer LCTOPC1, and/or the concomitant immunosuppression administered, i.e.,
  there were other factors (evidence) explaining the occurrence of the event (e.g.,
  progression of the underlying disease, concomitant medications more likely associated
  to the event).
- Related: LCTOPC1, the injection procedure used to administer LCTOPC1, and/or the concomitant immunosuppression administered, and the AE were reasonably related in time.

#### SERIOUS ADVERSE EVENT: DEFINITION AND REPORTING

An SAE was one that met any of the following criteria:

- Resulted in death.
- Was life threatening.
- Required inpatient hospitalization or prolongation of an existing hospitalization.
- Resulted in persistent or significant disability/incapacity.
- Was a congenital anomaly/birth defect in the offspring of an exposed participant.

An important medical event that did not result in death, was not life-threatening, and did not require hospitalization, may have been considered a serious adverse drug experience when,

based upon appropriate medical judgment, it jeopardized the participant and may have required medical or surgical intervention to prevent one of the outcomes listed in this definition. A life-threatening AE was defined as any adverse experience that placed the patient or participant, in the view of the Investigator, at immediate risk of death from the reaction as it occurred, i.e., it did not include a reaction that, had it occurred in a more severe form, might have caused death.

The Sponsor was notified by telephone, email or fax and informed of any serious AE within 24 hours of the Investigator learning that the AE had occurred. Telephone reports were followed by a written report within 24 hours. Follow-up reports were submitted in a timely fashion as additional information became available. The Sponsor notified the FDA and/or other regulatory authorities and all participating investigators of any AE that was serious, unexpected, and possibly related to the use of the study drug, in accordance with the reporting requirements in 21 CFR 312.32©, Investigational New Drug Safety Reports. Regulatory authorities were to be notified of any fatal and life-threatening experiences associated with the use of the drug as soon as possible but in no event later than 7 calendar days after the Sponsor's initial receipt of the information. Serious, unexpected, and possibly related AEs that were not fatal or life threatening were reported as soon as possible but in no event later than 15 calendar days after the Sponsor's initial receipt of the information. The Investigator was responsible for notifying their IRB or IEC of all serious, related, and unexpected AEs.

#### **MAGNETIC RESONANCE IMAGING**

Screening/Baseline MRI was obtained between 3 and 5 days prior to injection (Day -3 and Day -5) of LCTOPC1 but no earlier than 4 days after SCI. Screening/baseline MRI included the brain, cerebellum, and entire spinal cord, with and without contrast (gadolinium-diethylenetriamine pentaacetic acid [Gd-DTPA]). If surgery for LCTOPC1 injection was subsequently delayed for more than 3 days, then a repeat MRI of the thoracic spine, without contrast, was obtained. Follow-up MRIs of the spinal cord and cerebellum, with and without contrast (Gd-DTPA), were obtained on Days 7, 30, and 180 post-injection. A full central nervous system MRI, with and without contrast (Gd-DTPA), was obtained on screening and 365 as well as yearly between years 2-5. Image acquisition protocols were standardized. Image review was centralized and standardized by an independent radiologist, at Radiology Imaging Associates Denver.

#### **CELLULAR IDENTITY AND DERIVATION**

OPC1 is produced from the H1 uhESC line, which was originally derived at the University of Wisconsin in 1998. The H1 line was established by isolating the inner cell mass from a donated excess embryo and culturing the cells from this mass on a layer of irradiated murine embryonic feeder cells. The Sponsor subsequently adapted the H1 uhESC line to feeder-free culture conditions prior to generating the H1 master cell bank (MCB) that is used to produce OPC1. Every batch of the OPC1 used in the clinical (and non-clinical studies) were manufactured from the master cell bank that was originally generated by Geron Corporation. The manufacturing protocols were all identical for animal and human studies.

Every manufacturing batch of OPC1 was released against pre-defined set of release specifications, that included identity markers known to be associated with OPCs. The details of the release specifications are proprietary to the sponsor and not available to the authors.

#### **DOSE PREPARATION**

LCTOPC1 was supplied to the clinical sites in sterile, single-dose, single-use, 2.0 mL Corning<sup>TM</sup> cryovials. At the time of cryopreservation, each vial typically contained  $7.5 \times 10^6$  viable cells in 1.2 mL of cryopreservation medium. The components of the cryopreservation medium were the following: 1) Glial Progenitor Medium (GPM) - 86% (v/v) [98% DMEM/F12 with GlutaMAX supplement, 1.9% B-27 supplement and 0.1% T3]; 2) 25% Human serum albumin (HAS) - 3.6% (v/v); 3) 1 M HEPES - 0.9% (v/v); 4) DMSO - 9.5% (v/v). The cryopreserved drug product was thawed, washed, resuspended in the injection medium, and loaded into the injection syringe at the clinical sites.

#### **CELL IMPLANTATION**

LCTOPC1 is a cell population containing a mixture of oligodendrocyte progenitor cells (OPCs) and other characterized cell types that are obtained following differentiation of undifferentiated human embryonic stem cells (uhESCs). LCTOPC1 Drug Product (DP) is manufactured by a continuous process. Harvested LCTOPC1 Drug Substance is a transient

intermediate that is immediately formulated, vialed, and cryopreserved to LCTOPC1 DP without the use of a hold step. Compositional analysis of LCTOPC1 by immunocytochemistry (ICC), flow cytometry, and quantitative polymerase chain reaction (qPCR) indicates that the cell population is comprised primarily of neural lineage cells of the oligodendrocyte progenitor phenotype. Other neural lineage cells, namely astrocytes and neurons, are present at low frequencies. The only non-neural cells detected in the population are epithelial cells. Mesodermal and endodermal lineage cells, and uhESCs are routinely below the quantitation or detection limits of the assays.

#### *IMMUNOSUPPRESSION*

Immunosuppression with tacrolimus was initiated between 6 and 12 hours after injection of LCTOPC1. If the participant was unable to take oral medication, tacrolimus was administered intravenously at a starting dose of 0.01 mg/kg/day, given as a continuous intravenous infusion. Participants were switched to oral tacrolimus as soon as possible. The starting dose for oral tacrolimus was 0.03 mg/kg/day, divided into 2 daily doses. The tacrolimus dose was adjusted to achieve a target whole blood trough level of 3 to 7 ng/mL. This target range was slightly below the typical range for long-term maintenance therapy following solid organ transplantation and was selected based on the low allogenic reactogenicity of LCTOPC1.

On Day 46, the tacrolimus dose was decreased by 50% (rounded to the nearest 0.5 mg, as this was the smallest capsule size available) (Figure 2). On Day 53, the tacrolimus dose was decreased by another 50% (rounded to the nearest 0.5 mg). If the rounded total daily dose was

0.5 mg or lower, the participant received 0.5 mg once per day until tacrolimus was discontinued. Tacrolimus was discontinued at Day 60 (Figure 2). The dose of tacrolimus was lowered if the trough blood level exceeded 7 ng/mL. In addition, an expert reviewed all ISNCSCI examination forms to assess whether there were any changes in neurological function that may have been associated with tacrolimus tapering and/or discontinuation. Tacrolimus was discontinued if any of the following occurred: infection, uncontrolled fever, liver function test elevation, serum creatinine elevation, seizure, or tacrolimus-induced thrombotic thrombocytopenic purpura.

#### RATIONAL BEHIND IMMUNOSUPRESSION DOSING AND TIME FRAME

In vitro studies were also performed to assess the immunogenicity of OPC1 with respect to the allogeneic human immune system (Okamura 2007)<sup>1</sup>. These experiments demonstrated that OPC1 was capable of only weakly stimulating allogeneic T-cell proliferation in a mixed lymphocyte reaction assay. Although OPC1 was found to express Class I human leukocyte antigens, Class II expression was not detected. Further experiments in this study indicated that OPC1 is resistant to lysis by human natural killer cells as well as antibodies contained in normal human serum. These in vitro studies suggest that OPC1 may be a poor target for immunemediated responses in an allogeneic setting.

Based upon these results, it was hypothesized that if an immune response against OPC1 were to occur in a human subject, it would likely consist of a weak T-cell attack. Therefore, the previous trial of OPC1 utilized a low dose of tacrolimus for immunosuppression. In addition, the

tacrolimus dose was tapered beginning at Day 46, and tacrolimus was withdrawn completely at Day 60. Since it was not known whether this immunosuppression regimen was sufficient to prevent donor-specific immune responses to OPC1, extensive immune monitoring was performed. The details of immunosuppression and immune monitoring results are currently being prepared for publication.

1. Okamura RM, Lebkowski J, Au M, Priest CA, Denham J, Majumdar AS. Immunological properties of human embryonic stem cell-derived oligodendrocyte progenitor cells. J

Neuroimmunol. 2007 Dec;192(1-2):134-44.

#### **INCLUSION AND EXCLUSION CRITERIA**

Individuals with spinal cord injury were eligible for the study if the following major inclusion criteria were met prior to doing of LCTOPC1:

- Sensorimotor complete, traumatic SCI (ASIA Impairment Scale A) for cohorts 1,2,3
- Sensorimotor incomplete, traumatic SCI (ASIA Impairment Scale B) for cohorts 4,5
- Last fully preserved single neurological level (SNL) from C-4 to C-7
- From 18 through 69 years of age at time of injury
- Single spinal cord lesion on a post-stabilization magnetic resonance imaging (MRI) scan,
   with sufficient visualization of the spinal cord injury epicenter and lesion margins to
   enable post-injection safety monitoring

- Informed consent for this protocol and the companion long term follow-up protocol
  must be provided and documented (i.e., signed informed consent forms) no later than
  37 days following injury
- Able to participate in an elective surgical procedure to inject LCTOPC1 21-42 days following SCI

Individuals with spinal cord injury were not eligible for the study if the following major exclusion criteria were met prior to dosing with LCTOPC1:

- SCI due to penetrating trauma
- Traumatic anatomical transection or laceration of the spinal cord based on prior surgery or MRI
- Any concomitant injury that interferes with the performance, interpretation or validity of neurological examinations
- Inability to communicate effectively with neurological examiner such that the validity of patient data could be compromised
- Significant organ damage or systemic disease that would create an unacceptable risk for surgery or immunosuppression
- History of any malignancy (except non-melanoma skin cancers)
- Pregnant or nursing women
- Body mass index (BMI) > 35 or weight > 300 lbs.
- Active participation in another experimental procedure/intervention

## SUPPLEMENTAL TABLE 1. Schedule of Events

	ſ	Part A				
Procedure	Screen	Baseline	Surgery		Post-Injection	
	Days –11 to –3	Days −2 to −1	Injection Day	Days 1-6	Day 7 (+/- 1 day)	Days 8-29
Demographic data	Х					
Past and current medical history	X					
Complete physical exam	X					
Brief physical exam		Х		Day 1	Х	
Vital signs	X	X <sup>3</sup>	Х	Daily	X	
Neurological exam		X <sup>5</sup>			Х	
ISNCSCI exam	X	X <sup>1</sup>			Х	
GRASSP		X <sup>5</sup>				
SCIM		X <sup>5</sup>				
MRI <sup>2</sup>	Day -7 to -3				Х	
ECG	X				Х	
Hematology	X	Х		Day 1	X	
Blood chemistry	X	Х		Daily	Х	2/week
Serology for HIV, HBV, HCV	X					
Panel reactive antibodies	X					
Pregnancy test, if applicable	X					
48-hour blood culture	Day –3					
Fasting blood glucose		X <sup>4</sup>				
Blood for HLA typing		X <sup>5</sup>				
Blood for immune response monitoring		X <sup>5</sup>			X	
Blood for xenotransplantation archival		X <sup>5</sup>				
Withhold DVT prophylaxis		Day -1				
CSF via lumbar puncture			Х			
Begin tacrolimus			Х			
Restart DVT prophylaxis				Day 1		
Tacrolimus blood levels				Day 3 <sup>6</sup>	Х	2/weel
Concomitant medications <sup>7</sup>						
Adverse events <sup>7</sup>						

			Part B				
Procedure	Day 30 (+/- 3 days)	Days 31-59	Day 60 (+/- 7 days)	Day 90 (+/- 7 days)	Day 180 (+/- 14 days)	Day 270 (+/- 14 days)	Day 365 (+/- 14 days)
Complete physical exam							Х
Brief physical exam	Х		Х	Х	Х		
Vital signs	Х		Х	Х	Х		Х
Neurological exam	X		Х	Х	Х		Х
ISNCSCI exam	Х		Х	Х	Х	Х	Х
GRASSP				Х	Х	Х	Х
SCIM questionnaire	Х		Х	Х	Х	Х	Х
Pain questionnaire	Х			Х	Х		Х
Bowel/Bladder questionnaire	X				Х		Х
MRI <sup>2</sup>	Х				Х		Х
Hematology	Х		Х	Х	Х		Х
Blood chemistry	Х	1/week	Х	Х	Х		Х
Fasting blood glucose	X						
Blood for immune response monitoring	Х		Х	Х	Х		Х
Tacrolimus blood level	Х	1/week	Х				
CSF via lumbar puncture			Х				
Blood for xenotransplantation archival	Х						Х
Concomitant medications <sup>7</sup>							
Adverse events <sup>7</sup>	1						

Abbreviations: CSF, cerebrospinal fluid; GRASSP, Graded Redefined Assessment of Strength, Sensibility and Prehension; ISNCSCI, International Standards for Neurologic Classification of Spinal Cord Injury; MRI, magnetic resonance imaging; SCIM, Spinal Cord Independence Measure.

- <sup>1</sup> ISNCSCI exam (may be performed on Day -3 to -1, unless the screening ISNCSCI was performed on Day -3)
- MRI of cervical spine and brain at Screen & Day 365; MRI of cervical spine only at Days 7, 30, 180
- <sup>3</sup> Vitals on Day -2 and -1
- 4 May be done pre-op on Injection Day
- May be performed as early as Day -4 if required to accommodate clinical site staff availability
- <sup>6</sup> Tacrolimus blood level on Day 3 may be obtained +/- 1 day
- <sup>7</sup> Collected throughout the study period

# SUPPLEMENTAL TABLE 2. Participant Demographics

		Cohort 1 (N=3)	Cohort 2 (N=6)	Cohort 3 (N=6)	Cohort 4 (N=6)	Cohort 5 (N=4)	Overall (N=25)
		(N=3)	(N=6)	(N=6)	(N=6)	(N=4)	(N=25)
Age	n	3	6	6	6	4	25
	Mean (SD)	24.3 (6.1)	24.5 (7.4)	44.7 (14.7)	28.5 (14.1)	34.3 (20.7)	31.8 (14.8)
	Median	23	21.5	47.5	21.5	28.5	23.0
	Min, Max	19.0, 31.0	18.0, 37.0	19.0, 58.0	19.0, 55.0	18.0, 62.0	18.0, 62.0
Gender n(%)	Male	3 (100.0)	5 (83.3)	5 (83.3)	6 (100.0)	2 (50.0)	21 (84.0)
	Female	0	1 (16.7)	1 (16.7)	0	2 (50.0)	4 (16.0)
Race n(%)	White	3 (100.0)	5 (83.3)	6 (100.0)	6 (100.0)	2 (50.0)	22 (88.0)
• •	African American	O ,	1 (16.7)	O	O ,	O ,	1 (4.0)
	American Indian/Alaska Native	0	0	0	0	0	0
	Asian	0	0	0	0	1 (25.0)	1 (4.0)
	Native Hawaiian/ Other Pacific Islander	0	0	0	0	1 (25.0)	1 (4.0)
	Other	0	0	0	0	0	0
Ethnicity n(%)	Hispanic Or Latino	0	0	0	1 (16.7)	0	1 (4.0)
	Non-Hispanic Or Latino	3 (100.0)	6 (100.0)	6 (100.0)	5 (83.3)	4 (100.0)	24 (96.0)
Height (cm)	n	3	6	6	6	4	25
	Mean (SD)	182.9 (5.1)	181.6 (13.7)	179.5 (17.6)	179.4 (11.5)	175.1 (9.9)	179.7 (12.3)
	Median	182.9	186.7	182.9	180.2	172.7	182.9
	Min, Max	177.8, 188.0	155.0, 193.0	147.3, 200.7	160.0, 193.0	167.0, 188.0	147.3, 200.7
Weight (kg)	n	3	6	6	6	4	25
	Mean (SD)	75.3 (15.5)	84.0 (22.2)	88.2 (15.6)	82.9 (9.9)	69.0 (18.9)	81.3 (16.8)
	Median	74.8	82.5	95.3	84.0	64.0	86.2
	Min, Max	60.0, 91.0	52.0, 114.2	57.6, 97.7	71.6, 93.0	52.3, 95.7	52.0, 114.2
BMI (kg/m²)	n	3	6	6	6	4	25
	Mean (SD)	22.6 (5.2)	25.1 (4.4)	27.3 (2.3)	25.8 (1.8)	22.3 (4.5)	25.0 (3.7)
	Median	23.7	24.6	27.7	25.5	22.9	25.1
	Min, Max	17.0, 27.2	20.1, 32.3	24.3, 29.9	23.8, 28.0	16.5, 27.1	16.5, 32.3

## SUPPLEMENTAL TABLE 3. Adverse Events That Occurred in ≥ 3 Treated Participants

Preferred Term	A.F.	Number of Participants
Preferred Term	AE	(N=25)
Urinary tract infection	60	23
Decubitus ulcer	37	14
Hypokalemia	24	8
Headache	15	9
Hypomagnesemia	16	13
Musculoskeletal pain	13	10
Nausea	12	10
Procedural pain	9	8
Rash	8	7
Autonomic dysreflexia	7	5
Hemorrhoids	7	6
Muscle spasms	7	7
Pain in extremity	7	6
Pyrexia	7	5
Bone disorder	8	8
Erythema	6	4
Fall	6	4
Muscle spasticity	6	5
Cerebrospinal fluid retention	5	5
Diarrhea	5	4
Erectile dysfunction	5	5
Acne	4	3
Dry skin	4	4
Mental status changes	4	4
Pruritus	4	3
Skin abrasion	4	3
Blister	4	3
Dry eye	3	3
Ingrown nail	3	3
Insomnia	3	3
Arthralgia	3	3
Neuralgia	3	3

Abbreviations: AE – adverse event.

## SUPPLEMENTAL TABLE 4. ISNCSCI SUMMARY

Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	18	16	9	0	C5	C5	C5	C5	C5	Α	T2	T1	C6	C5
Baseline day 2	17	18	8	0	C5	C5	C5	C5	C5	Α	C5	T1	C5	C5
Post day 7	19	17	8	0	C5	C5	C5	C5	C5	Α	T1	T1	C5	C5
Post day 30	16	16	8	0	C5	C5	C5	C5	C5	Α	C5	C5	C5	C5
Post day 60	22	21	17	0	C5	C5	C6	C6	C5	Α	T2	T2	C6	C7
Post day 90	17	16	17	0	C5	C5	C6	C6	C5	Α	T1	C5	C6	C6
Post day 180	17	16	18	0	C5	C5	C6	C6	C5	Α	C6	C5	C7	C7
Post day 365	17	16	18	0	C5	C5	C6	C6	C5	Α	C6	C5	C6	C6
Cohort 1: Particip	ant 2			I	1	1	<u> </u>	<u> </u>	1			1		ı
Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	25	30	25	0	C6	C6	C6	C7	C6	Α	T3	T2	C7	C7
Baseline day 2	22	23	20	0	C6	C6	C6	C6	C6	Α	C8	C7	C6	C7
Post day 7	31	25	21	0	C6	C6	C6	C6	C6	Α	T4	T2	C6	C7
Post day 30	28	26	25	0	C6	C6	C6	C7	C6	Α	T1	T2	C7	C7
Post day 60	25	20	26	0	C6	C6	C7	C7	C6	Α	T1	T1	C7	C7
Post day 90	29	28	24	0	C6	C6	C6	C7	C6	Α	T2	T2	C7	C7
Post day 180	22	20	26	0	C6	C6	C7	C7	C6	Α	C8	C7	C7	C7
Post day 365	22	20	27	0	C6	C6	C7	C7	C6	Α	C8	C7	C7	C7

Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	21	20	24	0	C6	C6	C6	C7	C6	Α	C7	C6	C7	C7
Baseline day 2	22	21	24	0	C6	C6	C6	C7	C6	Α	C7	C7	C7	C7
Post day 7	22	21	25	0	C6	C6	C6	C7	C6	Α	C7	C7	C7	C7
Post day 30	21	22	25	0	C6	C6	C6	C7	C6	В	N/A	N/A	N/A	N/A
Post day 45 - 51	20	22	25	0	C6	C6	C6	C7	C6	Α	C7	C7	C7	C8
Post day 60	21	22	25	0	C6	C6	C6	C7	C6	В	N/A	N/A	N/A	N/A
Post day 90	20	21	26	0	C6	C6	C6	C7	C6	С	N/A	N/A	N/A	N/A
Post day 180	24	23	27	0	C6	C6	C7	C7	C6	С	N/A	N/A	N/A	N/A
Unscheduled	25	23	27	0	C6	C5	C7	C7	C5	В	N/A	N/A	N/A	N/A
Post day 365	23	24	28	0	C6	C7	C7	C7	C6	В	N/A	N/A	N/A	N/A
Cohort 2: Participa	ınt 4													
Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	30	29	30	0	C7	C7	C6	C6	C6	Α	T1	T1	C8	C8
Baseline day 2	31	29	32	0	C8	C7	C7	C7	C7	Α	T1	T1	C8	C8
Post day 7	31	27	32	0	C8	C7	C7	C7	C7	Α	T1	T1	C8	C8
Post day 30	33	28	34	0	C8	C6	C7	C7	C6	Α	Т3	T1	T1	T1
Post day 60	34	28	35	0	T1	C6	C7	C7	C6	Α	T1	T2	T1	T1
Post day 90	33	30	39	0	C8	C8	C8	C7	С7	Α	T1	T2	T1	T1
Post day 180	30	28	43	0	C8	C7	C8	C8	C7	Α	C8	T2	T1	T1

Post day 365

34

28

46

0

C8

C8

T1

C8

Α

C8

T2

T2

T1

T1

Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	32	30	33	0	T1	C7	C7	C7	C7	Α	T2	T2	T1	C7
Baseline day 2	25	27	30	0	C8	C6	C7	C6	C6	Α	T1	C7	T1	C7
Post day 7	29	26	33	0	C8	C5	C7	C7	C5	Α	T1	T1	T1	C7
Post day 30	32	31	35	0	T1	C7	C8	C6	C6	Α	T1	T2	T1	C7
Post day 45 -51	30	27	39	0	C8	C7	T1	C7	C7	Α	T2	C8	T1	C8
Post day 60	30	28	39	0	C8	C8	T1	C7	С7	Α	T1	C8	T1	C8
Post day 90	31	30	41	0	T1	C7	T1	C7	C7	Α	T2	T1	T1	C8
Post day 180	34	32	39	0	T1	T1	C8	C6	C6	Α	T2	T1	T1	C8
Post day 270	ND	ND	43	0	T1	C7	T1	C6	C6	Α	T1	ND	T1	C8
Post day 365	ND	ND	43	0	T1	T2	T1	C8	C8	ND	ND	ND	ND	ND
Cohort 2: Participa	ınt 6	I.	1	· ·	1	u.	•	•	1	II.		1	•	
Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	38	27	21	0	C6	C7	C6	C5	C5	Α	T2	T11	C7	T1
Baseline day 1	35	27	24	0	C6	C5	C6	C6	C5	Α	Т3	Т3	C7	T1
Post day 7	36	35	27	0	T1	T1	C6	C7	C6	Α	T3	T3	C8	C7
Post day 30	36	36	28	0	T1	T1	C7	C7	C7	Α	T3	T3	C7	C8
Post day 60	37	38	34	0	T1	T1	C7	C7	C7	Α	T5	T5	T1	C8
Post day 90	35	34	38	0	T1	C8	C8	C8	C8	Α	T5	ТЗ	C8	T1
Post day 180	33	32	40	0	C8	C8	C8	C8	C8	А	T2	T2	T1	T1
Post day 270	34	31	42	0	T1	C8	C8	C8	C8	Α	T5	T1	T1	T1
Post day 365	35	34	44	0	T1	T1	T1	C8	C8	Α	T1	T1	T1	T1

Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	22	20	14	0	C6	C6	C5	C5	C5	Α	C7	C7	C7	C6
Baseline day 2	22	20	15	0	C6	C6	C5	C5	C5	Α	C7	C7	C7	C6
Post day 7	22	22	17	0	C6	C6	C6	C5	C5	Α	C7	C7	C7	C6
Post day 30	22	21	21	0	C6	C6	C6	C6	C6	Α	C7	C7	C7	C7
Post day 60	22	22	21	0	C6	C6	C6	C6	C6	Α	C7	C7	C7	C7
Post day 90	27	24	21	0	C6	C6	C6	C6	C6	Α	T4	C7	C7	C7
Post day 180	24	23	21	0	C7	C6	C6	C6	C6	Α	T2	C7	C7	C7
Post day 270	24	22	21	0	C6	C6	C6	C6	C6	Α	Т3	C7	C7	C7
Post day 365	24	21	24	0	C6	C6	C6	C6	C6	Α	T4	C7	C8	C7
Cohort 2: Particip	ant 8	•	•			1	-	•	•	•	•		•	•
Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	18	12	9	0	C4	C4	C5	C4	C4	Α	C7	C6	C6	C5
Baseline day 1	17	13	7	0	C4	C4	C5	C4	C4	Α	C7	C6	C6	C5
Post day 7	23	13	7	0	C4	C4	C5	C4	C4	Α	C8	C6	C6	C5
Post day 30	27	21	11	0	C4	C4	C5	C4	C4	В	N/A	N/A	N/A	N/A
Post day 60	25	19	14	0	C6	C4	C6	C5	C4	В	N/A	N/A	N/A	N/A
Post day 90	26	14	12	0	C4	C4	C6	C5	C4	В	N/A	N/A	N/A	N/A
Post day 180	26	17	16	0	C5	C4	C6	C5	C4	В	N/A	N/A	N/A	N/A
Post day 270	30	17	18	0	C4	C4	C6	C6	C4	С	N/A	N/A	N/A	N/A
Post day 365	34	17	18	0	C5	C5	C6	C6	C5	В	N/A	N/A	N/A	N/A

Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	19	20	19	0	C5	C5	C6	C6	C5	Α	C6	C7	C6	C6
Baseline day 2	21	21	20	0	C6	C6	C6	C6	C6	Α	C6	C7	C7	C7
Post day 7	20	20	22	0	C6	C6	C6	C6	C6	Α	C6	C6	C7	C7
Post day 30	22	22	23	0	C6	C6	C6	C6	C6	Α	C7	T1	C7	C7
Post day 45–51	20	20	23	0	C6	C6	C6	C6	C6	Α	C6	C6	C7	C7
Post day 60	21	20	22	0	C6	C6	C6	C6	C6	Α	C7	C6	C7	C7
Post day 90	20	20	26	0	C6	C6	C7	C6	C6	Α	C6	C6	C8	C7
Post day 180	20	20	27	0	C6	C6	C7	C6	C6	Α	C6	C6	C7	C7
Post day 270	20	20	29	0	C6	C6	C7	C7	C6	Α	C6	C6	C8	C7
Post day 365	28	20	27	0	C6	C6	C7	C7	C6	Α	C8	C8	C7	C7
Cohort 3: Participa	ınt 10			1	•	•	· ·	-1	1			1	-1	
Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	21	18	10	0	C5	C5	C5	C5	C5	Α	T1	T1	C6	C6
Baseline day 2	21	18	10	0	C5	C5	C5	C5	C5	Α	T1	T1	C6	C6
Post day 7	22	16	10	0	C5	C5	C5	C5	C5	Α	T1	T1	C6	C6
Post day 30	19	16	10	0	C5	C5	C5	C5	C5	Α	T1	C5	C6	C6
Post day 60	24	18	12	0	C5	C5	C5	C5	C5	Α	T7	T1	C6	C6
Post day 90	20	16	13	0	C4	C4	C5	C5	C4	Α	Т6	C4	C5	C7
Post day 180	25	16	14	0	C4	C4	C5	C5	C4	Α	Т6	T1	C6	C7
Post day 270	18	12	14	0	C4	C4	C5	C6	C4	Α	T10	T1	C6	C6
Post day 365	26	19	18	0	C4	C4	C5	C6	C4	Α	T6	T1	C7	C7

Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	24	22	17	0	C5	C6	C5	C5	C5	Α	T1	T3	C7	C6
Baseline day 2	22	20	17	0	C5	C5	C5	C5	C5	Α	T1	T2	C7	C6
Post day 7	27	22	18	0	C5	C5	C6	C5	C5	В	N/A	N/A	N/A	N/A
Post day 30	35	26	19	0	C6	C5	C7	C5	C5	В	N/A	N/A	N/A	N/A
Post day 60	40	25	20	0	C7	C5	C7	C5	C5	В	N/A	N/A	N/A	N/A
Post day 90	44	22	21	0	C6	C6	C7	C6	C6	В	N/A	N/A	N/A	N/A
Post day 180	42	22	21	0	C6	C6	C7	C6	C6	В	N/A	N/A	N/A	N/A
Post day 270	56	23	25	0	C5	C6	C7	C6	C5	В	N/A	N/A	N/A	N/A
Post day 365	59	26	25	0	C5	C6	C7	C6	C5	В	N/A	N/A	N/A	N/A
Cohort 3: Particip	ant 12	•	•	•	1	1	-	•	•	•	•	•	-	•
Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	22	19	28	0	C6	C5	C7	C7	C5	Α	C7	C7	C7	C7
Baseline day 2	22	20	28	0	C6	C6	C7	C7	C6	Α	C7	C7	C7	C7
Post day 7	24	20	28	0	C6	C6	C7	C7	C6	Α	C7	C7	C7	C7
Post day 30	24	21	29	0	C6	C6	C7	C7	C6	Α	C7	C7	C7	C8
Post day 60	24	21	31	0	C6	C6	C7	C7	C6	Α	C7	C7	C8	C8
Post day 90	24	21	33	0	C6	C6	C7	C8	C6	Α	C7	C7	C8	C8
Post day 180	22	20	37	0	C6	C6	C8	C8	C6	Α	C7	C7	C8	T1
Post day 365	22	20	38	0	C6	C6	C8	C8	C6	Α	C7	C7	C8	T1

Visit	Light	Pin	UEMS	LEMS	Sensory	Sensory	Motor	Motor	NLI	AIS	ZPP	ZPP	ZPP	ZPP
	Touch	Prick			Level Right	Level Left	Level Right	Level Left			Sensory Right	Sensory Left	Motor Right	Motor Left
Screening	25	22	18	0	C7	C6	C6	C6	C6	Α	C7	C8	C6	C6
Baseline day 2	26	21	18	0	C6	C6	C6	C6	C6	Α	C8	C8	C6	C6
Post day 7	29	24	19	0	C7	C7	C6	C6	C6	Α	T2	C8	C6	C7
Post day 30	28	24	22	0	C7	C7	C6	C6	C6	Α	C8	C8	C7	T1
Post day 90	26	24	28	0	C7	C7	C7	C6	C6	Α	C8	C8	T1	T1
Post day 180	28	24	30	0	C7	C7	C7	C7	C7	Α	T1	T1	T1	T1
Post day 270	27	24	31	0	C7	C7	C5	C6	C5	Α	C8	C8	T1	T1
Post day 365	29	25	35	0	C7	C7	C7	C5	C5	Α	T1	C8	T1	T1
Cohort 3: Particip	ant 14	•							•					
Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	23	21	22	0	C6	C5	C6	C6	C5	Α	C7	C7	C7	C7
Baseline day 2	24	22	22	0	C6	C6	C6	C6	C6	Α	C7	C7	C7	C7
Post day 7	22	22	24	0	C6	C6	C7	C6	C6	Α	C7	C7	C7	C7
Post day 30	23	22	24	0	C6	C7	C7	C6	C6	Α	C7	C7	C7	C7
Post day 60	23	21	24	0	C6	C6	C7	C6	C6	Α	C7	C7	C7	C7
Post day 90	23	21	24	0	C6	C6	C7	C6	C6	Α	C7	C7	C7	C7
Post day 180	24	21	26	0	C6	C6	C7	C6	C6	Α	C7	C7	C7	C7
Post day 270	24	21	26	0	C6	C6	C7	C6	C6	Α	C7	C7	C7	C7
Post day 365	24	21	28	0	C6	C6	C7	C7	C6	Α	C7	C7	C8	C7

Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	18	12	7	0	C4	C4	C5	C5	C4	Α	C5	C6	C5	C5
Baseline day 2	18	14	7	0	C4	C5	C5	C5	C4	Α	C5	C6	C5	C5
Post day 7	20	16	7	0	C5	C5	C5	C5	C5	Α	C5	T1	C5	C5
Post day 30	18	16	10	0	C4	C4	C5	C5	C4	Α	C5	T3	C6	C6
Post day 60	18	16	9	0	C5	C5	C5	C5	C5	Α	C5	C7	C5	C5
Post day 90	19	15	10	0	C4	C4	C5	C5	C4	Α	C5	T1	C5	C5
Post day 180	18	14	10	0	C4	C4	C5	C5	C4	Α	C5	T2	C5	C5
Post day 270	21	13	8	0	C4	C4	C5	C5	C4	Α	C7	T5	C5	C5
Post day 365	23	15	13	0	C5	C4	C5	C6	C4	Α	C6	T5	C5	C6
Cohort 4: Participe	ant 16	I.	•	1	1	u .	•	•	1			1	•	
Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	ND	ND	18	0	C7	C6	C6	C5	C5	Α	S3	C7	C7	C7
Baseline day 2	ND	ND	18	0	C6	C6	C6	C5	C5	В	N/A	N/A	N/A	N/A
Post day 7	23	22	19	0	C6	C6	C6	C6	C6	Α	C7	C7	C7	C7
Post day 30	23	22	26	0	C7	C6	C7	C7	C6	Α	C7	C7	C7	C7
Post day 60	22	24	26	0	C6	C6	C7	C7	C6	Α	C7	C7	C7	C7
Post day 90	24	25	27	0	C7	C7	C7	C7	C7	Α	C7	C8	C7	C7
Post day 180	23	21	29	0	C6	C6	C7	C7	C6	Α	C7	C7	C7	C7
Post day 270	24	22	28	0	C6	C6	C7	C7	C6	Α	C7	C7	C7	C7
Post day 365	24	22	29	0	C6	C6	C7	C7	C6	Α	C7	C7	C7	C7

Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	28	23	29	0	C5	C7	C7	C7	C5	В	N/A	N/A	N/A	N/A
Baseline day 2	27	24	30	0	C6	C6	C7	C7	C6	В	N/A	N/A	N/A	N/A
Post day 7	26	24	30	0	C6	C6	C7	C7	C6	В	N/A	N/A	N/A	N/A
Post day 30	29	26	30	0	C6	C6	C7	C7	C6	В	N/A	N/A	N/A	N/A
Post day 60	30	28	31	0	C6	C7	C7	C7	C6	В	N/A	N/A	N/A	N/A
Post day 90	30	26	33	0	C7	C7	C7	C7	C7	В	N/A	N/A	N/A	N/A
Post day 180	31	25	33	0	C6	C7	C7	C7	C6	В	N/A	N/A	N/A	N/A
Post day 270	31	28	34	0	C6	C8	C7	C7	C6	В	N/A	N/A	N/A	N/A
Post day 365	29	27	33	0	C7	C7	C7	C7	C7	В	N/A	N/A	N/A	N/A
Cohort 4: Particip	ant 18										1			-
Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	17	15	15	0	C5	C4	C5	C6	C4	В	N/A	N/A	N/A	N/A
Baseline day 2	21	12	12	0	C4	C4	C5	C5	C4	В	N/A	N/A	N/A	N/A
Post day 7	25	16	14	0	C4	C5	C5	C6	C4	В	N/A	N/A	N/A	N/A
Post day 30	19	14	13	0	C4	C5	C5	C5	C4	В	N/A	N/A	N/A	N/A
Post day 60	21	17	15	0	C4	C5	C5	C6	C4	С	N/A	N/A	N/A	N/A
Post day 90	24	14	17	2	C4	C5	C5	C6	C4	С	N/A	N/A	N/A	N/A
Post day 180	21	14	16	4	C4	C5	C5	C6	C4	С	N/A	N/A	N/A	N/A
Post day 270	20	17	16	3	C5	C5	C5	C6	C5	С	N/A	N/A	N/A	N/A
Post day 365	21	16	16	7	C5	C5	C5	C6	C5	С	N/A	N/A	N/A	N/A

Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	23	24	24	0	C6	C6	C7	C6	C6	В	N/A	N/A	N/A	N/A
Baseline day 2	30	24	23	0	C6	C6	C6	C6	C6	В	N/A	N/A	N/A	N/A
Post day 7	27	24	26	0	C6	C6	C7	C6	C6	В	N/A	N/A	N/A	N/A
Post day 30	31	24	28	0	C6	C6	C7	C7	C6	В	N/A	N/A	N/A	N/A
Post day 60	29	22	27	0	C6	C6	C7	C6	C6	В	N/A	N/A	N/A	N/A
Post day 90	42	26	29	0	C6	6	C7	C7	C6	С	N/A	N/A	N/A	N/A
Post day 180	42	26	31	0	C6	C6	C7	C7	C6	С	N/A	N/A	N/A	N/A
Post day 270	52	25	31	0	C6	C6	C7	C7	C6	С	N/A	N/A	N/A	N/A
Post day 365	47	25	32	0	C6	C6	C7	C7	C6	С	N/A	N/A	N/A	N/A
Cohort 4: Particip	ant 20		•			1	•	•	•	•			-	
Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	27	31	20	0	C7	C7	C6	C6	C6	В	N/A	N/A	N/A	N/A
Baseline day 2	32	32	22	0	C7	C6	C7	C6	C6	В	N/A	N/A	N/A	N/A
Post day 7	36	28	23	0	T1	C7	C7	C6	C6	В	N/A	N/A	N/A	N/A
Post day 30	48	32	24	0	C7	T1	C7	C6	C6	В	N/A	N/A	N/A	N/A
Post day 60	57	28	26	0	C8	C7	C7	C6	C6	В	N/A	N/A	N/A	N/A
Post day 90	42	30	27	0	C8	C7	C7	C7	<b>C</b> 7	В	N/A	N/A	N/A	N/A
Post day 180	43	31	28	0	C7	C7	C7	C7	С7	В	N/A	N/A	N/A	N/A
Post day 270	51	31	30	0	C7	C7	C7	C7	C7	В	N/A	N/A	N/A	N/A
Post day 365	44	30	30	0	C8	C8	C7	C7	C7	В	N/A	N/A	N/A	N/A

Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	89	32	25	0	ND	ND	ND	ND	ND	ND	N/A	N/A	N/A	N/A
Screening	ND	ND	ND	ND	C6	C7	C7	C6	C6	В	N/A	N/A	N/A	N/A
Baseline day 2	43	45	25	0	C6	C6	C7	C6	C6	В	N/A	N/A	N/A	N/A
Post day 7	94	45	25	0	C7	C8	C7	C6	C6	В	N/A	N/A	N/A	N/A
Post day 30	107	52	27	0	T1	C6	C7	C7	C6	В	N/A	N/A	N/A	N/A
Post day 60	108	69	27	0	C8	C7	C7	C7	C7	С	N/A	N/A	N/A	N/A
Post day 90	111	66	27	0	Т6	T7	C7	C7	С7	С	N/A	N/A	N/A	N/A
Post day 180	112	65	26	0	T5	T6	C7	C7	C7	С	N/A	N/A	N/A	N/A
Post day 270	107	57	28	1	T4	T6	C7	C7	C7	С	N/A	N/A	N/A	N/A
Post day 365	109	50	30	1	C7	C6	C7	C7	C6	С	N/A	N/A	N/A	N/A
Cohort 5: Particip	ant 22	I	1	-11	1	1	1	II.	·	l		1		
Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	66	24	27	0	C6	C6	C6	C7	C6	В	N/A	N/A	N/A	N/A
Baseline day 2	55	23	25	0	C5	C6	C6	C7	C5	В	N/A	N/A	N/A	N/A
Post day 7	59	24	26	0	C5	C6	C6	C7	C5	В	N/A	N/A	N/A	N/A
Post day 30	62	23	26	0	C5	C6	C6	C7	C5	В	N/A	N/A	N/A	N/A
Post day 60	78	23	27	0	C6	C6	C7	C7	C6	В	N/A	N/A	N/A	N/A
Post day 90	69	25	29	0	C6	C6	C7	C7	C6	В	N/A	N/A	N/A	N/A
Post day 180	79	29	29	0	C6	C6	C7	C7	C6	В	N/A	N/A	N/A	N/A
Post day 270	67	28	29	0	C6	C6	C7	C7	C6	В	N/A	N/A	N/A	N/A
Post day 365	74	26	29	0	C6	C6	C7	C7	C6	В	N/A	N/A	N/A	N/A

Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	15	12	2	0	C4	C4	C4	C4	C4	В	N/A	N/A	N/A	N/A
Baseline day 2	13	12	2	0	C4	C4	C4	C4	C4	В	N/A	N/A	N/A	N/A
Post day 7	12	12	2	0	C4	C4	C4	C4	C4	В	N/A	N/A	N/A	N/A
Post day 30	16	12	2	0	C4	C4	C4	C4	C4	В	N/A	N/A	N/A	N/A
Post day 60	18	12	4	0	C4	C4	C4	C4	C4	В	N/A	N/A	N/A	N/A
Post day 90	21	12	4	0	C4	C4	C4	C4	C4	В	N/A	N/A	N/A	N/A
Post day 180	20	12	6	0	C4	C4	C5	C5	C4	В	N/A	N/A	N/A	N/A
Post day 270	21	12	7	0	C4	C4	C5	C5	C4	В	N/A	N/A	N/A	N/A
Post day 365	20	12	7	0	C4	C4	C5	C4	C4	С	N/A	N/A	N/A	N/A
Cohort 5: Particip	ant 24		I.		I	I	1	· L	ı	1	I.	l	1	ı
Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	79	22	12	0	C6	C5	C5	C5	C5	В	N/A	N/A	N/A	N/A
Baseline day 2	63	18	12	0	C6	C5	C5	C5	C5	В	N/A	N/A	N/A	N/A
Post day 7	67	19	14	0	C6	C5	C6	C5	C5	В	N/A	N/A	N/A	N/A
Post day 30	66	19	15	0	C6	C5	C6	C5	C5	В	N/A	N/A	N/A	N/A
Post day 60	65	18	19	0	C5	C5	C6	C6	C5	В	N/A	N/A	N/A	N/A
Post day 90	71	19	20	0	C6	C5	C6	C6	C5	В	N/A	N/A	N/A	N/A
Post day 180	70	19	20	0	C6	C5	C6	C6	C5	В	N/A	N/A	N/A	N/A
Post day 270	67	20	21	0	C6	C5	C6	C6	C5	В	N/A	N/A	N/A	N/A
Post day 365	70	18	21	0	C5	C5	C6	C6	C5	В	N/A	N/A	N/A	N/A

Cohort 5: Participal Visit	Light Touch	Pin Prick	UEMS	LEMS	Sensory Level Right	Sensory Level Left	Motor Level Right	Motor Level Left	NLI	AIS	ZPP Sensory Right	ZPP Sensory Left	ZPP Motor Right	ZPP Motor Left
Screening	53	31	29	0	C8	C7	C7	C7	C7	В	N/A	N/A	N/A	N/A
Baseline day 2	44	42	29	0	C8	C8	C7	C6	C6	В	N/A	N/A	N/A	N/A
Post day 7	50	54	31	0	T1	C8	C7	C7	C7	В	N/A	N/A	N/A	N/A
Post day 30	81	37	33	0	T1	C8	C7	C7	C7	С	N/A	N/A	N/A	N/A
Post day 60	62	40	30	1	T1	C8	C7	C7	C7	С	N/A	N/A	N/A	N/A
Post day 90	63	42	33	1	C8	C8	C7	C7	C7	С	N/A	N/A	N/A	N/A
Post day 180	68	41	36	1	T1	C8	C8	C7	C7	С	N/A	N/A	N/A	N/A
Post day 270	88	90	37	2	T1	C8	C8	C6	C6	С	N/A	N/A	N/A	N/A
Post day 365	97	80	38	2	T1	C8	C8	C8	C8	С	N/A	N/A	N/A	N/A

ND – Not Documented, N/A – Not Applicable; UEMS – Upper Extremity Motor Score; LEMS – Lower Extremity Motor Score; NLI- Neurological Level of Injury; AIS – The American Spinal Injury Association (ASIA) impairment scale; ZPP – Zone of Partial Preservation