MIMICS 2 Three-Year Results

Summary

MIMICS-2 is a prospective, single-arm, multicentre clinical study conducted under FDA-approved Investigational Device Exemption to evaluate the safety and effectiveness of the BioMimics 3D Vascular Stent System in the treatment of patients with symptomatic atherosclerotic disease of the femoropopliteal artery.

Results

Overview of 3 Year Results from MIMICS-2

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>30 days</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Safety Endpoint***</td>
<td>99.6%</td>
<td>99.6%</td>
</tr>
<tr>
<td>Primary Effectiveness Endpoint/Primary Stent Patency</td>
<td>73%</td>
<td>73%</td>
</tr>
<tr>
<td>Stent fracture/Core Lab review</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>KM freedom from loss of primary patency</td>
<td>83%</td>
<td>83%</td>
</tr>
<tr>
<td>KM freedom from CDTLR****</td>
<td>81%</td>
<td>81%</td>
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</tbody>
</table>

Baseline Demographics & Lesion Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N=271 Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Mean ± SD (N)</td>
<td>68.4 ± 9.5 (271)</td>
</tr>
<tr>
<td>Risk factor Diabetes Mellitus</td>
<td>45.4% (123/271)</td>
</tr>
<tr>
<td>Rutherford category 2/3/4</td>
<td>99.6% (270/271)</td>
</tr>
<tr>
<td>Lesion location Mid/Distal</td>
<td>88.5% (239/270)</td>
</tr>
<tr>
<td>Lesion length Mean ±SD (mm)</td>
<td>81.2 ± 38.4 (269/271)</td>
</tr>
<tr>
<td>Total occlusion %</td>
<td>30.0 (81/270)</td>
</tr>
<tr>
<td>Lesion calcification Moderate / Severe</td>
<td>45.9 (124/270)</td>
</tr>
<tr>
<td>BioMimics 3D Stents*</td>
<td>4 Stents / N 305 / 271</td>
</tr>
<tr>
<td>Stented Segment** Mean ± SD (mm)</td>
<td>112.3 ± 36.3 (269/271)</td>
</tr>
</tbody>
</table>

Continuing benefit at 3 years even in challenging cases

- Overall KM survival estimate for CDTLR at 3 years = 81%
- Log-Rank P-Value = 0.38
- Lesion Calcification
  - Overall KM survival estimate for CDTLR at 3 years: 81%
  - Log-Rank P-Value = 0.51
- Occlusion vs. No Occlusion
  - Overall KM survival estimate for CDTLR at 3 years: 81%
  - Log-Rank P-Value = 0.46
- Tercile of Lesion Length
  - Overall KM survival estimate for CDTLR at 3 years: 81%
  - Log-Rank P-Value = 0.38

Study Principal Investigators:
- Timothy M. Sullivan, MD
  Minneapolis, MN, USA
- Thomas Zeller, MD
  Bad Krozingen, Germany
- Masato Nakamura, MD
  Tokyo, Japan

- 43 investigational sites enrolled 271 subjects:
  - US: 31 sites N =162
  - Germany: 6 sites N =78
  - Japan: 6 sites N =31
- Duration of follow-up: 3 years.
- Independent committee adjudication of clinical events.
- Core laboratories: Duplex ultrasound; angiography and X-ray.

Rigorous, high quality data shows continuing benefit at 3 years
The BioMimics 3D Vascular Stent System has CE Mark approval.

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For additional information please contact your local representative.

Conclusions

MIMICS-2 shows continuing benefit of the BioMimics 3D Vascular Stent System at 3 Years, even in challenging cases:

- Reproducible, rigorous, high quality data from US, Japan and Europe.
- 81% freedom from CDTLR at 3 years.
- Comparable outcomes to DES/DCB despite more challenging lesions and without the need for lesion preparation.

- Providing ease-of-use simplicity and long-term benefits.
- Core Lab X-ray imaging review confirmed 0% stent fracture.

The BioMimics 3D Vascular Stent System reduces the burden of re-intervention for the patient and the health care system.¹²

The MIMICS Clinical Programme:

Gathering clinical evidence from a “real world” patient population from single de novo to complex, long and severely calcified lesions.

1750+ patients and growing

1. Data on file at Veryan Medical

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