Human Spinal Cord Modulation System (HSCMS)
Pre IDE Meeting
January 17th, 2013
Attendees

• Matthew Howard, III, MD – Professor and Head, Department of Neurosurgery, University of Iowa
• Timothy Brennan MD, PhD – Professor and Vice Chairman, Department of Anesthesiology, University of Iowa
• George T. Gillies, PhD – Research Professor, Department of Mechanical and Aerospace Engineering, University of Virginia
• Randy Nelson – Founder and President, Evergreen Medical Technologies
• Daniel O’Connell MBA – NeuroVentures Inc.
• Roy Martin, DVM – Chief Medical Officer, NAMSA – Integra Division
• Noelle Sutton – Principal Regulatory Consultant, NAMSA
• Jennifer Mischke, MPH – Director of Biostatistics, NAMSA
Spinal Cord Stimulation (SCS) History

1960’s - advent of human SCS treatment
Spinal Cord Stimulation (SCS) History

• Initially **intra**-dural and **extra**-dural device placement

• **Intra**-dural devices abandoned
  – Tethering between the spinal cord and dura
  – Increased risk of cerebrospinal fluid (CSF) leak
  – Poor control of electrode location relative to targeted sub-region of the spinal cord
Extra-Dural Spinal Cord Stimulators
(all current devices)
Key Anatomical Considerations
Derived from:

Functional Access to Spinal Cord Pathways
Functional Access to Spinal Cord Pathways Using Current SCS Devices

< 1 %
Poor Activation Pattern = Suboptimal Results

Percentage of patients reporting > 50% pain relief


- **53 %** (North RB et al. Spine 30:1412-1418, 2005)

- **48 %** (Kumar KA et al. Pain 132:179-188, 2007)
Spinal Cord Pathway Access
Current SCS vs. HSCMS
(* including penetrating electrode variants)
Direct Spinal Cord Stimulation
Neurosurgical procedures for pain: Relative risk profiles

- Standard spinal cord stimulator
- Spinal fusion (simple—1 level)
- Dorsal root entry zone
- Cordotomy
- Spinal fusion (complex multi-level)

**RELATIVE RISK RANGE**

**HSCMS?**
Background Information

• HSCMS is a thin, soft electrode-bearing array placed directly on the dorsal surface of the spinal cord.

• Designed to address major unmet public health need (medically refractory neuropathic pain affecting the back and legs).

• The HSCMS addresses a fundamental limitation of all existing human spinal cord modulation devices: an inability to deliver effective treatment, safely to a large population of chronic patients by selectively targeting locations within the human spinal cord parenchyma.
Background Information

Computational Results from Early Attempts at Finite Element Modeling

Human Spinal Cord Neural Pathways
HSCMS markedly increases the number of axons that are stimulated, resulting in a greater therapeutic effect.
Device Description

- The HSCMS is a thin, soft electrode-bearing array that is placed directly on the dorsal surface of the spinal cord.

- The HSCMS is designed to position electrodes directly on the surface of the spinal cord, and in the future within the parenchyma of the spinal cord, thus allowing safe and effective access to all regions of the spinal cord.

- The electrode-bearing portion of the device is gently held in place by flexible lead segments.
Device Components

- Electrode bearing portion
- ‘Inside loop’ malleable lead segments
- Attachment arms
- Dural cuff
- Titanium strap
- Stimulus delivery unit
GLP Study Design

Enrollment
- N=12
- Healthy
- CBC/profile
- Neuro exam
- Daily Observations
- Adverse Events

Implantation
- Procedure CRF
- Implant Radiology
- Baseline electrical performance

1-month Follow-up
- N=6
- Daily Observations
- Adverse Events
- Weekly neurologic exams
- Monthly impedance checks

Terminal Fluoroscopy
- Sacrifice
- Necropsy
- Histology
- Safety
- Effects of implantation
- Tox

3-month follow-up
- N=6
- Daily Observations
- Adverse Events

Terminal Fluoroscopy
- Sacrifice
- Necropsy
- Histology
- Safety
- Effects of implantation
- Tox
HSCMS Pilot Clinical Study Design

2 sites
12 patients
6-month endpoint outcomes assessment

Primary Objective
• To describe the safety and efficacy of HSCMS in patients that have received conventional treatments and have inadequate pain relief.

Design
• Prospective, single arm
• Screening, implant, 2 Week, Month 1, Month 3 and Month 6 visits

Endpoints
• Primary Safety: All serious, device related adverse events
• Primary Efficacy: Visual analog scale (VAS) for back pain and VAS for leg pain
• Secondary endpoints: Quality of life assessments and work status
• Additional endpoints: All adverse events (type, relationship, severity, seriousness)