Stellarex ILLUMENATE  
First-in-Human Study  
24-Month Results of the Direct-DCB Cohort  
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AZ Sint Blasius, Dendermonde, Belgium  
On behalf of Marianne Brodmann, MD

Disclosure slide

☐ 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

ILLUMENATE FIH Study Overview

Principal Investigator: Dr. Henrik Schröder (Jewish Hospital, Berlin, Germany)  
Objective: Assess safety and efficacy of Stellarex DCB for the treatment of femoropopliteal disease

- Prospective, multicenter EU study  
- Independent Duplex Ultrasound Core Lab
- Independent Angiographic Core Lab
- Independent Clinical Events Committee  
- Monitoring with 100% source data verification

Study Device  
Stellarex™ Drug-coated Angioplasty Balloon

EnduraCoat™ Proprietary Coating Technology  
- Paclitaxel dose: 2 µg/mm² PFS, crystalline formulation  
- Excipient: PEG (polyethylene glycol) - Hydrophilic, non-toxic, widely proven from pharma and cosmetics applications

Arterial Pharmacokinetics

High transfer efficiency  
Effective Residency (≥ 28 days)

Key Eligibility Criteria

Key Inclusion Criteria

- Rutherford class 2, 3 or 4  
- SFA or Popliteal Artery (P1)  
- De novo or restenotic lesion(s) ≥ 3 cm and ≤ 15 cm  
- Target vessel reference diameter ≥ 3 mm and ≤ 7 mm  
- Target lesions can be treated with maximum of 2 Stellarex DCBs

Key Exclusion Criteria

- Acute or sub-acute thrombus in target vessel  
- Prior vasc. surgery of target lesion  
- Inadequate distal runoff  
- Significant inflow disease  
- GI bleeding or any coagulopathy contradicting the use of anti-platelet therapy  
- Use of adjunctive therapies (i.e. debulking or plaque incision)
Patient Characteristics
Similar to pre-dilatation cohort

<table>
<thead>
<tr>
<th></th>
<th>Direct Cohort</th>
<th>Pre-dilatation Cohort</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in Years</td>
<td>65.7 ± 8.1 (28)</td>
<td>69.0 ± 9.3 (50)</td>
<td>0.1209</td>
</tr>
<tr>
<td>Female</td>
<td>28.6% (8/28)</td>
<td>38.0% (19/50)</td>
<td>0.4636</td>
</tr>
<tr>
<td>Current Smoker</td>
<td>67.9% (19/28)</td>
<td>52.0% (26/50)</td>
<td>0.2335</td>
</tr>
<tr>
<td>Hypertension</td>
<td>85.7% (24/28)</td>
<td>90.0% (45/50)</td>
<td>0.7145</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>78.6% (22/28)</td>
<td>80.0% (40/50)</td>
<td>1.0000</td>
</tr>
<tr>
<td>Diabetes</td>
<td>53.6% (15/28)</td>
<td>34.0% (17/50)</td>
<td>0.1010</td>
</tr>
</tbody>
</table>

Lesion Characteristics
Similar to pre-dilatation cohort

<table>
<thead>
<tr>
<th>Lesions Treated (N)</th>
<th>Direct Cohort</th>
<th>Pre-dilatation Cohort</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesions Length (mm)</td>
<td>63.9 ± 35.5 (27)</td>
<td>72.1 ± 46.7 (58)</td>
<td>0.0833</td>
</tr>
<tr>
<td>Percent Stenosis (%)</td>
<td>69.5 ± 16.2 (27)</td>
<td>75.1 ± 17.0 (58)</td>
<td>0.1127</td>
</tr>
<tr>
<td>MLD (mm)</td>
<td>5.3 ± 2.6 (27)</td>
<td>5.7 ± 3.1 (58)</td>
<td>0.4588</td>
</tr>
<tr>
<td>Rutherford CC</td>
<td>21.4% (6/28)</td>
<td>12.0% (6/50)</td>
<td>0.4127</td>
</tr>
</tbody>
</table>

Procedure Characteristics

<table>
<thead>
<tr>
<th>Pre-dilation</th>
<th>Direct Cohort</th>
<th>Pre-dilatation Cohort</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of DCBs</td>
<td>1.5 per lesion</td>
<td>1.5 per lesion</td>
<td>N/A</td>
</tr>
<tr>
<td>Mean Inflation time</td>
<td>2.2 min/DCB</td>
<td>2.1 min/DCB</td>
<td>N/A</td>
</tr>
<tr>
<td>Post-Dilation</td>
<td>22.1% (13/59)</td>
<td>12.1% (7/58)</td>
<td>0.6999</td>
</tr>
</tbody>
</table>

Device Success

| Device Success
<table>
<thead>
<tr>
<th>Direct Cohort</th>
<th>Pre-dilatation Cohort</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>99.2% (33/33)</td>
<td>96.6% (56/58)</td>
<td>0.2042</td>
</tr>
</tbody>
</table>

Lesion Success

| Lesion Success
<table>
<thead>
<tr>
<th>Direct Cohort</th>
<th>Pre-dilatation Cohort</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% (37/37)</td>
<td>100% (58/58)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Freedom from TLR

85.4% at day 365
81.7% at day 730
90.0% at day 365
85.8% at day 730
P = 0.7103 (log-rank test)

Primary Patency

86.2% at day 365
78.2% at day 730

Data in Context: 3 DCB trials with Core Lab Adjudicated 2-Year Patency Data

1. Rosenfield et al. JNM 2015;373:145-53
2. Laurich C. Oral Presentation. SVS Chicago IL, 2015
**Functional Outcomes**

Sustained improvements demonstrated in both cohorts

<table>
<thead>
<tr>
<th>Change in Walking Distance Score</th>
<th>Ankle-Brachial Index</th>
</tr>
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<tbody>
<tr>
<td>6 months</td>
<td>12 months</td>
</tr>
<tr>
<td>4 months</td>
<td>12 months</td>
</tr>
<tr>
<td>2 months</td>
<td>12 months</td>
</tr>
<tr>
<td>0 months</td>
<td>12 months</td>
</tr>
</tbody>
</table>

- Pre-Dil Cohort
- Direct Cohort

**Case example:** Bilateral SFA disease treated with Stellarex (right) and POBA (left)

**Conclusions**

**ILLUMENATE FIH Direct Cohort**

- Direct cohort findings support durable outcomes observed in pre-dil cohort
  - Primary Patency at 24 months: 78.2%
  - Freedom from TLR at 24 months: 81.7%
- Pre-dilatation potential solution to reduce need for provisional stenting
- Robust cadence of clinical studies with pre-dilatation in progress
  - ILLUMENATE EU RCT, ILLUMENATE PK, ILLUMENATE Pivotal (US IDE Study), and ILLUMENATE Global Registry – enrollment complete