2-year results of the AcoArt I RCT for the Use of the Orchid® DCB in Femoral popliteal Artery Disease

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on behalf of the AcoArt I Investigators
Disclosure

Speaker name: Wei Guo

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

✔ I do not have any potential conflict of interest
# AcoArt I Study Overview

<table>
<thead>
<tr>
<th>Objective</th>
<th>To evaluate the safety and efficacy of the Orchid® drug-coated balloon (DCB) for treatment femoropopliteal arterial disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Endpoint</td>
<td>Angiographic late lumen loss (LLL) at 6 months</td>
</tr>
</tbody>
</table>
| Key Secondary Endpoint | • Primary patency at 12 and 24 months  
• Clinically-driven TLR at 12 and 24 months |
| Complications | MAE (death, major amputation, cumulative) |
| Subjects | 10 sites, 200 pts, randomized 1:1 DCB vs. PTA |
Study device

**Orchid® DCB** produced by Acotec Scientific, Beijing, China

**Proprietary Coating Technology**
- Durable paclitaxel carrier for optimized drug delivery (Mg-stearate)
- Uniform coating of balloon treatment area
- Paclitaxel dose = 3μg/mm²

**Balloon sizes:**
- Diameter (mm)
  - 3.0 - 12.0, with half size design
- Length (mm)
  - 20, 30, 40, 60, 80, 100, 120, 150, 200, 250, 300
Study Design

200 Pts (10 sites)

DCB
N=100

6-month
Clinical: 99(99%)
Angio: 89(89%)

12-month
Clinical: 97(97%)

24-month
Clinical: 96(96%)

PTA
N=100

6-month
Clinical: 98(98%)
Angio: 89(89%)

12-month
Clinical: 96(96%)

24-month
Clinical: 95(95%)
Eligibility

**Inclusion criteria**
- SFA and/or PPA lesion
- Single target lesion
  - de novo or restenotic
  - ISR
  - stenosis (≥70%)
  - total occlusion
  - lesion length <400mm
- Rutherford Class 2-5
- Successful inflow treatment
- At least 1 infrapopliteal run-off vessel

**Exclusion criteria**
- Life expectancy < 2 years
- Acute thrombus in target vessel
- Prior vascular surgery or thrombolysis within 6 weeks
- No adequate distal outflow
- Unsuccessful lesion crossing
- Known allergy to paclitaxel
- Pregnant or breast feeding
- Plasma Cr >150 μmol/L
## AcoArt I Study Baseline

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>PTA</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diabetes (%)</strong></td>
<td>54/100 (54%)</td>
<td>57/100 (57%)</td>
<td>0.67</td>
</tr>
<tr>
<td><strong>Rutherford</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>14%</td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>46%</td>
<td>44%</td>
<td>0.94</td>
</tr>
<tr>
<td>4</td>
<td>24%</td>
<td>27%</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>16%</td>
<td>17%</td>
<td></td>
</tr>
<tr>
<td><strong>Lesion Length (mm)</strong></td>
<td>147.26±109.52</td>
<td>151.59±108.94</td>
<td>0.78</td>
</tr>
<tr>
<td><strong>Occlusion</strong></td>
<td>57% (57/100)</td>
<td>52% (52/100)</td>
<td>0.48</td>
</tr>
<tr>
<td><strong>ISR</strong></td>
<td>27% (27/100)</td>
<td>23% (23/100)</td>
<td>0.51</td>
</tr>
</tbody>
</table>
6-month LLL shows DCB’s superiority

<table>
<thead>
<tr>
<th>LLL (mm)</th>
<th>DCB 0.05 ± 0.73</th>
<th>PTA 1.15 ± 0.89</th>
<th>P value &lt; 0.001</th>
</tr>
</thead>
</table>

Primary patency through 24 months

Primary Patency: Freedom from clinically-driven target lesion revascularization (TLR) and freedom from restenosis as determined by DUS Peak Systolic Velocity Rate (PSVR) ≤2.4
Freedom from CD-TLR through 24 months

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>PTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients Number</td>
<td>96</td>
<td>95</td>
</tr>
<tr>
<td>Cumulative TLR events</td>
<td>15</td>
<td>49</td>
</tr>
<tr>
<td>3 TLR(pt)</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>2 TLR(pt)</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>1 TLR(pt)</td>
<td>11</td>
<td>31</td>
</tr>
</tbody>
</table>

Average time to first TLR, day
- DCB: 307
- PTA: 173
ISR subgroup: Freedom from CD-TLR

- **DCB**
  - Number: 27
  - Occlusion: 67%
  - Lesion length: 237.38 mm
  - LLL(mm): -0.04
  - 24-mon FU: 24/27
  - TLR: 3/24
  - Average Time to first TLR, day: 392

- **PTA**
  - Number: 23
  - Occlusion: 43%
  - Lesion length: 243.46 mm
  - LLL(mm): 1.69
  - 24-mon FU: 20/23
  - TLR: 15/20
  - Average Time to first TLR, day: 173
ISR subgroup: primary patency

- DCB
- PTA

Primary patency:
- DCB: 91.7% at 24 months
- PTA: 54.2% at 24 months
Major adverse events (MAE) through 24 months

<table>
<thead>
<tr>
<th>Event</th>
<th>DCB</th>
<th>PTA</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>8/96 (8.3%)</td>
<td>6/95 (6.3%)</td>
<td>0.59</td>
</tr>
<tr>
<td>Device- and procedure-related death</td>
<td>0/96 (0%)</td>
<td>0/95 (0%)</td>
<td>/</td>
</tr>
<tr>
<td>Major amputation</td>
<td>1/96 (1.0%)</td>
<td>3/95 (3.2%)</td>
<td>0.37</td>
</tr>
<tr>
<td>Death + Major amputation</td>
<td>9/96 (9.4%)</td>
<td>9/95 (9.5%)</td>
<td>0.98</td>
</tr>
</tbody>
</table>
Conclusions

• AcoArt I demonstrates safety and efficacy of Orchid DCB in treating femoropopliteal artery disease.
• Sustained durability of DCB treatment effect with no late catch-up through 2 years.
• Although the number of ISR lesions are small, the results of AcoArt I are promising. This should be further investigated.
Thank you for your attention

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2-year results of the AcoArt I

RCT for the Use of the Orchid® DCB in Femoral popliteal Artery Disease

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