Early look at the VISION Trial: OCT Guided Atherectomy Using Avinger’s Pantheris Catheter

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Disclosure

Speaker name:

.....Arne Schwindt, MD........................................................

I have the following potential conflicts of interest to report:

X Consulting Avinger, Biotronik, Boston Scientific, Medtronic, Jotec, Terumo

☐ Employment in industry

☐ Stockholder of a healthcare company

☐ Owner of a healthcare company

☐ Other(s)

☐ I do not have any potential conflict of interest
Pantheris Catheter: 
OCT guided directional atherectomy 
(Avinger, Inc.)

*Investigational Device. Limited by Federal (U.S.) law for investigational use only. Not available for sale until CE marked.
Passive Imaging Window

*Investigational Device. Limited by Federal (U.S.) law for investigational use only. Not available for sale until CE marked.*
Active Cutting Window

- Plaque
- Cutter [Active]
- Housing

*OCT confirms active confirmation

*Investigational Device. Limited by Federal (U.S.) law for investigational use only. Not available for sale until CE marked.
Actively Cutting Trough

*Investigational Device. Limited by Federal (U.S.) law for investigational use only. Not available for sale until CE marked.
To evaluate the safety and effectiveness of the Pantheris System to perform atherectomy while using directional visualization and imaging as an adjunct to fluoroscopy to aid removal of plaque from diseased lower extremity arteries.
Freedom from MAEs through 6 months:
1. CV related deaths,
2. Unplanned major index limb amputation,
3. Clinically driven TLR,
4. Myocardial Infarction,
5. Device related events (Acute):
   a. Clinically significant perforation,
   b. Clinically significant dissection,
   c. Embolus,
   d. Pseudoaneurysm

The percent of target lesions that have a residual diameter stenosis ≤ 50% post the Pantheris device alone as assessed by an independent Angiographic Core Lab
Endpoint Chronology

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<th>PRIMARY ENDPOINTS</th>
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<td>SAFETY</td>
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<td>≤ 50% Residual Stenosis</td>
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<td>SAFETY</td>
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<tr>
<td>Freedom from procedural emboli</td>
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<tr>
<td>Efficacy</td>
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<td>≤ 30% Post Pantheris and adjunctive treatment</td>
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<tr>
<th>Baseline</th>
<th>30 Days</th>
<th>6 Months</th>
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<td>Freedom from MAEs</td>
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MAJOR INCLUSION CRITERIA

- Patient is ≥ 18 years old
- Patient is candidate for percutaneous intervention for PAD
- Rutherford Classification 2-5
- RVD ≥ 3.0 mm and ≤7.0 mm by visual estimation
- De novo target lesion(s) with stenosis ≥70%. No more than 2 lesions may be treated.
- Target lesion length ≤15 cm (may be two tandem lesions that do not exceed 15 cm in length)
- At least one patent tibial run-off
MAJOR EXCLUSION CRITERIA

-Moderate to severe calcification
-Target lesion stenosis < 70%
-Target lesion within graft or target lesion in the iliac artery
-In-stent restenosis within the target lesion
-Acute ischemia and/or acute thrombosis
-Significant (≥70%) lesions proximal to the TL not successfully treated during the index procedure (i.e., iliac lesion treated prior to target lesion treatment on same day)
-Lesion in the contralateral limb requiring intervention during the index procedure or within 30 days from index procedure
Pantheris Tissue Histology

Intimal Plaque = 94.43%  Medial Tissue = 5.57%  Adventitial Tissue = 0%
VISION Histology Results
Lesions Analyzed to Date (n=138)

Average % Adventitia Area per Lesion = <1%

VISION Enrollment: 75% completed -- Efficacy and Safety Endpoints Under Analysis
Thank you for your attention.