The Abbott Vascular BVS Program
A Fully Bioresorbable Vascular Scaffold
Bioresorbable Scaffold – Rationale and Goals

**Rationale:** Vessel scaffolding is only needed transiently*

**Goal:** Revascularize the vessel like a metallic DES, then resorb naturally into the body.

**Potential benefits:**

- Restoration of natural physiologic vasomotor function in some patients
- Elimination of chronic sources of vessel irritation and sources for chronic inflammation
- Possibly avoid current challenges with leaving a metal implant behind
- Potentially reduce the need for prolonged DAPT
- No permanent implant to complicate future interventions and re-interventions, particularly in younger patients
- Non-invasive imaging with MSCT or MRA without ‘blooming artifact’

*Serruys PW, et al., *Circulation* 1988; 77: 361. Serial study suggesting vessels stabilize 3-4 months following PTCA.*
## Abbott Vascular Everolimus-Eluting Bioresorbable Vascular Scaffold Components

<table>
<thead>
<tr>
<th>ML VISION Delivery System</th>
<th>Bioresorbable Scaffold</th>
<th>Bioresorbable Coating</th>
<th>Everolimus</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Seven generations of MULTI-LINK success</td>
<td>• Polylactide (PLLA)</td>
<td>• Polylactide (PDLLA) coating</td>
<td>• Similar dose density and release rate to XIENCE V</td>
</tr>
<tr>
<td>• World-class deliverability</td>
<td>• Naturally resorbed, fully metabolized</td>
<td>• Fully biodegradable</td>
<td></td>
</tr>
</tbody>
</table>

All illustrations are artists’ renditions

Bioresorbable Polymer

**Everolimus/PDLLA Matrix Coating**
- Thin coating layer
- Amorphous (non-crystalline)
- 1:1 ratio of Everolimus/PLA matrix
- Conformal Coating, 2-4 μm thick
- Controlled drug release

**PLLA Scaffold**
- Highly crystalline
- Provides device integrity
- Processed for increased radial strength
Polylactide Degradation by Hydrolysis

• Primary mode of degradation is by hydrolysis of ester bonds

• Water preferentially penetrates amorphous regions of the polymer matrix

• Hydrolysis initially results in a loss of molecular weight, but not radial strength, as the strength comes from crystalline domains

• Once crystalline domains are hydrolyzed, there is mass loss

Polylactide Degradation & Lactate Metabolism

Lactate Shuttle
Lactate serves as a carbohydrate fuel source for multiple metabolic pathways


© 2010 Abbott Laboratories
Porcine Coronary Artery: Representative Photomicrographs (2x)

BVS Cohort A

1 month | 6 months | 1 year | 2 years | 3 years | 4 years

Photos taken by and on file at Abbott Vascular.

CYPHER

1 month | 6 months | 1 year | 2 years | 3 years | 4 years

Tests performed by and data on file at Abbott Vascular.

Vascular Response to BVS at 2, 3 & 4 years: Arterial Integration and Accommodation

- Mass loss data suggests 100% of material mass has been lost at 2 years
- The shape of struts is still apparent at 2 years, although the device is fully resorbed
- No inflammation around the pre-existing strut regions
- 3 years: struts fully replaced by tissue
- 4 years: sites of pre-existing struts are indiscernible

Photos taken by and on file at Abbott Vascular.

Tests performed by and data on file at Abbott Vascular.
What is Required of a Fully Bioresorbable Scaffold to Fulfill the Desire for ‘Vascular Restoration Therapy’?


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What is Required of a Fully Bioresorbable Scaffold to Fulfill the Desire for ‘Vascular Restoration Therapy’?

<table>
<thead>
<tr>
<th>Revascularization</th>
<th>Restoration</th>
<th>Resorption</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 3 months</td>
<td>3 to ~6-9 months +</td>
<td>~9 months +</td>
</tr>
<tr>
<td>Performance should mimic that of a standard DES</td>
<td>Transition from scaffolding to discontinuous structure</td>
<td>Implant is discontinuous and inert</td>
</tr>
<tr>
<td>- Good deliverability</td>
<td>- Gradually lose radial strength</td>
<td>- Resorb in a benign fashion</td>
</tr>
<tr>
<td>- Minimum of acute recoil</td>
<td>- Struts must be incorporated into the vessel wall (strut coverage)</td>
<td></td>
</tr>
<tr>
<td>- High acute radial strength</td>
<td>- Become structurally discontinuous</td>
<td></td>
</tr>
<tr>
<td>- Controlled delivery of drug to abluminal tissue</td>
<td>- Allow the vessel to respond naturally to physiological stimuli</td>
<td></td>
</tr>
<tr>
<td>- Excellent conformability</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Radial Strength

Tests performed by and data on file at Abbott Vascular.

* Agrawal, et al., Biomaterials 1992

Vessel Spasm Force ~175 mmHg*

Radial strength comparable to metal stent at T=0

Agrawal, et al., Biomaterials 1992

Tests performed by and data on file at Abbott Vascular.

What is the Minimum Duration of Radial Support?

Quantitative angiographic study in 342 consecutive patients at 1, 2, 3, and 4 months

$n = 342$ patients ($n = 93$ at 30-day F/U; $n = 79$ at 60-day F/U; $n = 82$ at 90-day F/U; $n = 88$ at 120-day F/U)

The lumen appears to stabilize **approximately three months** after PTCA.

Tests performed by and data on file at Abbott Vascular – in-vitro degradation testing (soaked at 37°C PBS).

Importance of Respecting Natural Vessel Curvature

Stiff Metal Stents

Pre Stent

Post Stent

Long-term flow disturbances and chronic irritation can contribute to adverse events

BVS (Cohort B case)

Pre BVS

Post BVS

Serruys, P., TCT 2009

91°

88°

BVS appears to maintain natural vessel curvature at implantation; long-term, scaffold is fully resorbed

Potential for Mechanical Conditioning

Design Goals:

Gradual disappearance of supportive scaffold

Vessel recovers the ability to respond to physiologic stimuli

Shear stress & pulsatility

Tissue adaptation

Structure and functionality

Mechanical conditioning may lead to improved cellular organization and vascular function

‘Vascular Restoration Therapy’
Mechanical Conditioning in Pre-Clinical Model (Porcine)

Transmission Electron Microscopy (TEM)

<table>
<thead>
<tr>
<th>Neointima</th>
<th>Media</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Month</td>
<td></td>
</tr>
<tr>
<td>36 Month</td>
<td></td>
</tr>
</tbody>
</table>

Smooth Muscle $\alpha$-Actin

Dense bodies

At 36 months, SMCs are well organized and have undergone transformation to a functional, contractile phenotype

Tests were performed by and data are on file at Abbott Vascular.

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First In Man Clinical Trial

Cohort A: 30 patients enrolled March – July 2006
Cohort B: 101 patients enrolled March – November 2009
ABSORB Cohort A

- N = 30; 6 sites* (Europe, New Zealand)

- Clinical follow-up schedule:
  - 30 days, 6 months, 12 months, annually to 5 years

- Imaging schedule:

<table>
<thead>
<tr>
<th>QCA, IVUS, OCT, IVUS VH</th>
<th>Baseline</th>
<th>6 Months</th>
<th>18 Months</th>
<th>24 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSCT (optional)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Patients were enrolled in only 4 of 6 sites

Derived from Serruys, PW., AHA 2009.
ABSORB Cohort A
Clinical Study Overall Population

Intent to treat

30 patients

- 6-month follow-up
  - 30 patients clinical
    - n = 1 missed F/U visits*

Per treatment

26 patients QCA

- 2 & 3-year follow-up
  - 29 patients clinical
    - n = 4 excluded in Per Treatment Population (3 received non-BVS stent, 1 device failure)
  - 19 patients QCA/IVUS
    - n = 1 missed F/U visits*
    - n = 1 non-cardiac death**
    - n = 5 refused angiography

*One patient missed the 9, 12, 18 month and 2 year visits
**Two patients died of non-cardiac causes at 706 and 888 days

Serruys, PW., AHA 2009.
# ABSORB Cohort A

## Clinical Results – Intent to treat

<table>
<thead>
<tr>
<th>Hierarchical</th>
<th>6 Months</th>
<th>12 Months</th>
<th>24 Months</th>
<th>36 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>30 Patients</td>
<td>29 Patients*</td>
<td>29 Patients*</td>
<td>29 Patients*</td>
</tr>
<tr>
<td>Ischemia Driven MACE</td>
<td>1 (3.3%)**</td>
<td>1 (3.4%)**</td>
<td>1 (3.4%)**</td>
<td>1 (3.4%)**</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>MI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q-Wave MI</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Non Q-Wave MI</td>
<td>1 (3.3%)**</td>
<td>1 (3.4%)**</td>
<td>1 (3.4%)**</td>
<td>1 (3.4%)**</td>
</tr>
<tr>
<td>Ischemia Driven TLR by PCI</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>by CABG</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>

## No new MACE between 6 and 36 months

## No thrombosis up to 3 years

(only one patient on clopidogrel)

*One patient withdrew consent and missed the 9, 12, 18 month and 2 and 3 year visits but the vital status of the patient and absence of cardiac event is known through the referring physician.

**This patient also underwent a TLR, not qualified as ID-TLR (DS = 42%) followed by post-procedural troponin qualified as non-Q MI and died from his Hodgkin’s disease at 888 days post-procedure.

Serruys, PW., AHA 2009.

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ABSORB Cohort A OCT Images – Baseline, 6 months and 2 years

Serruys, PW., ESC 2008.

ABSORB Cohort A
Side Branch Preservation by Angio, OFDI and OCT

Baseline
M2 1.0 mm/s

6 Month Follow Up
M3 1.0 mm/s

2 Year Follow Up
C7 20 mm/s

Serruys, PW., CCT 2010.

ABSORB Cohort A
Temporal Lumen Dimensional Changes, Per Treatment

Late lumen loss at 6 months mainly due to reduction in scaffold area

Very late lumen enlargement noted from 6 months to 2 years

The reappearance of vasomotion in the proximal, distal, as well as treated segments in response to methergin or acetylcholine suggests that vessel vasoreactivity has been restored and that a physiological response to vasoactive stimulus might occur anew.

BVS Device Optimization Objectives

• More uniform strut distribution
• More even support of arterial wall
• Lower late scaffold area loss
  – Maintain radial strength for at least 3 months
• Storage at room temperature
• Improved device retention
• Unchanged:
  – Material, coating and backbone
  – Strut thickness
  – Drug release profile
  – Total degradation Time

Photos taken by and on file at Abbott Vascular.
ABSORB Cohort B
Clinical Study Design

• Sponsor: Abbott Vascular
• Primary Investigators:
  – PW Serruys MD, PhD
  – J Ormiston MD
• DSMB: J Tijssen PhD, M Wiemer MD, P Urban MD
• CEC: C Hanet MD, R Tölg MD, V Umans MD
• Angiographic and IVUS Corelab: Cardialysis (Rotterdam, NL)

• Prospective, open label, FIM
• 3.0 x 18mm devices to treat lesion ≤ 14mm in length
• 12 sites Europe, Australia, New Zealand
• 101 patients enrolled between 19 March and 6 November 2009
• Group 1: 45 patients with imaging FUP at 180 days and 2 years
• Group 2: 56 patients with imaging FUP at 1 year and 2 years
ABSORB Cohort B

- N = 101; 12 sites (Europe, Australia, New Zealand)

- Clinical follow-up schedule:
  - 30 days, 6 months, 12 months, annually to 5 years

- Imaging schedule:

<table>
<thead>
<tr>
<th></th>
<th>Group 1 (n = 45)</th>
<th>Group 2 (n = 56)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>QCA, IVUS, OCT, IVUS VH</strong></td>
<td>Baseline</td>
<td>6 Months</td>
</tr>
<tr>
<td>MSCT (optional)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
ABSORB Cohort B Clinical Sites

12 Clinical Investigative Sites (Europe, New Zealand, Australia)

Netherlands (3):
- P. Serruys
- J. Koolen
- P. Smits

Poland (1):
- D. Dudek

France (1):
- B. Chevalier

Belgium (1):
- B. de Bruyne

Denmark (1):
- L. Thuesen

Switzerland (1):
- S. Windecker

New Zealand (2):
- J. Ormiston
- D. McClean

Australia (2):
- I. Meredith
- R. Whitbourn

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ABSORB Cohort B
Clinical/QCA/IVUS Patient Inclusion (Group 1)

- **45 patients**
- **6 months Clinical**
  - n = 3, ANGIO/IVUS not done

- **42 patients**
- **6 months QCA**
  - n = 1, IVUS could not reach the lesion
  - n = 1, no continuous pullback

- **40 patients**
- **6 months IVUS**

Serruys, PW., PCR 2010.
## Baseline Demographics (Group 1)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (%)</td>
<td>73</td>
</tr>
<tr>
<td>Mean age (years)</td>
<td>65</td>
</tr>
<tr>
<td>Previous MI (%)</td>
<td>36</td>
</tr>
<tr>
<td>Prior Cardiac Intervention on Target Vessel (%)</td>
<td>9</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>13</td>
</tr>
<tr>
<td>Hypercholesterolemia req. med. (%)</td>
<td>93</td>
</tr>
<tr>
<td>Hypertension req. med. (%)</td>
<td>60</td>
</tr>
<tr>
<td>Current smoker (%)</td>
<td>11</td>
</tr>
</tbody>
</table>

**ABSORB Cohort B**

**Baseline Lesion Characteristics/Acute Success**

<table>
<thead>
<tr>
<th>Group 1</th>
<th>N = 45</th>
</tr>
</thead>
<tbody>
<tr>
<td>N_Lesions = 45</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Location of lesion (%)</th>
<th>38</th>
<th>36</th>
<th>24</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LCX</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ramus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lesion classification (%)</th>
<th>2</th>
<th>45</th>
<th>50</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Clinical Device success (%) | 100 |
| Clinical Procedure success (%) | 98 |

**Clinical Device Success** = Successful delivery & deployment of the BVS at intended target lesion & successful withdrawal of the BVS delivery system w/ attainment of final residual stenosis of less than 50% of the target lesion by QCA (by visual estimation if QCA unavailable). Standard pre-dilation catheters & post-dilation catheters (if applicable) may be used. Bailout patients will be included as device success only if the above criteria for clinical device are met.

**Clinical Procedure Success** = Same as definition above and/or using any adjunctive device without occurrence of ischemia driven major adverse cardiac event (MACE) during the hospital stay w/ a maximum of first seven days post index procedure.

# ABSORB Cohort B
Clinical Results - Intent to treat (Group 1)

<table>
<thead>
<tr>
<th></th>
<th>30 Days N = 45</th>
<th>6 Months N = 45</th>
<th>9 Months N = 45</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-Hierarchical</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac Death (%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Myocardial Infarction n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q-wave MI</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Non Q-wave MI</td>
<td>1 (2.2)</td>
<td>1 (2.2)</td>
<td>1 (2.2)</td>
</tr>
<tr>
<td>Ischemia Driven TLR n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCI</td>
<td>0</td>
<td>1 (2.2)</td>
<td>1 (2.2)</td>
</tr>
<tr>
<td>CABG</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hierarchical MACE n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCI</td>
<td>0</td>
<td>1 (2.2)</td>
<td>1 (2.2)</td>
</tr>
<tr>
<td>CABG</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hierarchical TLF n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCI</td>
<td>0</td>
<td>1 (2.2)</td>
<td>1 (2.2)</td>
</tr>
<tr>
<td>CABG</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

No thrombosis by ARC or Protocol

MACE: cardiac death, MI, ischemia-driven TLR
TLF: cardiac death, MI, ischemia-driven TLR, ischemia-driven TVR

Ormiston, J., TCT 2010.
### ABSORB Cohort B

#### Angiographic Results (Group 1)

<table>
<thead>
<tr>
<th></th>
<th>Pre-Procedural</th>
<th>Post-Procedural</th>
<th>6 Months Follow-Up**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Length (mm)</td>
<td>10.24</td>
<td>2.32</td>
<td>2.13</td>
</tr>
<tr>
<td>RVD (mm)</td>
<td>2.65</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MLD (mm)</td>
<td>1.06</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DS (%)</td>
<td>60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-Scaffold Acute Gain* (mm)</td>
<td>1.26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-Scaffold MLD (mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-Scaffold DS (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-Scaffold Late Loss (mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-Scaffold ABR (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* N = 44 Lesions

** N = 42 Lesions

ABSORB Cohort B
6-Month QCA – Intent to Treat (Group 1)

Cumulative Incidence Curve for Late Loss

-0.5 0 0.5 1 1.5 2
In-Stent Late-Loss (mm)

% Patients

- Negative Loss

0.10 ± 0.23 mm
0.19 ± 0.18 mm
0.43 ± 0.37 mm
0.85 ± 0.36 mm

BVS Cohort A (N = 26)
BVS Cohort B (N = 42)
EES* (N = 23)
BMS* (N = 27)

*SPIRIT-First

## ABSORB Cohort B
### IVUS Results (Group 1)

<table>
<thead>
<tr>
<th></th>
<th>Post-Procedure</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 40</td>
<td>N = 40</td>
</tr>
<tr>
<td></td>
<td>N_{Lesions} = 40</td>
<td>N_{Lesions} = 40</td>
</tr>
<tr>
<td>Vessel Volume (mm(^3))</td>
<td>291</td>
<td>275</td>
</tr>
<tr>
<td>Scaffold Volume (mm(^3))</td>
<td>133</td>
<td>122</td>
</tr>
<tr>
<td>Plaque behind the scaffold Volume (mm(^3))</td>
<td>158</td>
<td>153</td>
</tr>
<tr>
<td>Vessel (EEM) Area (mm(^2))</td>
<td>14.35</td>
<td>14.46</td>
</tr>
<tr>
<td>Lumen Area (mm(^2))</td>
<td>6.60</td>
<td>6.36</td>
</tr>
<tr>
<td>Minimal Lumen Area (mm(^2))</td>
<td>5.50</td>
<td>5.15</td>
</tr>
<tr>
<td>Plaque Area (mm(^2))</td>
<td>7.75</td>
<td>8.11</td>
</tr>
</tbody>
</table>

Serruys, PW., PCR 2010.
## ABSORB Cohort B
### IVUS Results – Paired Analysis (Group 1)

<table>
<thead>
<tr>
<th>Metric</th>
<th>Intent-to-treat (n=37)</th>
<th>Post PCI</th>
<th>6 Months</th>
<th>% Difference</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Vessel Area (mm²)</td>
<td></td>
<td>14.2</td>
<td>14.5</td>
<td>2.4</td>
<td>0.06</td>
</tr>
<tr>
<td>Mean Scaffold Area (mm²)</td>
<td></td>
<td>6.58</td>
<td>6.44</td>
<td>-2.0</td>
<td>&lt;0.02</td>
</tr>
<tr>
<td>Minimum Scaffold Area (mm²)</td>
<td></td>
<td>5.51</td>
<td>5.24</td>
<td>-4.6</td>
<td>0.001</td>
</tr>
<tr>
<td>Neointimal Hyperplasia Area (mm²)</td>
<td></td>
<td>-</td>
<td>0.08</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>Minimum Lumen Area (mm²)</td>
<td></td>
<td>5.49</td>
<td>5.17</td>
<td>-5.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>% Lumen Area stenosis</td>
<td></td>
<td>17</td>
<td>19</td>
<td>15</td>
<td>0.24</td>
</tr>
</tbody>
</table>

Serruys, PW., PCR 2010.
# ABSORB Cohort B

## OCT Results – Paired Analysis (Group 1)

<table>
<thead>
<tr>
<th></th>
<th>Intent-to-treat (n=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Post PCI</td>
</tr>
<tr>
<td>Mean Scaffold Area (mm²)</td>
<td>7.53</td>
</tr>
<tr>
<td>Minimum Scaffold Area (mm²)</td>
<td>6.31</td>
</tr>
<tr>
<td>Mean Neointimal Area (mm²)</td>
<td>NA</td>
</tr>
<tr>
<td>Mean Flow Area (mm²)</td>
<td>6.79</td>
</tr>
<tr>
<td>% Area Stenosis</td>
<td>19</td>
</tr>
<tr>
<td>% Uncovered Struts</td>
<td>-</td>
</tr>
<tr>
<td>Incomplete Strut Apposition Area (mm²)</td>
<td>0.19 (n=12)</td>
</tr>
</tbody>
</table>

Serruys, PW., PCR 2010.
ABSORB Cohort B
Representative OCT Images (Group 1)

Serruys, PW., CCT 2010.
ABSORB Extend

- **N = up to 1,000 patients at up to 100 sites (Europe, Australia, New Zealand, Latin America, Asia)**

- **Device sizes:**
  - 2.5 x 18 mm
  - 2.5 x 28 mm *(overlap of two 18 mm long devices also permitted)*
  - 3.0 x 18 mm
  - 3.0 x 28 mm

- **Lesion length treatable: ≤ 28 mm**

- **Clinical follow up:**
  - ID-MACE, ID-TVF, ID-TLR, ID-TVR, 'stent' thrombosis
  - 30 days, 6 months, and annually 1-3 years

- **Angiography, IVUS and OCT follow up:**
  - Subgroup of patients at selected investigational sites who receive planned overlapping BVS scaffolds to treat long lesions
Summary

• Results from ABSORB Cohort A continue to be encouraging, with only one MACE and no thrombosis through 3 years of follow up

• ABSORB Cohort B has demonstrated a low incidence of adverse events, no thrombosis, and metallic DES-like angiographic late loss at 6 months follow up

• ABSORB EXTEND is aimed at building a body of scientific data to support this revolutionary technology

• If fully bioresorbable technology permits restoration of natural vascular integrity and function, it may provide unique physiologic benefits to patients

• In the future, ‘Vascular Restoration Therapy’ could provide greater durability of results following PCI, a concept that must be tested in future trials