Midterm Results Of The ROADSTER Pivotal Trial Of The Silk Road System For TransCarotid Artery Stent Revascularization (TCAR) In High Risk Patients With Carotid Stenosis

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On behalf of the ROADSTER Investigators

Acknowledgement

National Co-Principal Investigators
ROADSTER 1 Pivotal/Continued Access

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Acknowledgement

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ROADSTER 1 Long Term Follow-Up

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Acknowledgement

Disclosures

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Principal Investigator at Johns Hopkins:
1. CREST
2. ACT I
3. CAPTURE II
4. CHOICE
5. FREEDOM
6. ROADSTER
7. SAPHIRE W
8. ROADSTER II
9. CREST II
10. CREST Companion Study
11. ROADSTER Long-Term Follow up Study

TCAR: Less invasive, surgically inspired alternative to CEA

ENROUTE® Transcarotid Neuroprotection & Stent System

ROADSTER 1: Study Overview

DESIGN: Prospective, multi-center study

• Primary Endpoint: 5/0/MI at 30 days

OBJECTIVE: Evaluate safety and efficacy of the ENROUTE Transcarotid Neuroprotection System

• Direct carotid access
• High rate flow reversal
• All FDA-approved carotid stents
• Symptomatic ≥ 50% stenosis
• Asymptomatic ≥ 70% stenosis

NATIONAL CO-PRINCIPAL INVESTIGATORS:
• Richard Cambria, MD
  Massachusetts General Hospital
• Christopher Kwolek, MD
  Massachusetts General Hospital

INDEPENDENT REVIEW: CEC, DSMB, Core labs (angiography, duplex, ultrasound, cardiology)
Physiologic HSR Inclusion
- Severe cardiac disease; severe COPD; chronic renal insufficiency
- Age ≥75

Anatomic HSR Inclusion
- Contralateral occlusion; bilateral or high or tandem stenosis
- Restenosis post-CEA
- Hostile neck
- Irradiation
- Radial neck dissection
- General spine immobility

Other
- 1 year life expectancy

Exclusion: Common to CAS
- AFib; recent valve or MI; bleeding
- Evolving stroke; neuro disorders
- Occlusion; ostial CCA or intracranial stenosis; string sign; previous stent

Exclusion: Transcarotid
- CCA disease at entry site
- ≤1cm stenosis @ bifurcation

ROADSTER 1:
Key Inclusion/Exclusion

ROADSTER 1*:
30-Day Outcomes on Par with CEA

Today's Meeting:
ROADSTER 1:
Long-Term Follow-Up (LTFU)

Objective:
To evaluate the incidence of ipsilateral stroke at 31 to 365 days post-procedure for patients treated with the ENROUTE Neuroprotection System in the ROADSTER 1 Study

Assessment Phases:
- Phase One:
  Patients treated per protocol in the Pivotal Phase of ROADSTER 1 are evaluated retrospectively by chart review
- Phase Two:
  Patients treated per protocol in the Continued Access Phase of ROADSTER 1 are prospectively assessed with a 12-month follow-up visit (NIHSS)

ROADSTER 1:
Baseline Characteristics

ROADSTER 1:
Ipsilateral Stroke Day 31-365

Follow-Up Duration in Years (n=87)
- Median: 1.3
- Range: 0.5 – 2.9
Historical Ipsilateral Stroke Rates (Day 31-365)

<table>
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<td>N</td>
<td>87</td>
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<td>465</td>
<td>165</td>
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<td>78</td>
<td>154</td>
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<tr>
<td>Ipsilateral Stroke</td>
<td>1.8%</td>
<td>1.7%</td>
<td>0.8%</td>
<td>2.2%</td>
<td>1.2%</td>
<td>1.1%</td>
<td>0.7%</td>
<td>1.1%</td>
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Conclusions: **ROADSTER 1** Long Term Follow-Up

- The ipsilateral stroke rate is **1.1%** at Day 31-365 for high surgical risk patients treated in the pivotal phase of **ROADSTER 1** (interim analysis).
- **TCAR** does not impact the long term durability of any FDA-approved carotid artery stent platform.
- Long term outcomes with **TCAR** in high surgical risk patients are **comparable to CEA in standard surgical patients**.
- The periprocedural stroke rate with **TCAR** (1.4%) remains **the lowest reported in any prospective trial of carotid revascularization**.