Extreme SFA Lesions: DETOUR I 12-Month Results in Lesions ≥30cm

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Disclosure

Speaker name: Sean Lyden MD

I have the following potential conflicts of interest to report:

☒ Consulting Phillips, Endologix, Shockwave, Abbott, BSC, Spectranetics, Medtronic, PQ Bypass

Employment in industry: None

Stockholder of a healthcare company: None

Owner of a healthcare company: None

☒ Other(s) VIVA Physicians Inc 501c3 Board Member
20 Years into the Endo Revolution, Patients with Long-Segment SFA Disease Have Limited Treatment Options

Live with debilitating, lifestyle-limiting pain

50% failure rate by 12M, assuming patient has access to expert care
Existing Endovascular Devices Designed for Shorter Lesions, Deliver Sub-Optimal Results in Long Lesions

Further confounded by complex morphologies: CTO, Ca++, ISR

LIMITED TREATMENT OPTIONS

~50% Patency at 12M
**DETOUR I Study Design**

**DESIGN**
Prospective, single-arm, multi-center clinical evaluation of the DETOUR™ System and Procedure for Percutaneous Bypass

**INCLUSION CRITERIA**
De novo, CTO, or ISR femoropopliteal lesion ≥10 cm

**INDEPENDENT REVIEW**
Core Lab (DUS, CT, Angio) by Cleveland Clinic; Clinical Events Committee by Syntactx

- **77 Patients/ 81 Limbs Enrolled**
- **Follow up at 30D, 3M, 6M, 12M, 18M, 24M, 36M**

**Primary Safety:**
MAE at 30D (Death, TLR, Amputation)

**Primary Efficacy:**
Primary Patency at 6M (PSVR ≤2.5) with no TLR

**STATUS:** CE Mark granted February 2017
DETOUR I Lesion Distribution by Length

Lesion Length (mm)

97.5% ≥25 cm
86.4% ≥30 cm
71.6% ≥35 cm
33.1% ≥40 cm

Lesion Distribution N=81
## Baseline Characteristics

### Extreme (≥30 cm) Lesions

### Clinical Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N=67 Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male Gender</td>
<td>88.1% (59/67)</td>
</tr>
<tr>
<td>Age, Years</td>
<td>65.1± 7.3</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>26.9% (18/67)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>86.6% (58/67)</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>40.3% (27/67)</td>
</tr>
<tr>
<td>History of CAD or MI</td>
<td>49.3% (33/67)</td>
</tr>
<tr>
<td>History of Smoking</td>
<td>77.6% (52/67)</td>
</tr>
<tr>
<td>Previous Peripheral Intervention</td>
<td>31.3% (21/67)</td>
</tr>
<tr>
<td>ABI</td>
<td>0.64 ± 0.18</td>
</tr>
<tr>
<td>Rutherford 3</td>
<td>94.0% (63/67)</td>
</tr>
<tr>
<td>Rutherford 4-5</td>
<td>6.0% (4/67)</td>
</tr>
</tbody>
</table>

### Lesion Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N=71 Lesions / 67 Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lesion Length</strong></td>
<td>38.7 cm ± 3.8 cm</td>
</tr>
<tr>
<td>Range</td>
<td>30.0 cm – 47.2 cm</td>
</tr>
<tr>
<td>% CTO</td>
<td>98.6% (70/71)</td>
</tr>
<tr>
<td><strong>Calcification</strong></td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>71.8% (51/71)</td>
</tr>
<tr>
<td>Moderate</td>
<td>12.7% (9/71)</td>
</tr>
<tr>
<td>Mild</td>
<td>15.5% (11/71)</td>
</tr>
<tr>
<td><strong>TASC II Lesion Type</strong></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>54.9% (39/71)</td>
</tr>
<tr>
<td>D</td>
<td>45.1% (32/71)</td>
</tr>
<tr>
<td><strong>Vessel Run-off</strong>*</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>7.5% (5/67)</td>
</tr>
<tr>
<td>2</td>
<td>31.3% (21/67)</td>
</tr>
<tr>
<td>3</td>
<td>61.2% (41/67)</td>
</tr>
</tbody>
</table>

*Run-off Not applicable or unavailable for 4 patients
DETOUR I 12-Month Patency

Extreme (>30cm) Lesions

- **Primary Patency**: 76.1% (54/71)
- **Primary Assisted Patency**: 81.7% (58/71)
- **Secondary Patency**: 94.4% (67/71)
# Safety Outcomes Through 12 Months

## Extreme (>30cm) Lesions

<table>
<thead>
<tr>
<th>MAE</th>
<th>Freedom from MAE through 30 Days</th>
<th>Freedom from MAE through 12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from Death</td>
<td>100% (67/67)</td>
<td>98.6% (70/71)</td>
</tr>
<tr>
<td>Freedom from CD-TLR</td>
<td>93.0% (66/71)</td>
<td>77.5% (55/71)</td>
</tr>
<tr>
<td>Freedom from Acute Limb Ischemia</td>
<td>100% (71/71)</td>
<td>98.6% (70/71)</td>
</tr>
<tr>
<td>Freedom from Major Amputation</td>
<td>100% (71/71)</td>
<td>100% (71/71)</td>
</tr>
</tbody>
</table>

## Venous Health at 12 Months

<table>
<thead>
<tr>
<th>Scale</th>
<th>Baseline</th>
<th>12 Months</th>
<th>Change from Baseline</th>
<th>P=Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VCSS Scale</td>
<td>Mean ± SD</td>
<td>0.65 ± 0.97</td>
<td>0.93 ± 1.48</td>
<td>0.25 ± 1.21</td>
</tr>
<tr>
<td>Villalta Scale</td>
<td>Mean ± SD</td>
<td>0.38 ± 0.80</td>
<td>0.46 ± 0.95</td>
<td>0.07 ± 0.94</td>
</tr>
</tbody>
</table>
Functional Improvement at 12 Months

Extreme (>30cm) Lesions

Rutherford Becker Clinical Classification

Baseline

12 Months

Ankle Brachial Index

Baseline

12 Months

0% 20% 40% 60% 80% 100%

0 1 2 3 4 5

Significant improvement at 12M (p<0.0001)

Significant improvement at 18M (p<0.0001)
The DETOUR Procedure has the Potential to Fill a Significant Gap in the Endovascular Market

An Endovascular Solution that is Complex-Lesion Neutral: CTO, Ca++, ISR
Percutaneous Bypass for the Treatment of Complex, Long-Segment Peripheral Artery Disease Within in the Femoropopliteal Artery

18-Month Preliminary Results From the DETOUR I Trial

Ehrin Armstrong, MD
Rocky Mountain Regional VA Medical Center
Denver, Colorado

Primary Patency: 67.6%
Primary Assisted Patency: 78.9%
Secondary Patency: 94.4%
N= 68
**DETOUR II Study (currently enrolling)**

**DESIGN**
Prospective, single-arm, multi-center clinical evaluation of the DETOUR™ System and Procedure for Percutaneous Bypass

**INCLUSION CRITERIA**
De novo, CTO, or ISR femoropopliteal lesion ≥15 cm

**INDEPENDENT REVIEW**
Core Lab (DUS, CT, Angio) by Cleveland Clinic; Clinical Events Committee by Syntactx

**Primary Efficacy:**
Primary Patency at 12M (PSVR ≤2.5) with no TLR

**Primary Safety:**
MAE at 30D (Death, TLR, Amputation, DVT)

- STATUS: Enrollment Ongoing
- Follow up at 30D, 6M, 12M, 24M, 36M
- 292 Subjects across 40 centers in US and Europe
- Primary Safety: MAE at 30D (Death, TLR, Amputation, DVT)
- Primary Efficacy: Primary Patency at 12M (PSVR ≤2.5) with no TLR
- STATUS: Enrollment Ongoing
Conclusions

DETOUR I trial extreme lesion cohort contains 99% CTO, 72% Severe Ca++, and the largest prospective series evaluating the percutaneous treatment of SFA lesions with an average lesion length of 39 cm.

Excellent long-term safety in patients with advanced disease and extremely long, complex lesions, with venous health maintained through 12M.

Promising Durability at 12 months compares favorably with existing therapeutic durability, even in lesions long enough to be excluded from traditional peripheral trials.

The DETOUR II IDE will build upon the growing body of clinical evidence.

Enrollment ongoing: Up to 292 subjects • Up to 40 centers in US and Europe.
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