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.

<table>
<thead>
<tr>
<th>Baseline Demographics &amp; Lesion Characteristics</th>
<th>N=271 Subjects</th>
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</thead>
<tbody>
<tr>
<td>Age Mean years ± 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># Stents / N</td>
</tr>
<tr>
<td>Stented Segment* Mean ± SD (mm)</td>
<td>112.3 ± 36.3 (269/271)</td>
</tr>
</tbody>
</table>

Results

Overview of 3 Year Results from MIMICS-2

<table>
<thead>
<tr>
<th>Primary Safety Endpoint***</th>
<th>30 days</th>
<th>99.6%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent fracture/Core Lab review</td>
<td>Maintained out to 3 years</td>
<td>0%</td>
</tr>
<tr>
<td>KM freedom from loss of primary patency</td>
<td>12 months</td>
<td>83%</td>
</tr>
<tr>
<td>KM freedom from CDTLR****</td>
<td>12 months</td>
<td>89%</td>
</tr>
<tr>
<td></td>
<td>2 Years</td>
<td>84%</td>
</tr>
<tr>
<td></td>
<td>3 Years</td>
<td>81%</td>
</tr>
</tbody>
</table>

Continuing benefit at 3 years even in challenging cases

Rigorous, high quality data shows continuing benefit at 3 years

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.

* Investigator-reported
** CoreLab-reported
*** Major Adverse Events comprising death, major amputation on index limb or CDTLR through Day 30.
**** Core Lab adjudicated, clinically-driven TLR with objective evidence. Subjects are censored at their last known follow-up, or at time of study exit (withdrawal or lost to follow-up) or death.
## 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.**

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### The MIMICS Clinical Programme:

**An evolving database of the safety and effectiveness of the BioMimics 3D Vascular Stent System.**

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

<table>
<thead>
<tr>
<th>MIMICS 3D</th>
<th>N = 1750+ patients and growing</th>
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<table>
<thead>
<tr>
<th>MIMICS FIH</th>
<th>MIMICS RCT</th>
<th>MIMICS 2</th>
<th>MIMICS 3D</th>
<th>MIMICS 3D USA</th>
<th>MIMICS et seq</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 10</td>
<td>N = 50</td>
<td>N = 271</td>
<td>N = 507</td>
<td>N = c. 500</td>
<td>N = c. 400</td>
</tr>
<tr>
<td>1 site</td>
<td>8 sites</td>
<td>43 sites</td>
<td>23 sites</td>
<td>40 sites</td>
<td>Multiple sites</td>
</tr>
<tr>
<td>Germany</td>
<td>Germany</td>
<td>USA/Japan/Germany</td>
<td>Pan European</td>
<td>USA</td>
<td>Europe</td>
</tr>
</tbody>
</table>

**MIMICS RCT**

A randomised study comparing safety and effectiveness of the BioMimics 3D Vascular Stent System to a straight stent control. Freedom from loss of primary patency through 2 years for BioMimics 3D Vascular Stent System was superior (P = 0.05) to straight control stents (72% vs 55%). There were no stent fractures at 2 years for patients treated with the BioMimics 3D Vascular Stent System.³

**MIMICS 2**

A multicentre, international (USA, Japan and Germany) IDE study. At 3 years follow-up BioMimics 3D demonstrated continuing benefit with CDTLR showing comparable outcomes to DES/DCB. Core Lab X-ray imaging review confirmed 0% stent fracture in any MIMICS-2 subject treated with BioMimics. MIMICS-2 represents a more challenging patient population than in DES/DCB pivotal trials.⁴,⁵

**MIMICS 3D**

A prospective observational registry evaluating the BioMimics 3D Vascular Stent System in a real-world clinical population with a dedicated subgroup analysis of device performance as a complementary treatment in procedures involving drug-coated balloons. MIMICS-3D enrolled 507 patients across 23 clinical sites in Europe.

**MIMICS 3D USA**

A prospective, multicentre observational study evaluating the safety, effectiveness and device performance of the BioMimics 3D Vascular Stent System within a real-world clinical population of patients undergoing femoropopliteal intervention. MIMICS-3D USA will enrol a minimum of 500 patients in up to 40 sites across the United States.

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1. Data on file at Veryan Medical

The BioMimics 3D Vascular Stent System has CE Mark approval.

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