Long term results from the LegDeb registry

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Disclosure

Speaker name: Eugenio Stabile

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
Excipient
-- lipophilic and polymeric ammonium-salt-based

Paclitaxel
-- 3.0 μg/mm²

Optical Imaging (100x)
LEGFLOW DCB
Homogeneous, smooth amorphous coating
Hydrophilic Coating DCB
White powder of brittle crystalline coating

The ‘SAFEPAX’ drug coating technology should provide proper protection from low mass-related risk for distal embolization and prothrombotic effects
LegDeb Registry Design

- Prospective
- Multicenter
- Femoropopliteal lesions
- PTA according to local standard practices

FOLLOW-UP
- Clinical examinations
- Duplex US
- Repeated angio in presence of intermediate or severe restenosis

ASSESSMENTS
- **Primary end point:** freedom from restenosis at 12 and 24 months
- **Secondary end point:** freedom from CD-TLR
LEGDEB Registry 24-months analysis

- 70 patients initially enrolled
- 37% available for 24-months analysis (n:54)

- University of Napoli "Federico II" (26)
- Vascular Clinica ZNA Hospital Stuivenberg, Antwerp (44)

77.1% available for 24-months analysis (n:54)
## Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>70</td>
</tr>
<tr>
<td>Male</td>
<td>78%</td>
</tr>
<tr>
<td>Age</td>
<td>66 ± 11</td>
</tr>
<tr>
<td>Diabetes</td>
<td>50%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>77%</td>
</tr>
<tr>
<td>Hypercholesterolaemia</td>
<td>57%</td>
</tr>
<tr>
<td>Smoking history</td>
<td>56%</td>
</tr>
<tr>
<td>CLI (Rutherford Class ≥4)</td>
<td>31%</td>
</tr>
<tr>
<td>Rutherford Class</td>
<td>3.2 ± 0.8</td>
</tr>
<tr>
<td>de novo lesions</td>
<td>49%</td>
</tr>
<tr>
<td>Restenosis</td>
<td>18%</td>
</tr>
<tr>
<td>In-stent restenosis</td>
<td>33%</td>
</tr>
<tr>
<td>Lesion length (overall)</td>
<td>99 ± 37</td>
</tr>
<tr>
<td>de novo lesion length</td>
<td>90 ± 41</td>
</tr>
<tr>
<td>In-stent restenosis lesion length</td>
<td>120 ± 17</td>
</tr>
<tr>
<td>Restenosis lesion length</td>
<td>86 ± 36</td>
</tr>
</tbody>
</table>

- **SFA** | **FEM / POP**

15% | 85%
LegDeb Registry Results at 24-months

- Freedom from TLR: 83.3%
- Freedom from Restenosis: 72.2%
LegDeb Registry Results at 24-months

<table>
<thead>
<tr>
<th>FREEDOM FROM RESTENOSIS</th>
<th>FREEDOM FROM CD-TLR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>2 years</td>
</tr>
<tr>
<td>81%</td>
<td>72%</td>
</tr>
<tr>
<td>83%</td>
<td>83%</td>
</tr>
</tbody>
</table>

1 year results indicate 81% freedom from restenosis and 83% freedom from CD-TLR.
2 year results show 72% freedom from restenosis and 83% freedom from CD-TLR.
LegDeb Registry Results at 24-months

<table>
<thead>
<tr>
<th>Category</th>
<th>Freedom from TLR</th>
</tr>
</thead>
<tbody>
<tr>
<td>OVERALL</td>
<td>83%</td>
</tr>
<tr>
<td>IC</td>
<td>84%</td>
</tr>
<tr>
<td>CLI</td>
<td>82%</td>
</tr>
<tr>
<td>RESTENOSIS</td>
<td>88%</td>
</tr>
<tr>
<td>ISR</td>
<td>94%</td>
</tr>
<tr>
<td>DE NOVO</td>
<td>76%</td>
</tr>
</tbody>
</table>
LegDeb Peculiarities

CLI %*

0% 5% 10% 15% 20% 25% 30% 35% 40% 45% 50% 60% 70% 80% 90% 100% 110% 120% 130% 140% 150% 160%

- LegDeb
- IN.PACT SFA
- ILLUMENATE

Lesion Characteristics

- Lesion Length mm
- Occlusions

* No patients enrolled in Rutherford class ≥4
DCB 24-months outcome

**Freedom from TLR**

- **FREEDOM FROM RESTENOSIS**
  - LegDeb: 72%
  - IN.PACT SFA: 79%
  - ILLUMINATE: 76%

- **FREEDOM FROM CD-TLR**
  - LegDeb: 83%
  - IN.PACT SFA: 91%
  - ILLUMINATE: 89%
Summary and conclusions

In a real-world population with SFA, Legflow achieved favourable outcomes:

- 100% procedural and technical success rates
- 83.3% freedom from TLR at 24 months

This was achieved in a population with worse clinical status than in most clinical trials:

- 31% had CLI
- Average lesion: 99 mm

Legflow is a safe and effective treatment option in this challenging population
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