ABSORB III:
The Pivotal Approval Randomized Trial
of Bioabsorbable Scaffolds vs. Metallic DES in Coronary Artery Disease

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Disclosure Statement

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

Affiliation/Financial Relationship
- Consultant
- Study chairman (uncompensated)

Company
- Reva Corp.
- Abbott Vascular

Absorb BVS

- Everolimus/PDLLA (1:1) matrix coating
  - 7 µm
  - Conformal coating
  - Controlled drug release similar to Xience CoCr-EES

PLLA Backbone
- Semi-crystalline
- Circumferential sinusoidal rings connected by linear links
- Strut thickness 150 µm
- Platinum markers in each end ring

Phases of Absorb Functionality

- Revascularization
- Restoration
- Resorption


Healing and Scaffold Resorption

Karanasos A et al. Circulation. 2012;126:e89-e91

Lumen Enlargement Over Time with Absorb

Karanasos A et al. Circulation. 2012;126:e89-e91
Absorb Program Objectives

• Demonstrate similar (non-inferior) results with ABSORB BVS compared to Xience CoCr-EES at 1 year
• Demonstrate superior results compared to Xience CoCr-EES between 1 and 5 years

ABSORB III Study Design

Prospective, multicenter, single-blind, trial
~2,000 patients randomized
2:1 Absorb BVS vs. Xience CoCr-EES

Clinical follow-up:
30 d 6 mo 12 mo 24 mo 36 mo 48 mo 60 mo
No routine angiographic follow-up

Target Lesion Failure

Device Thrombosis to 1 Year

<table>
<thead>
<tr>
<th></th>
<th>Absorb (N=1322)</th>
<th>Xience (N=686)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Thrombosis (def*/prob)</td>
<td>1.54%</td>
<td>0.74%</td>
<td>0.13</td>
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<tr>
<td>- Early (0 to 30 days)</td>
<td>1.06%</td>
<td>0.73%</td>
<td>0.46</td>
</tr>
<tr>
<td>- Late (&gt; 30 to 1 year)</td>
<td>0.46%</td>
<td>0.00%</td>
<td>0.10</td>
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<tr>
<td>- Definite* (1 year)</td>
<td>1.38%</td>
<td>0.74%</td>
<td>0.21</td>
</tr>
<tr>
<td>- Probable (1 year)</td>
<td>0.15%</td>
<td>0.00%</td>
<td>0.55</td>
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*One “definite ST” in the Absorb arm by ITT was in a pt that was treated with Xience

Outcomes by QCA RVD 2.25 mm

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<tr>
<th>RVD &lt;2.25 mm</th>
<th>RVD ≥2.25 mm</th>
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<td>Median based on pooled Absorb and Xience</td>
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Summary and Conclusions

• The ABSORB III trial has demonstrated safety and efficacy of Absorb BVS at 1 year in patients with stable CAD and stabilized ACS when used in appropriate patients and lesions
• Longer term evaluation is ongoing to determine if ABSORB improves late outcomes compared to metallic DES