The SAHAJANAND (SMT) Bioabsorbable Polymer based SES Stent Trial Program

SERIES and MAXIMUS RESULTS

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Escorts Heart Institute & Research Centre
NEW DELHI
INDIA
Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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<tbody>
<tr>
<td>Grant/Research Support</td>
<td></td>
</tr>
<tr>
<td>Consulting Fees/Honoraria</td>
<td>Sahajanand Medical Technologies</td>
</tr>
<tr>
<td>Major Stock Shareholder/Equity</td>
<td></td>
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<tr>
<td>Royalty Income</td>
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<tr>
<td>Ownership/Founder</td>
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<tr>
<td>Intellectual Property Rights</td>
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<tr>
<td>Other Financial Benefit</td>
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Supralimus – Sirolimus ES

- Slow Release profile
  - 27% release within 1 week
  - 100% within 7 weeks.
- No residual drug-polymer in long term
- Drug is released by diffusion
- PLGA, PLL, PVP Polymeric matrix breaks up into CO₂ and H₂O.
SERIES I

Safety and Efficacy of Supralimus™
(Sirolimus Eluting Stent)
SERIES I: Study Design

N = 100 pts non randomized pros. registry

Real world coronary artery lesions
Diameter: 2.5 to 4.0mm
Length: < 25mm

Supralimus: Sirolimus Eluting Stent

Primary EP: 30-day MACE & 6-month in-stent restenosis
Secondary EP: Angiographic success & 9-month MACE
SERIES I: Patient & Lesion Characteristics

- Diabetes: 29%
- CHF: 7%
- MV disease: 27%
- CTO: 11.6%
- Thrombotic Lesions: 13.7%
- ISR Lesions: 0.7%
- Ostial Lesions: 5.5%
- Bifurcated Lesions: 3.4%

Target Vessel

<table>
<thead>
<tr>
<th>Vessel</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAD</td>
<td>56</td>
</tr>
<tr>
<td>RCA</td>
<td>25</td>
</tr>
<tr>
<td>LCx</td>
<td>16</td>
</tr>
<tr>
<td>LMCA</td>
<td>0.79</td>
</tr>
<tr>
<td>Others</td>
<td>2,38</td>
</tr>
</tbody>
</table>
## SERIES I: 6-month QCA

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Length</td>
<td>10.50 ± 4.30 mm</td>
</tr>
<tr>
<td>Minimal luminal diameter</td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>0.73 ± 0.61 mm</td>
</tr>
<tr>
<td>Post</td>
<td>2.53 ± 0.43 mm</td>
</tr>
<tr>
<td>FUP</td>
<td>2.44 ± 0.48 mm</td>
</tr>
<tr>
<td>Diameter stenosis</td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>72.42 ± 21.70 mm</td>
</tr>
<tr>
<td>Post</td>
<td>11.51 ± 6.63 mm</td>
</tr>
<tr>
<td>FUP</td>
<td>14.20 ± 9.50 mm</td>
</tr>
<tr>
<td>In-Stent Late Loss</td>
<td>0.09 ± 0.28 mm</td>
</tr>
<tr>
<td>In Segment Late Loss</td>
<td>0.02 ± 0.37 mm</td>
</tr>
<tr>
<td>Clinical FUP</td>
<td>1 M</td>
</tr>
<tr>
<td>-------------------</td>
<td>------</td>
</tr>
<tr>
<td><strong>Death (%)</strong></td>
<td>0 (0.0)</td>
</tr>
<tr>
<td><strong>TLR (%)</strong></td>
<td>0 (0.0)</td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td>0 (0.0)</td>
</tr>
<tr>
<td><strong>MACE (%)</strong></td>
<td>0 (0.0)</td>
</tr>
<tr>
<td><strong>Angiogr.</strong></td>
<td>0 (0.0)</td>
</tr>
<tr>
<td><strong>Stent</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Thrombosis</strong></td>
<td></td>
</tr>
</tbody>
</table>

**SERIES I: 30-month Adverse Events**
CONCLUSION

- Supralimus – Sirolimus coated novel stent with biodegradable polymer produced excellent clinical results and very low angiographic late loss at 6 months. 30 month clinical follow up exhibited low overall MACE rates.
SUPRALIMUS CORE™ Stent

COBALT CHROMIUM PLATFORM (thin struts: 0.0024”/60 micron)
LOW SYSTEM PROFILE (0.035”)

POLYMER COATING
Three Different Biodegradable Polymers
Poly L-Lactide
50/50 Poly-DL-Lactide-co-Glycolide
Poly Vinyl Pyrrolidone

DRUG
SIROLIMUS
The Maximus Study

SAFETY AND EFFICACY EVALUATION OF SIROLIMUS ELUTING SUPRALIMUS-CORE™ STENT AT MAX DDHV INSTITUTE IN THE TREATMENT OF DE NOVO NATIVE CORONARY ARTERY LESIONS
• **OBJECTIVE**

To assess the safety and efficacy of the Supralimus-Core™ Sirolimus Eluting Stent in de novo native obstructive coronary artery disease.

• **STUDY DESIGN**
  - Single centre, non randomized, prospective observational study. (Real world patient)

• **STUDY POPULATION**
  - 100 patients with *de novo* native vessel obstructive coronary artery disease with no specific anatomical requirement criteria. Patients from the daily practice included (except AMI)
**Primary safety endpoint**
Major Adverse Cardiac Events (MACE) at 30 days.

**Primary efficacy endpoint**
Binary restenosis rate at 8-month Angiography follow up
SECONDARY END POINT

Secondary safety endpoints
- MACE at 12 months
- Device related serious adverse events (SAEs) until 12 months
- Angiographic stent thrombosis:
  - Subacute (30 days)
  - Late (30 days - 12 months)

Secondary efficacy endpoints
- Angiographic success
- Procedure success
- Quantitative Coronary Angiography derived vessel parameters in-stent and 5 mm proximal and 5 mm distal from the edge of the stent: acute gain, MLD, % DS, late loss, mean diameter. In-stent pre-, post and at 8-month follow-up
- Clinically justified Target Lesion Revascularization (TLR) at 12 months
Principal Investigator:  Dr. Ashok Seth

Co-Investigator:  Dr. Praveen Chandra

Independent Angiographic core lab. & Data monitoring:
Cardialysis B.V., Westblaak 92  3012 KM Rotterdam, The Netherlands

Clinical trial Sponsor:  Sahajanand Medical Technologied Pvt. Ltd
PATIENT RISK FACTORS

- Male: 79%
- Diabetes Mellitus: 37%
- Hypertension: 48%
- Smoker: 30%
- Dyslipidemia: 35%
- Previous MI: 33%

- Insulin requiring: 7%
- Non-insulin requiring: 30%
- Male: 48%
- Diabetes Mellitus: 37%
- Hypertension: 48%
- Smoker: 30%
- Dyslipidemia: 35%
- Previous MI: 33%
MAXIMUS – 105 patients, 194 lesions and 234 Stents (2.3 stents per patient) mean stent length was 19.72 ± 9.2 mm

**Lesion Morphology**
- TYPE B1: 40%
- TYPE B2: 50%
- TYPE C: 7%
- TYPE A: 3%

**Vessel Distribution**
- LAD: 39%
- CIRC: 29%
- RCA: 32%

**Stent Diameters Used**
- 3.0 MM: 41%
- 3.5 MM: 16%
- 2.75 MM: 8%
- 2.5 MM: 35%

**Stent Lengths Used**
- 8 mm: 4%
- 12 mm: 21%
- 16 mm: 24%
- 20 mm: 32%
- 24 mm: 0.40%
- 28 mm: 12%
- 32 mm: 8%
MAXI MUS TRIAL

49 year old male, with Angina Class III

LAD  LCX  RCA

20 YEARS OF INNOVATION
TCT 2008

MAXI MUS TRIAL

49 year old male, with Angina Class III

LAD  LCX  RCA

20 YEARS OF INNOVATION
TCT 2008

MAXI MUS TRIAL

49 year old male, with Angina Class III

LAD  LCX  RCA

20 YEARS OF INNOVATION
TCT 2008
MAXI MUS TRIAL

49 year old male, with Angina Class III

8 MONTHS ΣΤΟΤΕ

F/UF/U
MAXI MUS TRIAL

49 year old male, with Angina Class III
MAXI MUS TRIAL

49 year old male, with Angina Class III

RCA POST

8 MONTHS F/U
MAXI MUS TRIAL

49 year old male, with Angina Class III
MAXI MUS TRIAL

8 Month Final Analysis

Corelab: Cardialysis, The Netherlands
## 8 months QCA analysis

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
<th>Fup</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RVD, mm</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-Stent</td>
<td><strong>2.48± 0.5</strong></td>
<td>2.63± 0.46</td>
<td>2.37± 0.40</td>
</tr>
<tr>
<td>In-Segment</td>
<td></td>
<td>2.55± 0.49</td>
<td>2.33± 0.43</td>
</tr>
<tr>
<td><strong>MLD, mm</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-Stent</td>
<td>0.89± 0.44</td>
<td>2.3± 0.42</td>
<td>1.91± 0.43</td>
</tr>
<tr>
<td>In-Segment</td>
<td></td>
<td>2.05± 0.47</td>
<td>1.72± 0.44</td>
</tr>
<tr>
<td><strong>Late loss, mm</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-Stent</td>
<td></td>
<td></td>
<td><strong>0.39± 0.33</strong></td>
</tr>
<tr>
<td>In-Segment</td>
<td></td>
<td></td>
<td><strong>0.33± 0.35</strong></td>
</tr>
<tr>
<td><strong>Diameter Stenosis %</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-Stent</td>
<td>63.77± 16.63</td>
<td>12.32± 6.38</td>
<td>19.20± 12.86</td>
</tr>
<tr>
<td>In-Segment</td>
<td></td>
<td>20.02 ± 8.68</td>
<td>25.98 ± 12.02</td>
</tr>
<tr>
<td><strong>Binary Angiographic Restenosis, %</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-Stent</td>
<td></td>
<td></td>
<td><strong>5 (3.3%)</strong></td>
</tr>
<tr>
<td>In-Segment</td>
<td></td>
<td></td>
<td><strong>7 (4.6%)</strong></td>
</tr>
<tr>
<td><strong>Stent thrombosis</strong></td>
<td></td>
<td></td>
<td>2(2%)</td>
</tr>
</tbody>
</table>
## Clinical follow up data

<table>
<thead>
<tr>
<th></th>
<th>1 Month</th>
<th>8 months</th>
<th>12 Months</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>TVR</td>
<td>1</td>
<td></td>
<td>1</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>TLR</td>
<td></td>
<td>1</td>
<td></td>
<td>1 (1%)</td>
</tr>
<tr>
<td>CABG</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Stent Thrombosis</td>
<td>1</td>
<td>1</td>
<td></td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td></td>
<td>1</td>
<td></td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Non cardiac death</td>
<td></td>
<td>3</td>
<td></td>
<td>3 (3%)</td>
</tr>
</tbody>
</table>
Conclusion:

# In a cohort of **real world patients with smaller vessels** (RVD 2.48mm) and high incidence of **diabetes** (36%) Supralimus Core stent implant was associated with **extremely low TLR** (1%) Stent Thrombosis (2%) at 1 year and low angiographic **in segment restenosis rates** (4.6%) at 8 months

# The extremely promising results of the MAXIMUS trial formed the basis of the pivotal randomized, prospective, non inferiority, multicentric, Intercontinental **SERIES III Run In** trial

Randomized between **Supralimus Core and Xience V** in total of 400 patients