The ILLUMINA Study: 2-year results with a polymer free Sirolimus eluting DES in femoropopliteal arteries

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Disclosure

Advisory Board /Consultant:

Abbott, Alvimedica, Bayer, Boston Scientific, Cook Medical, Cardionovum, CR Bard, Gardia Medical/Allium, Medtronic, Philips, Upstream Peripheral Technologies
NiTiDES features description

- **Polymer-Free self-expanding DES**
  Avoids all the well known drawbacks due to the presence of a polymer interface with blood flow or vessel wall

- **Abluminal Reservoir Technology**
  Controlled and directed elution to the vessel wall

- **Amphilimus™ Formulation**
  (Sirolimus + Fatty Acid)
  Enhanced drug bioavailability, permeability and maximized product overall safety and efficacy

- **Bio Inducer Surface (BIS)**
  2nd generation pure carbon coating
  Optimal haemo-compatibility vs. lumen blood flow
ILLUMINA study design

Innovative sirolimus self expanding drug-eluting stent for the treatment of peripheral disease: evaluation of safety and efficacy

Prospective, Single arm; 10 centers in Europe (n= 100 pts)
Prof. Dierk Scheinert (Coordinating Clinical Investigator, Leipzig-Germany)

Efficacy:

- **SAFETY**: Composite of Major Adverse Events – MAE (death, target limb amputation, target limb ischemia requiring surgical intervention or surgical repair of target vessel or clinically-driven target lesion revascularization and freedom from worsening of the Rutherford score by 2 classes, or to class 5 or 6)
- **EFFICACY**: Primary patency at 12 months. Primary patency is defined as absence of clinically-driven target lesion revascularization or binary restenosis (PSVR >2.4 - duplex evaluation)

Phone Call

1 month 6 month 12 month 24 month

Duplex ultrasound Clinical FU
# ILLUMINA study
## Centers and enrolled pts.

<table>
<thead>
<tr>
<th>Sites</th>
<th>Patients</th>
<th>Country</th>
<th>Pts. Per Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Universitätsklinikum Leipzig</td>
<td>Scheinert</td>
<td>Germany</td>
<td>46</td>
</tr>
<tr>
<td>Universitäts-Herzzentrum Freiburg Bad Krozingen</td>
<td>Zeller</td>
<td>Germany</td>
<td></td>
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<tr>
<td>Regiomed GefäBzentrum Sonneberg</td>
<td>Thieme</td>
<td>Germany</td>
<td></td>
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<tr>
<td>St. Gertrauden Krankenhaus GmbH - Berlin</td>
<td>Langhoff</td>
<td>Germany</td>
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</tr>
<tr>
<td>San Raffaele Hospital - Milan</td>
<td>Chiesa/Kahlberg</td>
<td>Italy</td>
<td>19</td>
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<tr>
<td>Maria Cecilia Hospital - Cotignola</td>
<td>Cremonesi</td>
<td>Italy</td>
<td></td>
</tr>
<tr>
<td>Fondazione IRCCS Policlinico San Matteo - Pavia</td>
<td>Marone</td>
<td>Italy</td>
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</tr>
<tr>
<td>Clinique Pasteur - Toulouse</td>
<td>Sauguet</td>
<td>France</td>
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</tr>
<tr>
<td>Polyclinique Les Fleurs - Ollioules</td>
<td>Commeau</td>
<td>France</td>
<td></td>
</tr>
<tr>
<td>Centre Prive Claude Galien - Quincy</td>
<td>Garot</td>
<td>France</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td></td>
<td>100</td>
</tr>
</tbody>
</table>
ILLUMINA study
Baseline characteristics

Enrolled Patients [n]: 100
Mean age [y]: 67

Male: 78%
Smoker: 39%
Diabetic: 35%
Hypertension: 69%
Hypercholesterolemia: 54%
ILLUMINA study
Pre-procedure information

**Location**
- Middle SFA: 49%
- Distal SFA: 38%
- Proximal SFA: 8%
- Popliteal P1: 5%

**Calcification**
- None: 25%
- Little: 20%
- Moderate: 35%
- Heavy: 20%
- Total: 55%

**Lesion**
- Average length*: 72.54 ± 37.99 mm
- RVD: 5.11 ± 0.72 mm

* In hospital assessment
# ILLUMINA study

## Procedural results

<table>
<thead>
<tr>
<th>Procedure results</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent deployment success</td>
<td>100%</td>
</tr>
<tr>
<td>Procedural success</td>
<td>100%</td>
</tr>
<tr>
<td>Stent per patient (n)</td>
<td>1.09 ± 0.32</td>
</tr>
<tr>
<td>Total mean length of stent (mm)</td>
<td>86.7 ± 40.8</td>
</tr>
</tbody>
</table>
## 24 months results: SAFETY

<table>
<thead>
<tr>
<th>Major Adverse Event (MAE)</th>
<th>Device Related</th>
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</thead>
<tbody>
<tr>
<td>Clinically driven Target Lesion Revascularization (TLR)</td>
<td>6</td>
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<tr>
<td>Deaths throughout the entire study period*</td>
<td>3</td>
</tr>
<tr>
<td>Target limb amputation</td>
<td>0</td>
</tr>
<tr>
<td>Target limb ischemia requiring surgical intervention or surgical repair of the target vessel**</td>
<td>1</td>
</tr>
<tr>
<td>Worsening of the Rutherford score by two classes, or class 5 and 6***</td>
<td>1</td>
</tr>
<tr>
<td><strong>MAE</strong></td>
<td>11</td>
</tr>
</tbody>
</table>

*1 death due to Myocardial Infarction @ 5 months - non stent or procedural related (CEC adjudicated)
1 death due to severe septic shock @ 13 months - non stent or procedural related (CEC adjudicated)
1 death due to lung cancer @ 17 months - non stent or procedural related (CEC adjudicated)

**1 thrombo-endo-arterectomy (far proximal to the lesion - CRFA) @ 18 months - non stent related (CEC adjudicated)

***Patient, asymptomatic at 1year, had femoral fracture 5months before 2years FU visit (Rutherford classes are not CEC adjudicated)
ILLUMINA study
24 months results: SAFETY

91.9%
ILLUMINA study
24 months results: EFFICACY

89.3%
83.4%
ILLUMINA study
24 months results: TLR

Freedom from TLR

FU duration (months)

93.1%
NiTiDES represents the first and only Sirolimus eluting self-expanding peripheral stent today available.

Although the ILLUMINA study included complex patients and complex lesions (2pts Rutherford 5, lesions up to 140mm and 55% of mod./ heavy calcifications), the study results at 24 months are remarkable:

- **SAFETY** → 91.9% Freedom from device related MAE confirms the long term excellent performance of the NiTiDES device.

- **EFFICACY** → 93.1% Freedom from TLR and 83.4% Primary Patency rate demonstrate that the high product efficacy is maintained over long time.

The ILLUMINA study results stand NiTiDES at the top of excellence in today peripheral DES scenario.
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