Seneca Biopharma (NASDAQ: SNCA)

Partnering Opportunities for CNS Diseases

Summary of Opportunity

Assets: first-in-class stem cell-based treatments for neurological diseases

Clinical Stage: ALS and Chronic Stroke (Phase II), Spinal Cord Injury (Phase I)

Seeking Partnership & Business Development Opportunities

Allogeneic

Off the shelf
Cell Therapy

ALS & SCI

Stroke

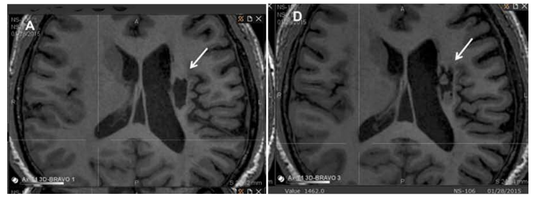
Seneca Biopharma: Neural Stem Cell Platform

Product

- Allogeneic human neural stem cells: long-lasting therapeutic, require temporary immune suppression
- Committed neuronal lineage; CNS restricted; differentiate into functional neurons and glia
- Stable, off-the-shelf product & manufacturing is scalable for commercialization

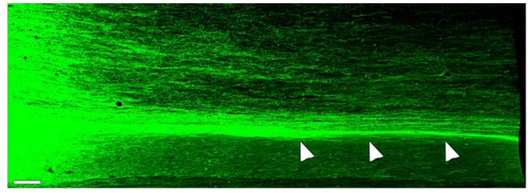
Mechanism of action: functional integration of human neural cells into host CNS

- Neurotrophic protection and support
- Regeneration of damaged neural tissue



(A) Regeneration of tissue adjacent to infarct site at 24 months after transplantation in human stroke subjects

- Neuronal bridge across damaged circuits



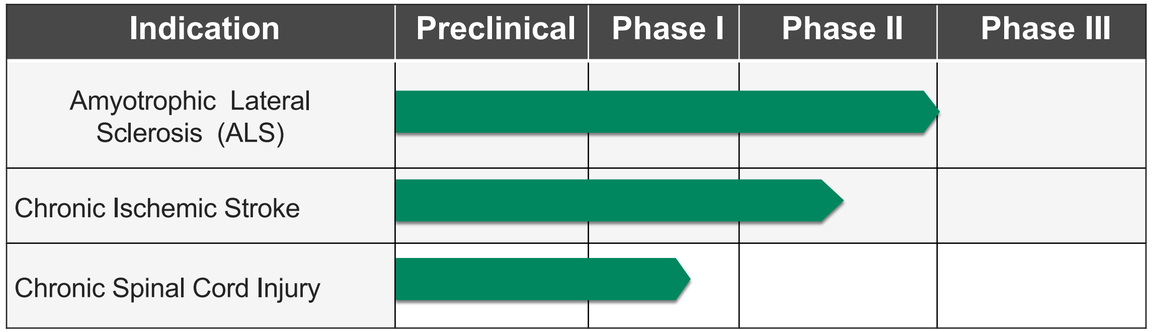
(B) Graft-derived neurons integrate, extend and form synaptic connections with healthy host neurons in non-human primate model

Intellectual Property: 76 issued and pending patents globally (13 in U.S.) providing broad coverage

- Methods of culturing human neural stem cells and treating neurodegenerative diseases
- Exclusive licensee of patents covering devices used to administer the Company's stem cell therapies

NSI-566: Clinical Catalyst Across Three Indications

MOA: Regeneration, Circuit Bridging and Neuroprotection



FDA meeting, March 2020

Controlled study readout: 3Q 2020

Phase I study completed: 4Q 2019

ALS: Phase I & II (n=30)—Demonstrated preliminary clinical benefit against historical data

- Pivotal study in the US planned
- Seeking partnerships

Chronic Stroke: Phase I & II (n=31)—Phase I trial demonstrated safety and preliminary clinical benefit improvement in motor function from baseline levels

- Pursuing partnership in China/Asia-Pacific

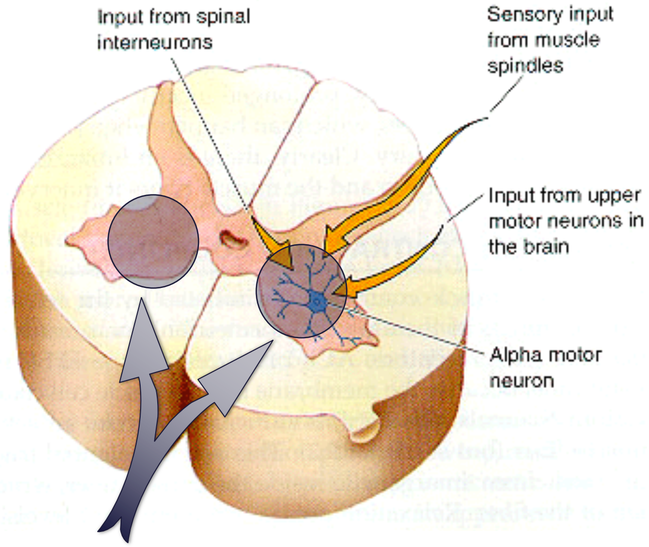
Chronic Spinal Cord Injury: Phase I (n=7)—Gain of some voluntary muscle below injury

- Phase I completed Q4 2019

Newly Diagnosed ALS Population: $1B+ Opportunity for NSI-566

ALS market opportunity

- 5,600 ALS patients newly diagnosed in United States annually & larger patient population in China
- 50% increase in developing World expected 2015-2040
- Limited treatment options with poor efficacy
- Median time from onset of symptoms to death is 3 years



Transplantation into ventral horn (adjacent to motor neurons)

US NSI-566 addressable market

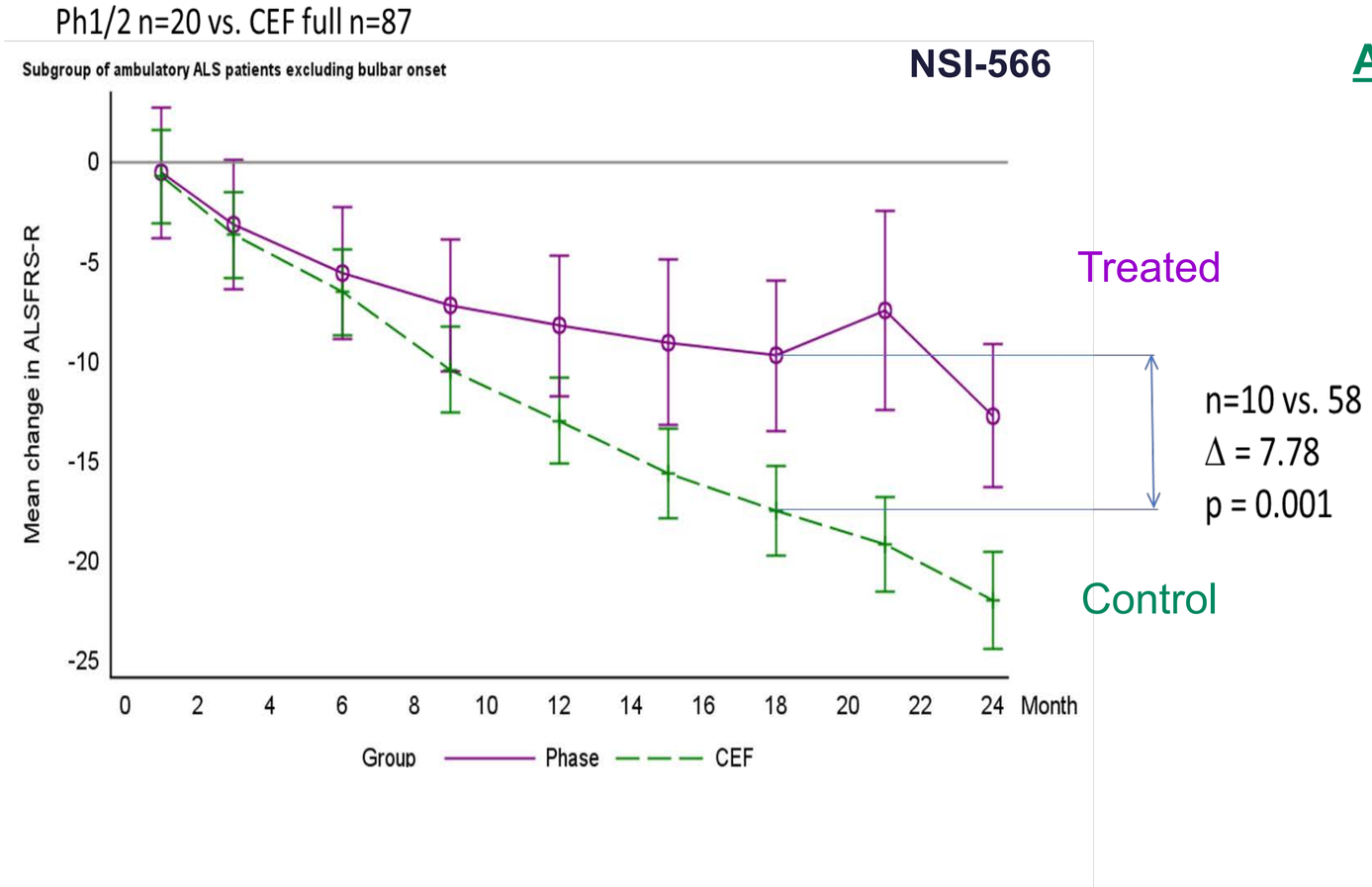
- ~65% of newly diagnosed patients likely eligible for NSI-566
- Pricing from $300K to $500K, similar to launched cell therapies
  (Assumption is pricing will be reduced in China)

Initial launch at major neurosurgery centers attached to major ALS centers

- US surgical capacity at such centers sufficient to treat 4,500 patients per year

Sources: ALS Association, Lancet. 2016 Oct 8; 388(10053): 1459–1544. US neurologist neurosurgeon and payer interviews conducted by Bionest research

NSI-566 treatment of ALS – Phase I/II Ambulatory Subjects: Indication of Efficacy Compared to Historical Controls



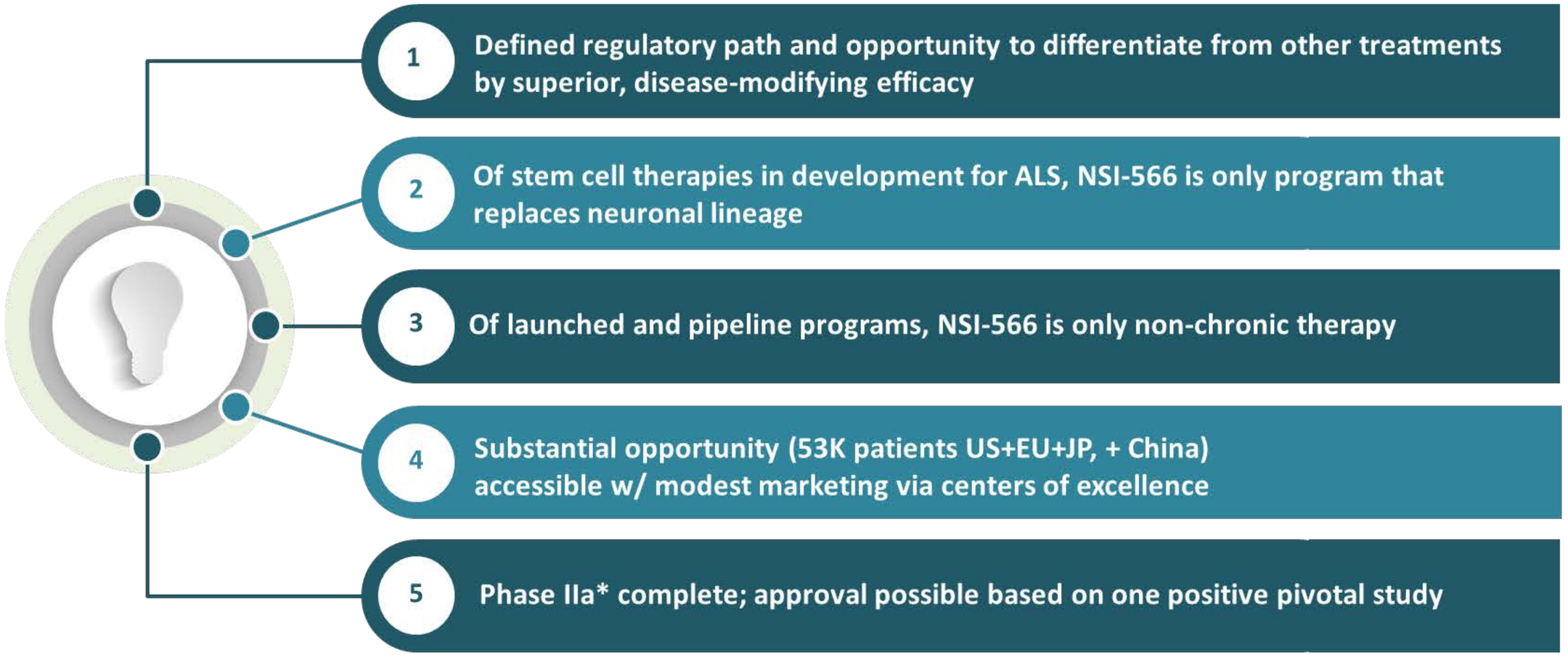
ALS Phase I & II (ambulatory, non-bulbar patients):

- **NSI-566 treated patients showed clinical benefit compared to historical data (untreated controls)**
- **Autopsies of deceased trial participants revealed *persistent graft* in all patients evaluated: *up to 2.5 yrs. after treatment AND 1.75 yrs. after immunosuppression ended***

Edaravone is the only FDA approved treatment for ALS in the past 20 years:

- Reduced decline of ALSFRS by 2.5 pts over 6 mo.
- Multiple cycles of IV infusion required

ALS is an Attractive Orphan Opportunity where NSI-566 would be a Differentiated Offering



*open-label, no control group. Efficacy signal identified when compared to historical controls.

Chronic Ischemic Stroke:
Commercially Attractive Indication with Few Competitors

Substantial population size:

- The most common cause of disability in the United States
- Estimated survivor population of 7MM (US) and 17MM (Worldwide)
- Prevalent cases will grow from 5.3 to 8.0 million in China over 10 yrs.

High unmet need:

- No restorative therapy for chronic stroke
- Focus is on rehabilitation

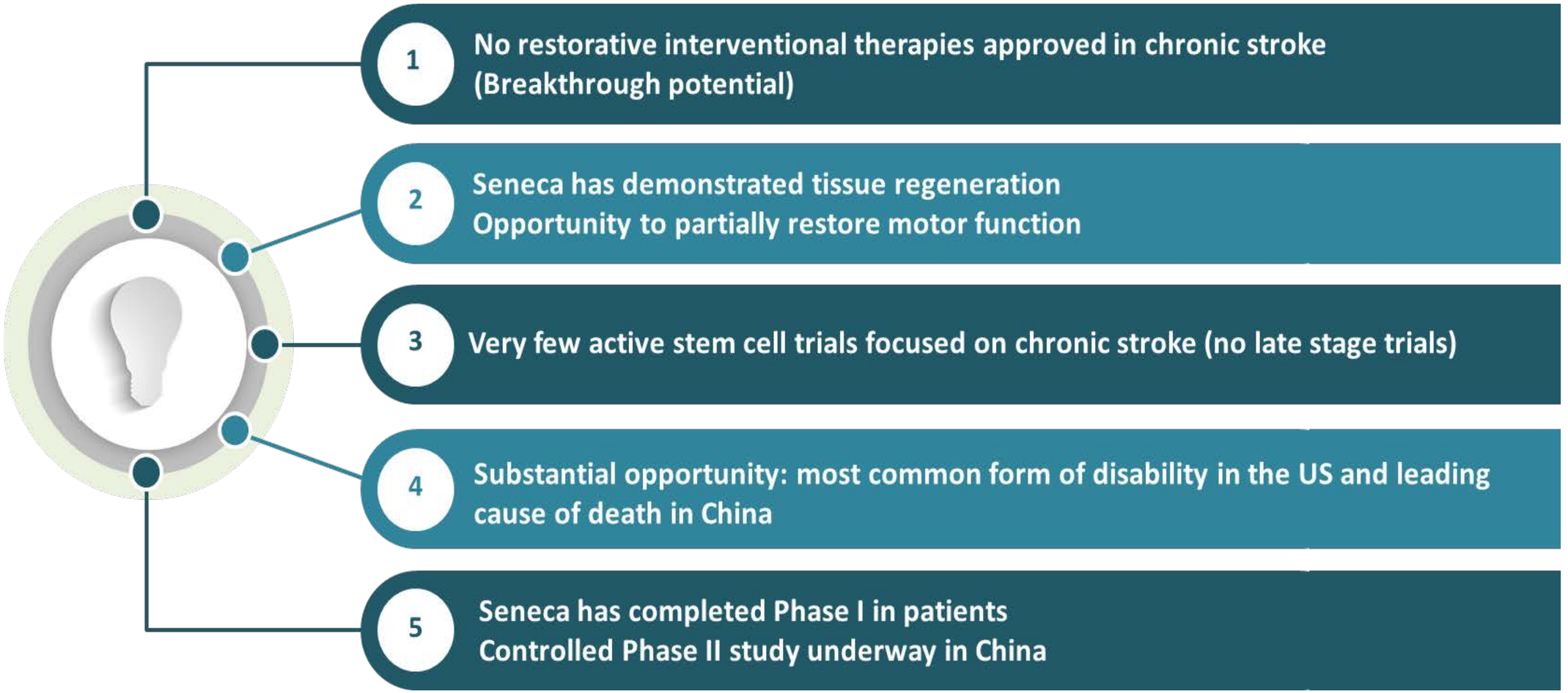
Relatively weak competitive drug pipeline:

- Few competitors
- No advanced trials for chronic ischemic stroke
- Significant focus on acute stage for stem cells.

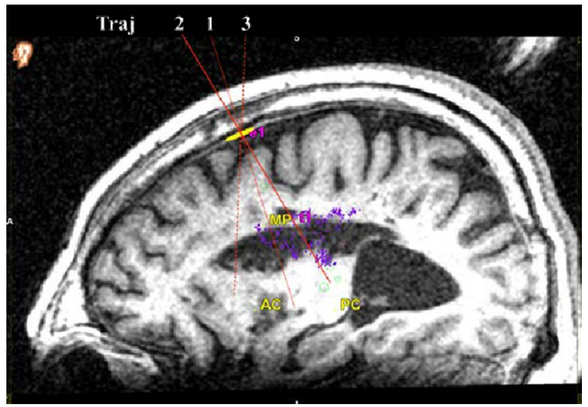
NSI-566 market opportunity:

- Conservative estimate of eligible patients is 175K
- 10% market penetration (15-20,000 patients)

Chronic Stroke: Very Large Opportunity, NSI-566's Potential to Partially Restore Motor Function where No Interventional Therapy Currently Exists



NSI-566 Chronic Stroke: Phase I Data at 12/24 months

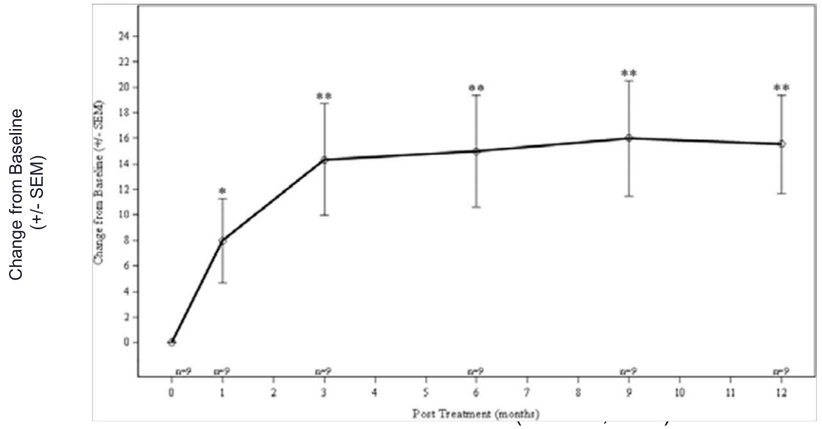


Stem Cells Transl Med. 2019 Oct; 8(10): 999–1007.

One-time administration of 12-72 million cells:

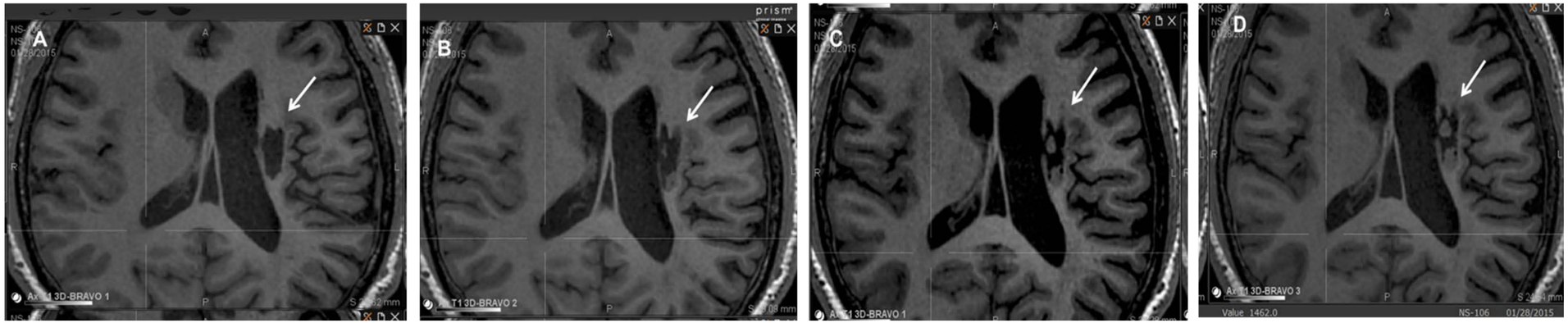
- Direct injections into the lesion area of brain
- 4 weeks of immunosuppression
- Evidence of long-term graft survival (≥ 2 yrs)
- Evidence for tissue regeneration

Fugl-Meyer Motor Score



Meaningful Clinical Benefits:
>10 points of improvement in Fugl-Meyer Motor Score

Baseline **6 Months** **12 Months** **24 Months**



Engraftment over 24 Months: NSI-566 produce neurotrophic environment that regenerates tissue at infarct site

Chronic Spinal Cord Injury: 3rd Indication Presents Upside Potential

Significant global market opportunity

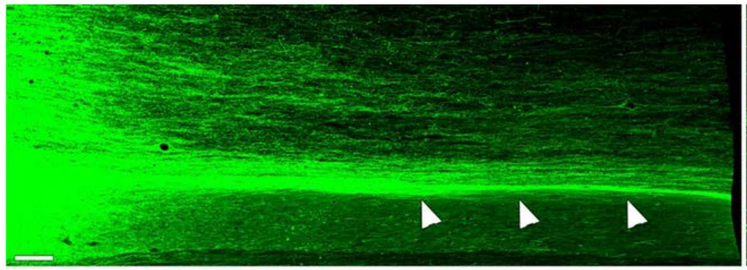
- 17K incidences in United States annually and between 250K-500K globally
- Managed symptomatically with minimal improvement
- No therapeutic to restore neurological function

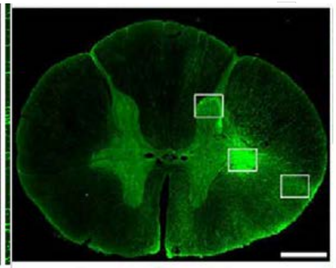
NSI-566 in Phase 1 for cSCI

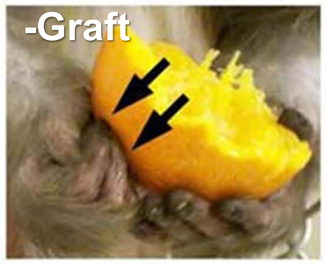
- Major upside potential given non-dilutive funding strategy in this indication to date
- Trial completed Q4 2019
- Therapy was well-tolerated
- Some patients showed evidence of improvements in neurological function
  (Curtis et al. (2018) Cell Stem Cell 22, 941-950)

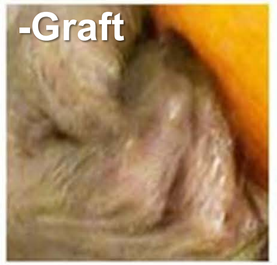
SCI: Effect of NSI-566 in Monkey Model and Potential Benefit in Humans

NSI-566 has a restorative effect in a primate model of subacute SCI:



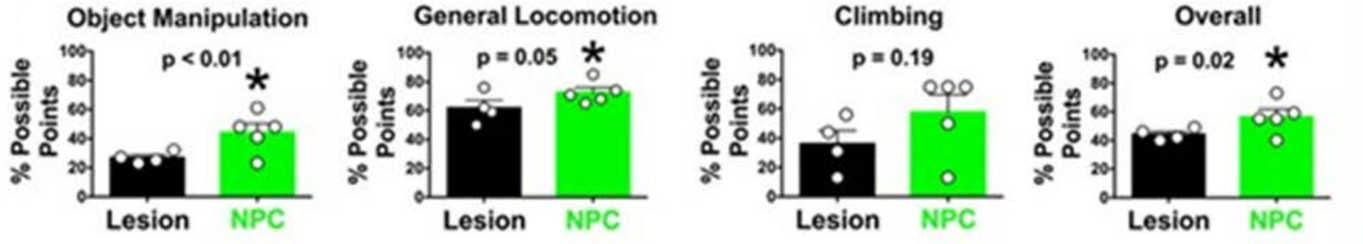






Graft-derived neurons integrate, extend long processes and form synaptic connections w/ healthy host neurons

Grafts confer improvement in motor function



Rosenzweig et al., Nat Med. 2018 Feb 26. doi: 10.1038/nm.4502

NSI-566 shows potential for clinical benefit in Phase I trials:

2 of 4 subjects in first cohort experienced stable improvements in neurological level of injury (ISNCSCI)

Improvement detected at 6 months after surgery, consistent with MOA

Subject	Baseline	6 months	12 months	18 months
001	T8	T10	T10	T10
006	T7	-	T7	T7
008	T2	-	T2	-
010	T5	T6	T6	T6

Conclusions: Promising Partnering Opportunity

- Clinical stage portfolio of novel allogeneic stem cell therapies
- CNS diseases: ALS, Chronic Stroke, Chronic Spinal Cord Injury
- Strong fundamental science and technology platform, significant development to date
- Existing Global academic partnerships & footprint
- Several upcoming clinical milestones

Initiating partnership discussions with several interested parties

Open to various structures: License/co-development, asset sale, or JV