The 4-year Clinical Outcomes of the ABSORB II Trial: First Randomized Comparison between the Absorb Everolimus Eluting Bioresorbable Vascular Scaffold and the XIENCE Everolimus Eluting Stent

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on behalf of the ABSORB II Investigators
Presentor Disclosures

Bernard Chevalier was a Consultant for Abbott Vascular and is currently consultant for Biotronik, Colibri, Cordis, Medtronic, Terumo.

Patrick Serruys is a Member of the International Advisory Board of Abbott Vascular
**Study Objective**
Randomized against XIENCE control. First Patient In: 28-Nov-2011

**Co-primary Endpoints**
- 36 months
  - Vasomotion assessed by change in Mean Lumen Diameter between pre- and post-nitrate at 3 years (superiority)
  - Minimum Lumen Diameter (MLD) at 3 years post nitrate minus MLD post procedure post nitrate (non-inferiority, reflex to superiority)

**Treatment**
- Up to 2 *de novo* lesions in different epicardial vessels
- Planned overlapping allowed in lesions ≤ 48 mm

**Device Sizes**
- Device diameters: 2.5, 3.0, 3.5 mm
- Device lengths: 12 (3.5 mm diameter only), 18, 28 mm

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**Clinical Follow-Up**

<table>
<thead>
<tr>
<th>30d</th>
<th>6m</th>
<th>12m</th>
<th>24m</th>
<th>36m</th>
<th>48m</th>
<th>60m</th>
</tr>
</thead>
</table>

**QoL follow-up**

**Angio, IVUS follow-up**

**MSCT follow-up (Absorb arm only)**

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The ABSORB II study is sponsored by Abbott Vascular. [NCT01425281]
4-Year Patient Flowchart

Intent To Treat
N=501

Absorb BVS
N=335
- 7 withdrawal
- 4 death
- 3 withdrawal
- 1 LFU

XIENCE
N=166
- 1 death
- 2 withdrawal

Baseline

1-year
N=328
N=163
- 3 withdrawal
- 5 death, 1 LFU
- 2 MV

2-year
N=320
N=160

3-year
N=308*
N=152**
- 1 death,
- 2 MV, 1 withdrawal
- 11 no consent
- 3 still in study but missed 3yr FUP

4-year
N=289 (86%)
N=139 (84%)

At 4 years patients with missing visits (MV) were confirmed as alive and well by site PI.

20 patients did not sign protocol amendment for 4 & 5 year follow-up

311* and 154** patients still in the study but 5 missed 3 yr FUP

* and ** indicate patients still in the study but missed 3 yr FUP
Device oriented Composite Endpoint (DOCE)/Target Lesion Failure (TLF)

DoCE/TLF: Cardiac death, target-vessel myocardial infarction, and clinically indicated target-lesion revascularisation (TLR)

HR [95% CI]=[2.04 [0.98, 4.24]  
\[ p=0.050 \text{ (Log rank test)} \]

Δ=0.3%
Patient oriented Composite Endpoint (PoCE)/DMR

**Overall Endpoint:**

- **HR [95% CI]** = 0.90 [0.61, 1.33]
- **p** = 0.60 (Log rank test)

**Four Year Outcome:**

- **BVS**
  - 0% at 0 days
  - 22.9% at 180 days
  - HR [95% CI] = 0.90 [0.61, 1.33]
  - p = 0.60 (Log rank test)

- **XIENCE**
  - 0% at 0 days
  - 24.9% at 180 days
  - HR [95% CI] = 3.14 [0.71, 13.93]
  - p = 0.11 (Log rank test)

**Delta (Δ):**

- **BVS vs. XIENCE**
  - Δ = 2.9%

**Legend:**

- BVS
- XIENCE

**Note:**

PoCE = DMR: All Death, all Myocardial infarction, and all Revascularisation
Clinical Outcomes Non Hierarchical Events

<table>
<thead>
<tr>
<th></th>
<th>3-4 years</th>
<th></th>
<th></th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Absorb BVS</td>
<td>XIENCE</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N=335</td>
<td>N=166</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death* n(%)</td>
<td>2(0.7)</td>
<td>1(0.7)</td>
<td>1.0000</td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>1(0.3)</td>
<td>1(0.7)</td>
<td>0.5408</td>
<td></td>
</tr>
<tr>
<td>Vascular</td>
<td>0(0.0)</td>
<td>0(0.0)</td>
<td>1.0000</td>
<td></td>
</tr>
<tr>
<td>Non-cardiovascular</td>
<td>1(0.3)</td>
<td>0(0.0)</td>
<td>1.0000</td>
<td></td>
</tr>
<tr>
<td>Myocardial Infarction n(%)</td>
<td>1(0.3)</td>
<td>0(0.0)</td>
<td>1.0000</td>
<td></td>
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<tr>
<td>Q-wave</td>
<td>0(0.0)</td>
<td>0(0.0)</td>
<td>1.0000</td>
<td></td>
</tr>
<tr>
<td>Non Q-wave</td>
<td>1(0.3)</td>
<td>0(0.0)</td>
<td>1.0000</td>
<td></td>
</tr>
<tr>
<td>All Revascularization* n(%)</td>
<td>10(3.3)</td>
<td>1(0.7)</td>
<td>0.1142</td>
<td></td>
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<tr>
<td>All TLR</td>
<td>2(0.7)</td>
<td>0(0.0)</td>
<td>1.0000</td>
<td></td>
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<tr>
<td>All NTL-TVR</td>
<td>4(1.3)</td>
<td>0(0.0)</td>
<td>0.3102</td>
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<tr>
<td>All NTVR</td>
<td>6(2.0)</td>
<td>1(0.7)</td>
<td>0.4373</td>
<td></td>
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</tbody>
</table>

*Per ARC. Cutlip et al., Circulation. 2007;115:2344-2351
Definite/Probable Scaffold/Stent Thrombosis*

- BVS
- HR [95% CI] = NA [NA]
- p = 0.033 (Log rank test)

- XIENCE
- HR [95% CI] = NA [NA]
- p = (Log rank test)

No stent/scaffold thrombosis between 3 and 4 years

*Per ARC. Cutlip et al., Circulation. 2007;115:2344-2351
# Post-Procedure Usage of Antiplatelet Medication through 4 years

<table>
<thead>
<tr>
<th></th>
<th>Absorb BVS N=335</th>
<th>XIENCE N=166</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>On Aspirin (%)</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>at 1 year</td>
<td>95.8</td>
<td>95.2</td>
<td>0.7473</td>
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<tr>
<td>at 4 years</td>
<td>84.4</td>
<td>81.3</td>
<td>0.3794</td>
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<tr>
<td><strong>On DAPT (%)</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>at 1 year</td>
<td>81.0</td>
<td>80.7</td>
<td>0.9357</td>
</tr>
<tr>
<td>at 2 years</td>
<td>28.6</td>
<td>28.9</td>
<td>0.9442</td>
</tr>
<tr>
<td>at 3 years</td>
<td>29.8</td>
<td>27.7</td>
<td>0.6254</td>
</tr>
<tr>
<td>at 4 years</td>
<td>25.9</td>
<td>21.1</td>
<td>0.2372</td>
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Limitations

• The ABSORB II study was not powered for clinical endpoints

• Patients in the ABSORB II Study were enrolled before the current recommendations for scaffold implantation
Conclusions

• The Absorb scaffold polymer has been reported to be completely bio-resorbed by 3 years. Between 3 and 4 years follow up
  – there were no ST events in the Absorb arm
  – DOCE/TLF events were similar between Absorb and Xience

• In a trial which was not powered for clinical events, at 4 years there were no statistically significant differences in the clinical outcomes between the two arms:
  – PoCE (all death, all MI and all revascularization)
    Absorb BVS: 23.6% vs XIENCE: 26.7%, p=0.47
  – DoCE/TLF (cardiac death, TV-MI and TLR)
    Absorb BVS: 11.5% vs XIENCE: 6.0%, p=0.06

• The exploratory observations presented in this report are hypothesis generating and need to be confirmed in larger randomized trials such as ABSORB III and ABSORB IV
Title: Four-year follow-up of the randomised comparison between an everolimus-eluting bioresorbable scaffold and an everolimus-eluting metallic stent for the treatment of coronary artery stenosis (ABSORB II trial).

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