Update on the Value of the Chocolate Touch DCB incl. Results of the ENDURE Study

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Disclosures
Study support by BART, Bayer, BBraun, Biotronic, Gore, Phillips, Medtronic, Shockwave, Verian

Angioplasty with POBA

Key Unmet Challenge:
Acute Arterial Trauma produced by Conventional Balloons

Constrained expansion to reduce Acute Arterial Trauma

The Chocolate Solution

Chocolate Touch

Attributes
Nominal dose density of paclitaxel on Chocolate Touch is 3µg/mm², similar to other drug coated balloons
Unique excipient
20% more drug-coated surface compared to conventional balloons.
One step device, does not require pre-dilatation.
The ENDURE Trial: Chocolate Touch Feasibility Study

ENDURE Study Design

- Single or Tandem de novo lesion
- Total lesion length ≤ 150 mm
- RVD 4.5 – 6.0 mm
- Rutherford Grade 3-5

Clinical

- ATK: 30D 6MO 12MO
- DUS, QVA

Chocolate Touch Clinical Data

**ENDURE Study Design (Cont’d)**

- **4** Sites in Germany and NZ (single-arm study)
- **67** Total Patients Enrolled
- **70** Target Lesions

- Principal Investigators:
  - Dr. Thomas Zeller, Universitäts-Herzzentrum Freiburg-Bad Krozingen GmbH, Bad Krozingen, Germany
  - Dr. Andrew Holden, Auckland City Hospital, Auckland, New Zealand
  - Prof. Gunnar Tepe, Rosenheim Medical Center, Germany
  - Dr. Sebastian Sixt Hamburg University Cardiovascular Center, Germany

- Treatment Strategy:
  - No pre-dilatation is required
  - Single or tandem de novo lesion
  - Additional PTA balloon required if >30% residual stenosis / Type C or worse dissection
  - Bail-out stent permitted if >50% residual stenosis or flow-limiting dissection

Chocolate Touch Clinical Data

**ENDURE Study: Lesion Characteristics**

<table>
<thead>
<tr>
<th>Core Lab Adjudicated Data (N=70)</th>
<th>Minimum Lesion Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Dilatation Conducted 28.6% (16/56)</td>
<td>Pre-treatment (NoP): 31.8 mm ± 0.97</td>
</tr>
<tr>
<td>Superficial Femoral Artery 92.9% (65/70)</td>
<td>In lesion (NoP): 31.4 mm ± 0.97</td>
</tr>
<tr>
<td>Radial Artery 3.9% (5/70)</td>
<td>Post Treatment (NoP): 24.7 mm ± 0.57</td>
</tr>
<tr>
<td>None to Mild Calcification 45.7% (32/70)</td>
<td>Diameter 10.6% 8.1%</td>
</tr>
<tr>
<td>Severe Calcification 22.9% (16/70)</td>
<td>Total Occlusions 29.6% 25.4%</td>
</tr>
<tr>
<td>Severe Dissection 13% (15/70)</td>
<td>Short Occlusion 10.4% 6.9%</td>
</tr>
<tr>
<td>Lesion Length (Mean) 7.3cm (1.5 – 16.5cm)</td>
<td></td>
</tr>
<tr>
<td>% DS (N=69) 76.3% ± 19.1</td>
<td></td>
</tr>
<tr>
<td>Total Occlusions 33.3% (23/69)</td>
<td></td>
</tr>
<tr>
<td>Minimum Lumen Diameter 26.6% (19/70)</td>
<td></td>
</tr>
<tr>
<td>Pre-Dilatation Conducted 28.6% (16/56)</td>
<td></td>
</tr>
</tbody>
</table>

Chocolate Touch Clinical Data

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**ENDURE Study: Procedural Results**

Confirm high rates of procedural and device success with low rates of dissection (1.4%) and bail-out stenting (1.4%)

**ENDURE Study: Assessment of Clinical Improvement**

Patients treated with Chocolate Touch demonstrated material improvement in ABI and Rutherford Category

- **Average Change in ABI**
- **Average Change in Rutherford**

<table>
<thead>
<tr>
<th>Compared to Pre-Treatment</th>
<th>30 days (N=56)</th>
<th>6 months (N=46)</th>
<th>12 months (N=36)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Change in ABI</td>
<td>0.28 (0.2 to 1.2)</td>
<td>0.26 (0.1 to 1.1)</td>
<td>0.29 (0.1 to 1.3)</td>
</tr>
<tr>
<td>Average Change in Rutherford</td>
<td>-2.7 (-4.0 to 0.0)</td>
<td>-2.5 (-4.0 to 0.0)</td>
<td>-2.6 (-5.0 to 0.0)</td>
</tr>
</tbody>
</table>
**ENDURE Study: Major Adverse Events**

<table>
<thead>
<tr>
<th>Per Protocol</th>
<th>6 Months (Cumulative)</th>
<th>12 Months (Cumulative)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinically driven TLR</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Amputation</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>All-Cause Death</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total MAE</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

**ENDURE Study: Patency**

<table>
<thead>
<tr>
<th>Reported Rate</th>
<th>Kaplan Meier*</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 Months</td>
<td>88.8% (48/54)</td>
</tr>
<tr>
<td>12 Months</td>
<td>83.6% (46/55)</td>
</tr>
</tbody>
</table>

**Chocolate Touch Clinical Data**

**ENDURE Study Conclusions**

- Combination of Chocolate platform and paclitaxel-coating offers potential to avoid stents almost entirely.
- Achieved low residual diameter stenosis (similar to stents) and no flow limiting dissections, resulting in extremely low rate of per protocol bail-out stenting.
- Shows promising evidence of drug effect by way of low late lumen loss and high patency at 12 months.
- The constraining structure may have protective effect on the paclitaxel (to be evaluated in upcoming IDE Study).

**IDE Study Overview**

- **Design**: Randomized, Multi-center, Prospective, Adaptive Design
- **Patient Population**: Subjects with claudication or ischemic rest pain and an angiographically significant lesion in the superficial femoral or popliteal arteries
- **Enrollment**: 510 randomized subjects at up to 50 investigational sites
  - More than 50% of enrollment will occur in the U.S.
- **Randomization**: Subjects will be randomized 1:1 to Chocolate Touch or Lutonix
- **Duration**: 6 years: 1 year enrollment and 5 years of follow-up
- **Follow-up**:
  - 1, 6, 12, 24 and 36 Months: Clinical Assessment
  - 1, 6, 12, 24 and 36 Months: Duplex Ultrasound (DUS)
  - 48 and 60 months: Telephone Contact
- **Adaptive Design**:
  - Study success is defined as Non-Inferiority. Company can test and continue to enroll to show superiority.
  - Non-Inferiority Interim Analysis: 162 evaluable patients in each arm
    - If non-inferiority is achieved at interim analysis, data review by FDA can start
    - Superiority to Lutonix will be tested at interim analysis and final analysis.

**Chocolate Touch Clinical Data**

**IDE Study Overview**

- **Design**: Pivotal Study Design
- **Study has received IDE approval from FDA**
- **Sites in US, Germany, Austria, and NZ**
- **Total Patients Enrolled**: 120
  - **Patients Randomized**: 100
  - **Principal Investigators**:
    - Prof. Dr. Thomas Zeller, Universitäts-Herzzentrum Freiburg-Bad Krozingen GmbH, Bad Krozingen, Germany
    - Dr. Medhi Shishehbor, University Hospital Cleveland Medical Center, Cleveland, OH, USA

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