The technology behind SELUTION SLR: The first limus-eluting DEB for treating PAD

John E Shulze
CTO
MedAlliance SA
Disclosure

Speaker name: John E Shulze

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
### Clinical Results at 6M, 12M and 24M

<table>
<thead>
<tr>
<th>Measure</th>
<th>6M</th>
<th>12M</th>
<th>24M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cumulative Clinical Events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Minor and Major Amputation</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Primary Patency (ITT)</td>
<td>88.4%</td>
<td>75.7%</td>
<td>81.6%</td>
</tr>
<tr>
<td>Primary Patency (PP)</td>
<td>95.2%</td>
<td>88.9%</td>
<td>94.4%</td>
</tr>
<tr>
<td>Freedom from Index Limb Amputation and CD TVR</td>
<td>97.7%</td>
<td>87.6%</td>
<td>85.4%</td>
</tr>
<tr>
<td>TLR (ITT)</td>
<td>1 (2.3%)</td>
<td>6 (12.5%)</td>
<td>6 (12.5%)</td>
</tr>
<tr>
<td>TLR (PP Lesion Prep)</td>
<td>1 (2.3%)</td>
<td>2 (4.3%)</td>
<td>2 (4.3%)</td>
</tr>
<tr>
<td>TLR (Ca++)</td>
<td>0 (0%)</td>
<td>1 (6.6%)</td>
<td>1 (7.7%)</td>
</tr>
</tbody>
</table>

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1. Inadequate Lesion Prep: Residual Stenosis >35% by CoreLab Assessment
2. Moderately Severe/Severe Calcification = Calcification score 3 or 4 by 360Score = outside of Protocol

ITT: all patients enrolled in the trial, whether or not they were treated the Investigational Device
PP: all patients enrolled and treated with the Investigational Device and had no bailout. Includes only patients who had a post-procedure angio residual stenosis ≤ 30%
SELUTION SFA Clinical Improvement
Rutherford, ABI & WiQ

Baseline, 6M, 12 M and 24M

Rutherford Classification
Improvement from Baseline to 24M
> 2 categories in 67% of patients
> 1 category in 84% of patients

Change from Baseline to 24M: p 0.0242
Change from Baseline to 12M: p < 0.0001
Change from 6M to 12M: p = 0.0125
SELUOTION SLR Efficacy Confirmed in Complex Lesions

Subset analysis in Ca++ and long lesion subgroups demonstrated similar LLL compared to the overall cohort.

![Graph showing LLL at 6M for different subgroups](image)

- Overall: N = 34, LLL = 0.19
- Long Lesions: N = 12, LLL = 0.23
- Ca++: N = 17, LLL = 0.07

* Primary Endpoint of Trial
MicroReservoirs in a coating

SELUTION™ SLR FIRST SIROLIMUS-ELUTING BALLOON DESIGNED FOR “SUSTAINED LIMUS RELEASE” DRUG KINETICS

Use of micro-reservoirs made from biodegradable polymer intermixed with Sirolimus coated onto the balloon:
- Controlled and sustained drug release mechanism
- Maintains therapeutic effect in tissue over long period of time

Proprietary Cell Adherent Technology – CAT™:
- Transfer membrane that contains and protects micro-reservoirs during balloon insertion, lesion crossing and inflation
- Transfer membrane releases from balloon surface and adheres to vessel lumen during short balloon inflation
- Less drug loss during transit to lesion
- Less drug loss during inflation

Graphs showing:
- Continued ECM formation
- Cell Proliferation

Bar graph showing tissue drug concentration over time for different procedures:
- Therapeutic Effect ≥ 1 µg/g
- 1 hour: Med Alliance SELUTION - RAP = 262, Bard LUTONIX - PAX = 59, Medtronic IN.PACT - PAX = 35
- 7 days: Med Alliance SELUTION - RAP = 44, Bard LUTONIX - PAX = 11, Medtronic IN.PACT - PAX = 3
- 28 days: Med Alliance SELUTION - RAP = 21, Bard LUTONIX - PAX = 0.3, Medtronic IN.PACT - PAX = 3
- 60 days: Med Alliance SELUTION - RAP = 19, Bard LUTONIX - PAX = 0, Medtronic IN.PACT - PAX = 0
Attraction of CAT™ coating to cell membranes

CAT™ coating
SELUTION SLR™ vs. Competition

Drug Transfer

<table>
<thead>
<tr>
<th>% of Total Device Drug Load</th>
<th>Med Alliance</th>
<th>Bard LUTONIX</th>
<th>Medtronic IN.PACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lost during procedure</td>
<td>36%</td>
<td>83%</td>
<td>83%</td>
</tr>
<tr>
<td>Retained on balloon</td>
<td>25%</td>
<td>12%</td>
<td>14%</td>
</tr>
<tr>
<td>Transferred to vessel (1 hr)</td>
<td>39%</td>
<td>5%</td>
<td>3%</td>
</tr>
</tbody>
</table>

Source: Med Alliance – Bench Test Data on File
Coating Durability during handling and deployment

NO FLAKING
Next Steps

- **CE Mark Approval – Imminent**

Ongoing and Next Clinical Trials

- **SELUTION PMCF**
  - Post Market Registry
  - 300 patients

- **SELUTION BTK Feasibility (ENROLLMENT COMPLETE)**
  - 20 patients (Singapore)
  - Prospective, Historical control

- **SELUTION BTK (FDA Breakthrough Designation)**
  - 400 patients RCT (Enrollment expected to begin Q4 2020)

- **SAVE Trial - SELUTION DEB for dysfunctional AV access**
  - 86 patients
  - RCT: POBA vs SELUTION, RCT, n=86

- **STEP Trial - SELUTION in the Foot Feasibility**
  - 20 Patient
• THANK YOU!
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