Potential conflicts of interest

Speaker's name: Stefan Verheye

☐ **I have the following** potential conflicts of interest to report:

- ☐ Research contracts
- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

X ***I do not have any potential conflict of interest***

DESolve™ Myolimus Eluting Bioresorbable Coronary Scaffold First-in-Man Trial

6-month Imaging and Clinical Results

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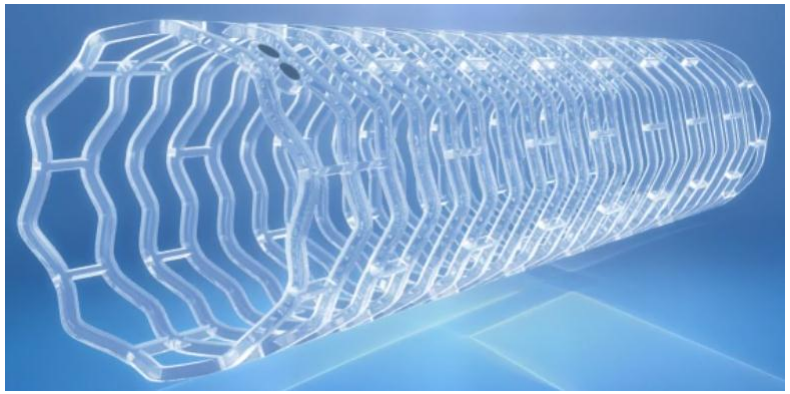
DESolve™ Bioresorbable Coronary Scaffold

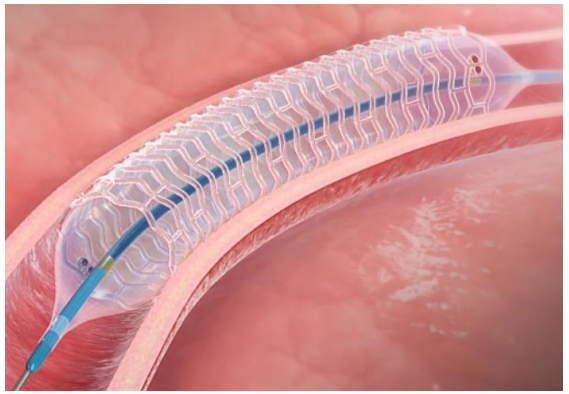
Taking advanced technologies from Elixir's DES platforms …

- Excellent radial strength
- Low recoil
- Drug release to provide sustained neointimal inhibition
- Low drug dose

… and incorporating them into a scaffold that bioresorbs over 1 – 2 years

- PLLA-based polymer with excellent durability and flexibility
- Proven biocompatibility
- Proprietary fabrication and processing technology
- Broad range of sizes
  - 3.0, 3.25, and 3.5 mm diameters
  - 2.5, 2.75, and 3.75 available soon
  - 14 and 18 mm lengths



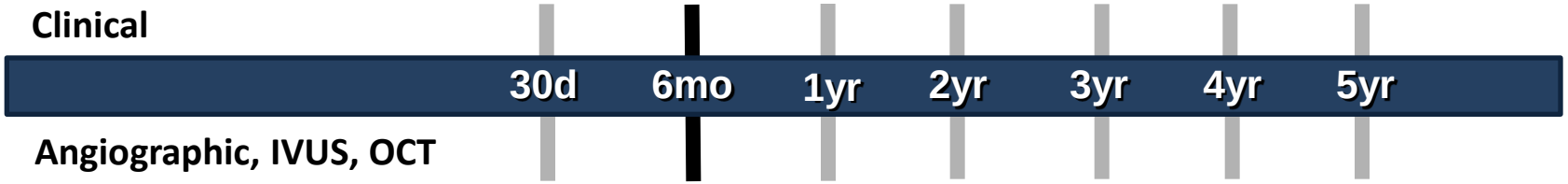


DESolve FIM Study Design

Single, *de novo* coronary artery lesions
reference vessel diameter: 3.0mm
lesion length: ≤10mm, DAPT 12 months
Myolimus 3mcg/mm

↓

3 sites
16 patients enrolled
Belgium and New Zealand



Principal Imaging Endpoint:

- **6-month in-stent late lumen loss**

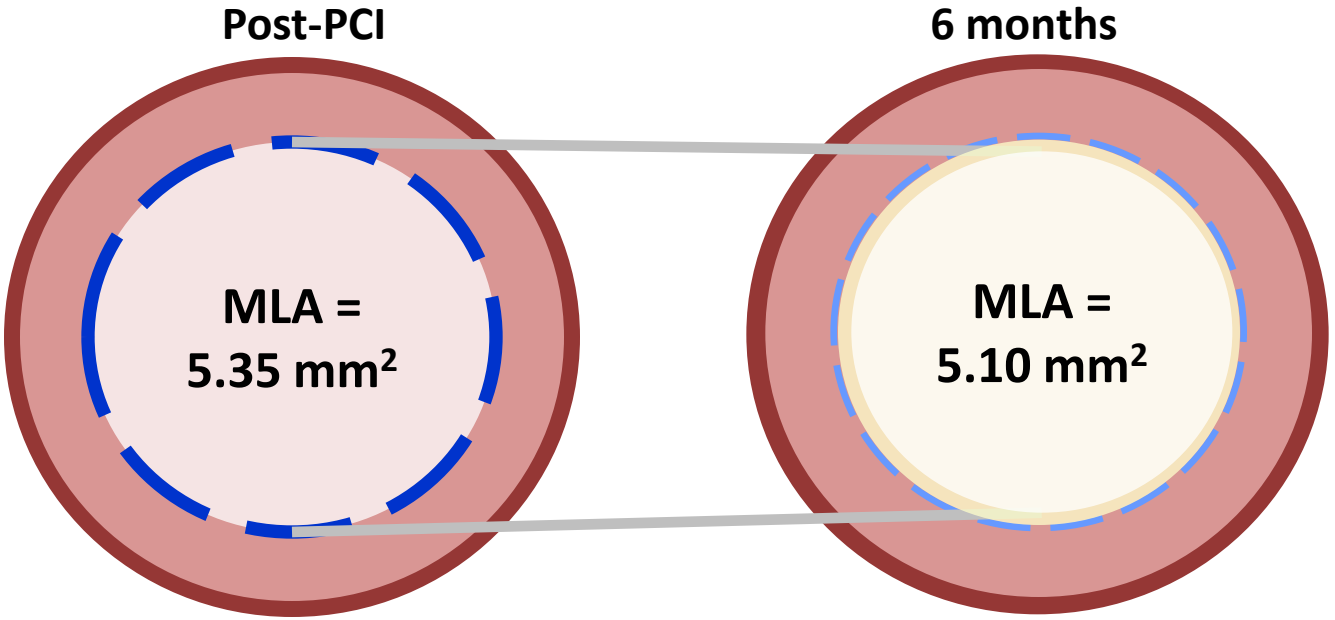
Key Endpoints

- **Clinical:** Major adverse cardiac events (cardiac death, target vessel MI, and clinically indicated TLR), and stent thrombosis
- **QCA:** In-segment late lumen loss, binary restenosis, and percent diameter stenosis
- **IVUS:** In-stent percent volume obstruction
- **OCT:** Descriptive and quantitative analysis of lesion/vessel morphometry and scaffold strut composition
- **MSCT:** 12 and 24-month descriptive and quantitative analysis of lesion/vessel morphology

Angiographic Results

In-scaffold Analysis	n=14 (paired)
RVD (mm)	
post-procedure	2.84 ± 0.23
at 6 months	2.78 ± 0.27
MLD (mm)	
post-procedure	2.60 ± 0.19
at 6 months	2.41 ± 0.28
% Diameter Stenosis	
post procedure	8.05 ± 7.90
at 6 months	12.63 ± 11.37
Acute Recoil (%)	6.4 ± 4.6
Late Lumen Loss (mm) at 6 months	0.19 ± 0.19
Binary Restenosis (%) at 6 months	0.0

DESolve FIM: IVUS Results



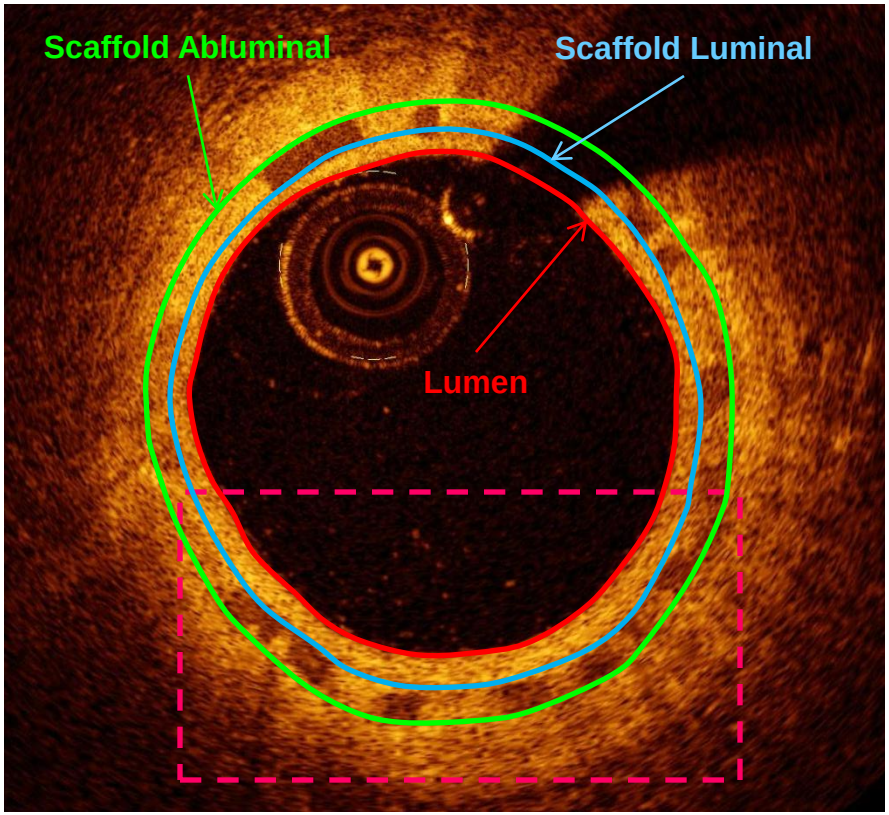
n=11 (paired)

In-scaffold Serial Analysis	Post-procedure	6 months
Mean Scaffold Area (mm^2)	5.35 ± 0.78	5.61 ± 0.81*
Mean Lumen Area (mm^2)	5.35 ± 0.78	5.10 ± 0.78*
% Volume Obstruction at 6 months	--	7.18 ± 3.37
Malapposition (%)	0	0

*p=ns between baseline and follow-up

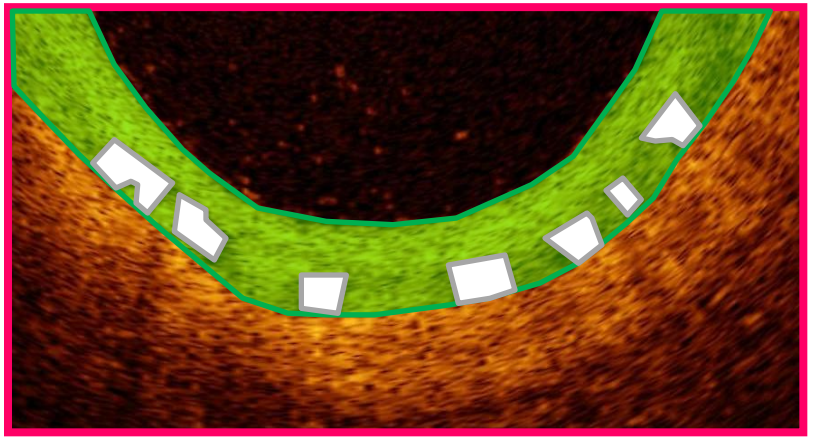
DESolve FIM: Methodology OCT Analysis

6-month Follow-Up



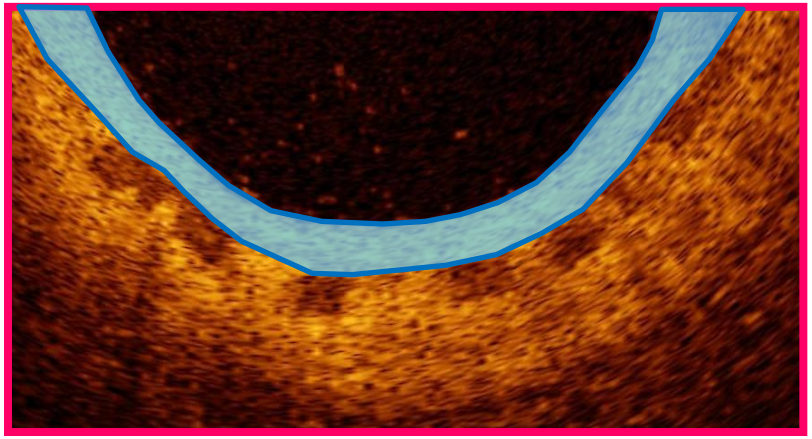
Total NIH

[Scaffold Abluminal – (Strut Core + Lumen Area)]



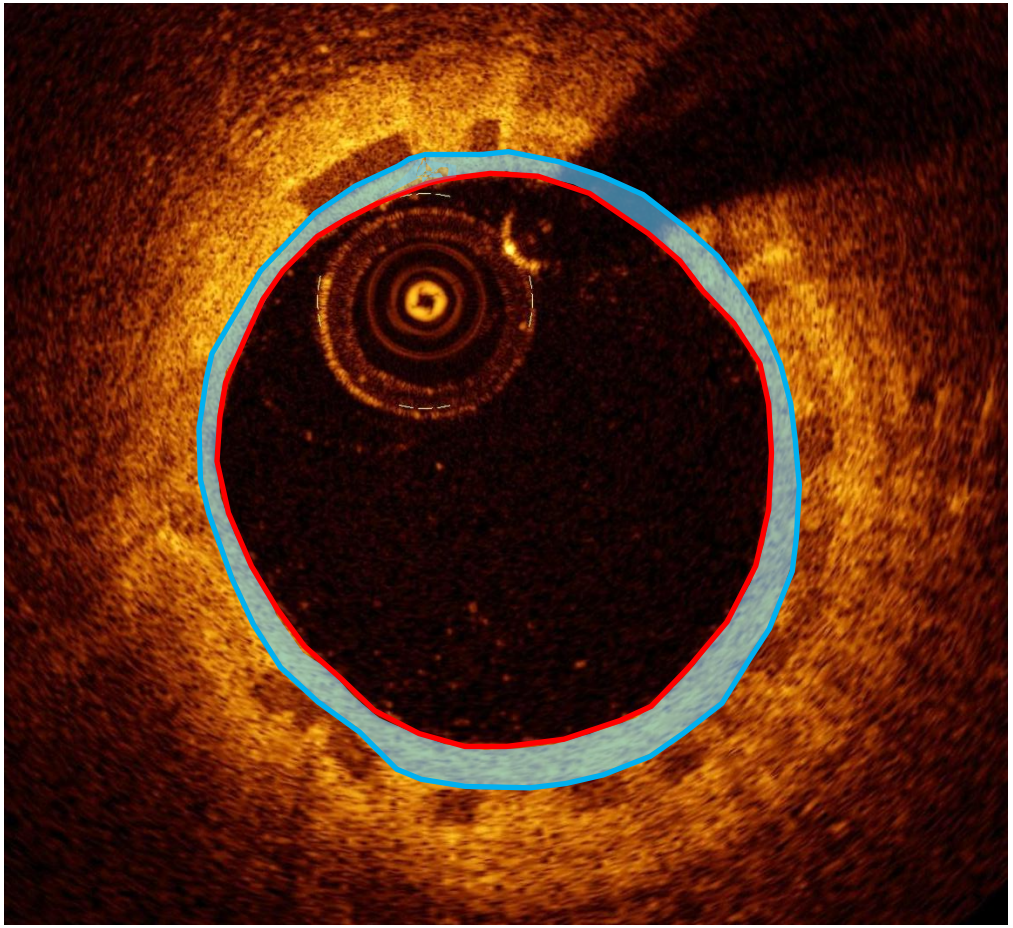
Obstructive NIH

[Scaffold Luminal – Lumen Area]

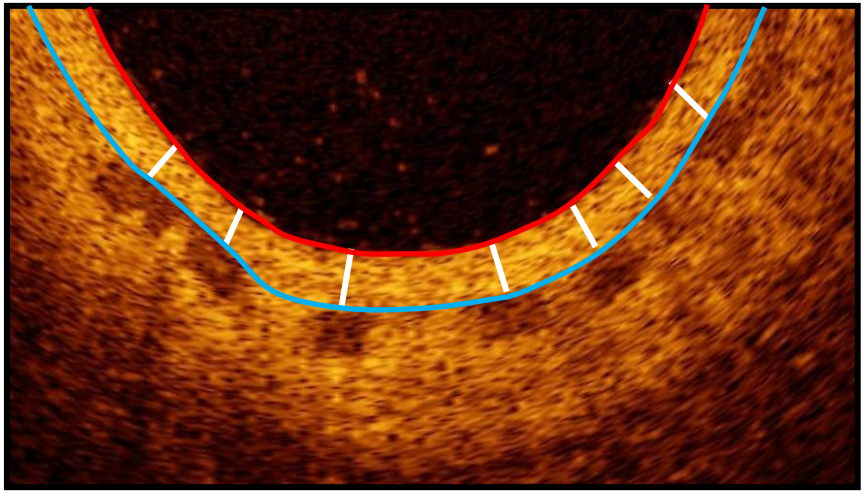


DESolve FIM: Methodology OCT Analysis

Obstructive NIH Area [Cross-Section Level]



Obstructive NIH Thickness [Strut Level]



DESolve FIM: OCT Results

In-scaffold Cross Section Level Serial Analysis	Baseline	6-month Follow-up
	n=10 (paired)	
Mean Scaffold area (mm^2)	6.57 ± 0.68	6.80 ± 0.85*
Mean NIH Area (obstructive) (mm^2)	--	0.71 ± 0.36
Mean NIH Obstruction (%)	--	13.16 ± 5.59
In-scaffold Strut Level Serial Analysis		
Total number of Analyzed Struts	2,984	2,575
Frequency of covered Struts/patient (%)	--	98.68 ± 2.44
Mean NIH Thickness over Covered Struts (mm)	--	0.12 ± 0.04

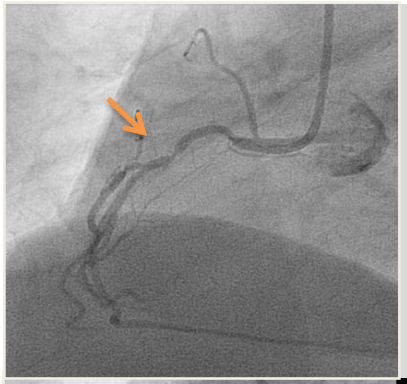
*p=ns between baseline and follow-up

Summary

- The DESolve FIM Study demonstrated feasibility of delivery and deployment of the DESolve™ Coronary Scaffold System
- The DESolve scaffold provides excellent mechanical support to the vessel wall with low acute recoil (6.4%)
- Imaging results demonstrated excellent neointimal hyperplasia suppression at 6 months with an in-scaffold late lumen loss of 0.19 ± 0.19mm with no late recoil or scaffold shrinkage
- Neointimal suppression was verified by IVUS with a low percent volume obstruction of 7.2%
- As observed by OCT, over 98% of the struts were covered by a thin layer of neointima (0.12mm) at 6 months
- Clinical event rates were low through 6 months with only one patient requiring revascularization due to a stenosis located proximal to the implanted scaffold. The scaffold itself was widely patent

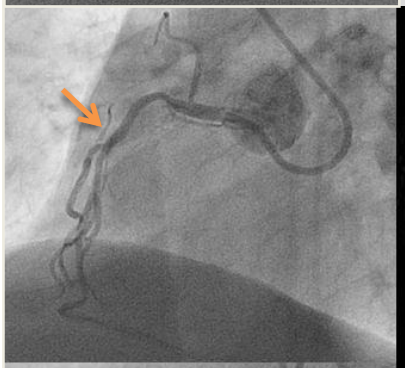
Case Example

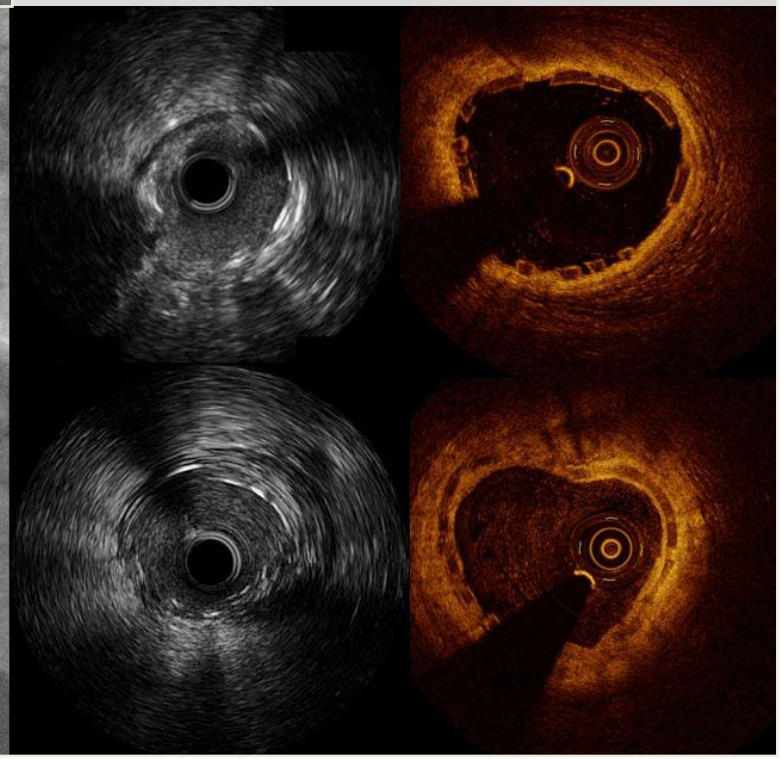
pre-stenting



- *80 year-old male*
- *Smoking, hypertension, hyperlipidemia*
- *Prior stent in mid lad, moderate aortic stenosis, pacemaker, EF=47%*
- *Stable angina*

post-stenting (baseline)





6 month follow-up