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New 24-month data from the FANTOM II clinical trial

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Potential conflicts of interest

Speaker's name: Alexandre Abizaid, MD

☒ I have the following potential conflicts of interest to report: None

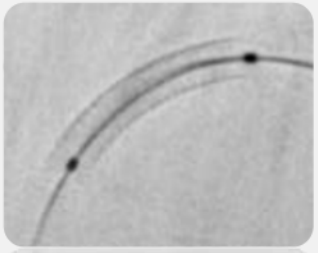
Second Generation Fantom Bioresorbable Scaffold

Scaffold Design

- **Thin struts: 125 µm**
- **Enhanced radial strength**
- **Minimal recoil**
- **Single-step balloon inflation**
- **0.75 expansion over nominal (3.0 mm)**

Tyrocore™

- **Radiopaque**
- Provides strength during healing
- **Vessel uncaged in one year**
- Complete resorption in ~4 years



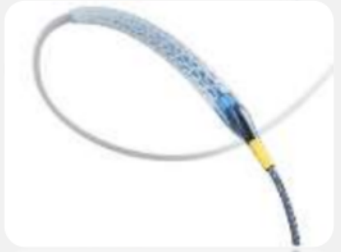
Sirolimus

- First anti-proliferative agent used in drug eluting stents
- Highly lipophilic with broad therapeutic window
- Demonstrated across multiple clinical studies and drug eluting stents

(c) molekuul www.fotosearch.com

Delivery System

- Semi-compliant nylon balloon
- High 18 atm rated burst pressure
- Rapid exchange
- **1.35 mm crossing profile**



FANTOM II Trial

Safety & Performance Study for the
Fantom Bioresorbable Scaffold

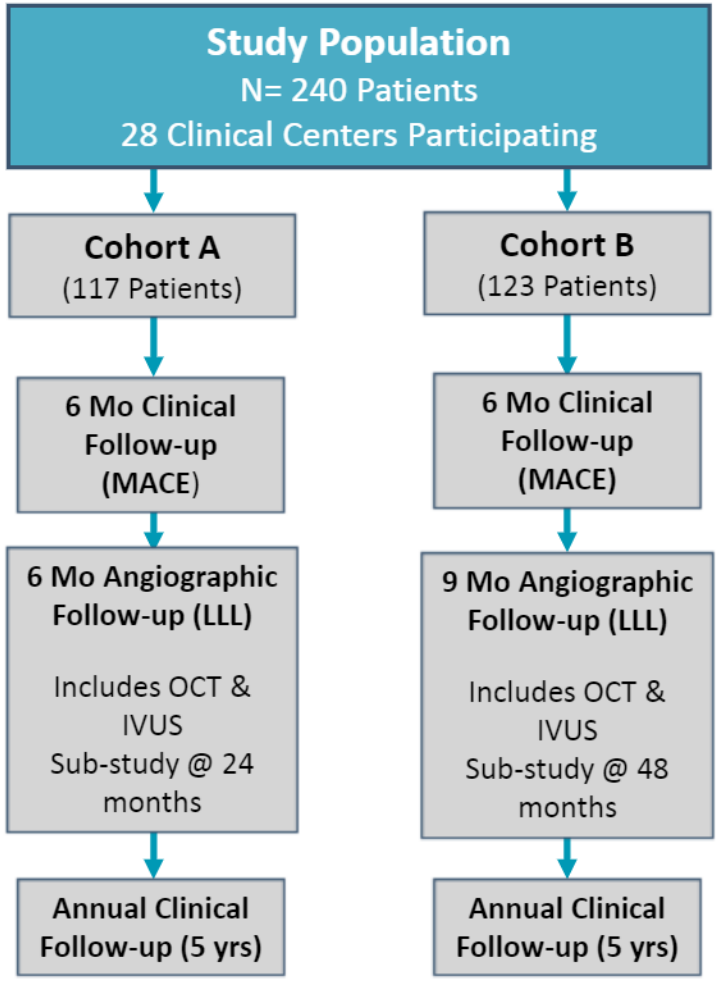
FANTOM II Study Investigators

- Australia
  - Dr. Muller, Dr. Jepson, Dr. Walters
- Belgium
  - Dr. De Bruyne
- Brazil
  - Dr. Abizaid, Dr. Costa, Dr. Chamie, Dr. Perin
- Denmark
  - Dr. Christiansen, Dr. Lassen, Dr. Okkels-Jensen
- France
  - Dr. Carrié, Dr. Chevalier, Dr. Fajadet, Dr. Collet
- Germany
  - Dr. Weber-Albers, Dr. Naber, Dr. Achenbach, Dr. Frey, Dr. Lutz, Dr. Kische, Dr. Ince, Dr. Brachmann
- Netherlands
  - Dr. Amoroso, Dr. Wykrzykowska, Dr. Daemen
- Poland
  - Dr. Dudek, Dr. Kochman, Dr. Koltowski, Dr. Lesiak, Dr. Wojdyla

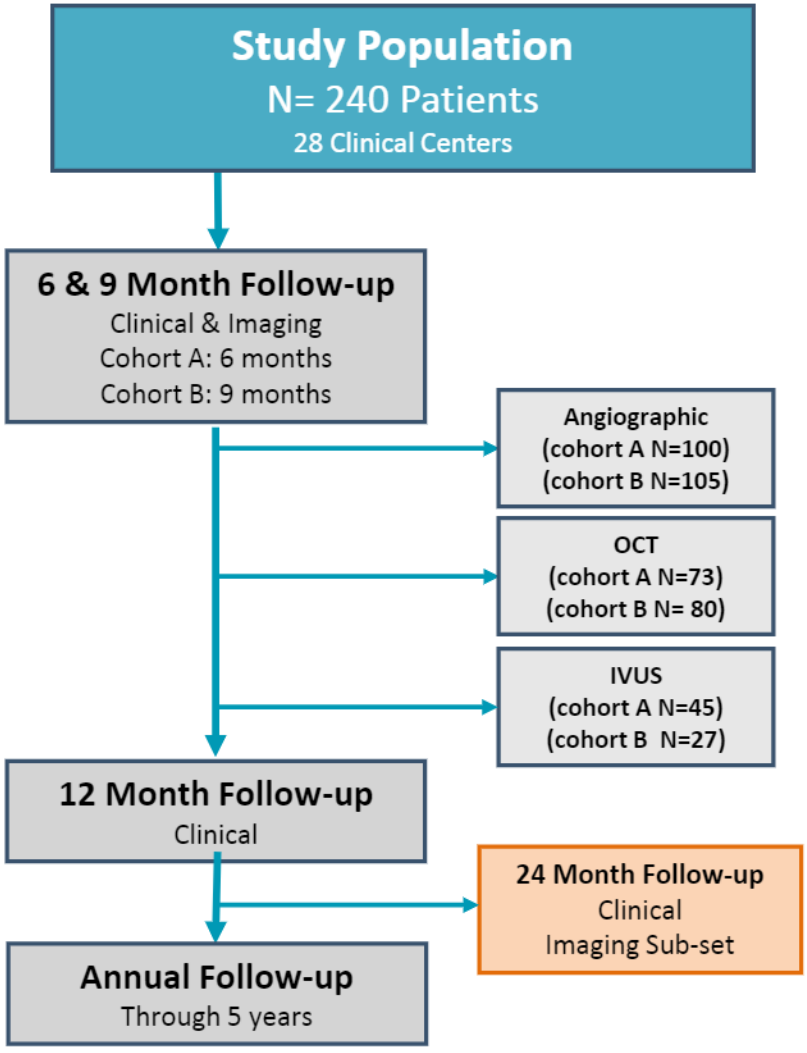
FANTOM II
Study Design and Endpoints

Study Design

- Safety and Performance Trial
- 240 patients in 2 cohorts
- 2.5mm to 3.5mm vessels
- Lesion length ≤ 20mm
- Angiographic follow-up
  - Cohort A: 6 months 117 Pts.
  - Cohort B: 9 months 123 Pts.
- Serial imaging sub-studies
  - Cohort A: 24 months (25 Patients)
  - Cohort B: 48 months (25 Patients)



FANTOM II – Cohorts A & B
Patient Flow and Baseline Characteristics



Patient Characteristics (N=240)	
Patient Age (average years)	62.7 ± 10.1
Male	70.4%
Diabetes	23.8%
Current/Former Smoker	59.6%
Hypertension	73.8%
Hyperlipidemia	70.8%
Prior PCI	43.8%
Prior CABG	2.9%
Prior MI	26.3%
Recent LVEF <40%	0.0% (N=231)

FANTOM II – Cohorts A & B

Lesion Characteristics and Procedural Outcomes

Lesion Characteristics

Target Lesion Location (n=238)[1]	
LAD	48.7% (116)
LCX	31.3% (74)
RCA	20.2% (48)

ACC/AHA Lesion Class (n=238)[1]	
Type A	18.5% (44)
Type B1	49.6% (118)
Type B2	29.4% (70)
Type C	2.5% (6)

(1) Two pre-procedure angiograms were not available

Procedural Outcomes

Acute Procedural Outcomes	
Acute Technical Success (1)	95.8%
Acute Procedural Success (2)	99.1%
Clinical Procedural Success (3)	99.6%

(1) Defined as successful delivery and deployment of the intended scaffold in the intended lesion without device related complications.

(2) Defined as acute technical success (see definition above), resulting in a residual stenosis of ≤50 percent with no immediate (in-hospital) MACE.

(3) Defined as acute procedural success (see definition above), with no MACE thirty days post-intervention and with a final diameter stenosis ≤50 percent.

FANTOM II – Cohorts A & B
Previously Presented Results

Components of 6-Month Primary Endpoint (modified ITT): non-Hierarchical	6 Month (n = 240)	12 Months (n = 240)
MACE	**2.1% (5)**	**4.2% (10)**
Cardiac Death	0.4% (1)[1]	0.8% (2)[1,2]
MI	1.3% (3)	1.3% (3)
Clinically Driven TLR	0.8% (2)	2.5% (6)

* As adjudicated by an independent Clinical Events Committee

(1) One patient died between 0-6 months. Exact cause of death not determined. Patient died at home 4 weeks after subsequent TAVI procedure.

(2) One death occurred between 6-12 months. Patient was reported to have died of COPD by treating physician but cardiac relation could not be excluded.

FANTOM II – Cohorts A & B
Previously Presented Results

Components of 6-Month Primary Endpoint (modified ITT): non-Hierarchical	6 Month (n = 240)	12 Months (n = 240)	24 Months (n=240)
MACE	**2.1% (5)**	**4.2% (10)**	**5.0% (12)**
Cardiac Death	0.4% (1)[1]	0.8% (2)[1,2]	0.8 % (2)
MI	1.3% (3)	1.3% (3)	1.7% (4)[3]
Clinically Driven TLR	0.8% (2)	2.5% (6)	2.9% (7)

- As adjudicated by an independent Clinical Events Committee

(1) One patient died between 0-6 months. Exact cause of death not determined. Patient died at home 4 weeks after subsequent TAVI procedure.
(2) One death occurred between 6-12 months. Patient was reported to have died of COPD by treating physician but cardiac relation could not be excluded.
(3) Three target vessel related MI and one non-target vessel related MI.

FANTOM II – Cohorts A & B

24-Month Scaffold Thrombosis

Definite or Probable Scaffold Thrombosis (N = 240 Patients)	
Acute (0 – 1 day)	0.0% (0)
Sub-acute (2 – 30 days)	0.4% (1)[1]
Late (31 – 365 days)	0.0% (0)
Very Late (>365 days)**	0.4% (1)[2]

- As adjudicated by an independent Clinical Events Committee

** Maximum day=761 days

(1) Target lesion was not fully covered with scaffold. Significant untreated stenosis was present at index procedure. Patient returned 5 days post procedure with a scaffold thrombosis

(2) Distal segment of scaffold was in a 2.0mm vessel and the scaffold had significant malaposition that was not corrected

FANTOM II

Angiographic – QCA Results

In-Scaffold Analysis	Baseline (n=238)[1]	Cohort A – 6 Mo. (n=100)	Cohort A – 24 Mo.[3] (Subset n=36)
RVD (mm)	2.71 ± 0.37	2.70 ± 0.36	2.67 ± 0.33
MLD (mm)	0.82 ± 0.31	2.23 ± 0.41	2.18 ± 0.48
Diameter Stenosis (%)	69.5 ± 11.0	15.3 ± 15.2	15.1 ± 17.9
Acute Gain (mm)	1.68 ± 0.41		
Acute Recoil (%)	4.0 ± 8.3[2]		
Mean LLL (mm)		0.25 ± 0.40	0.23 ± 0.49
In-Segment Analysis			
Mean LLL (mm)		0.17 ± 0.34	0.21 ± 0.49

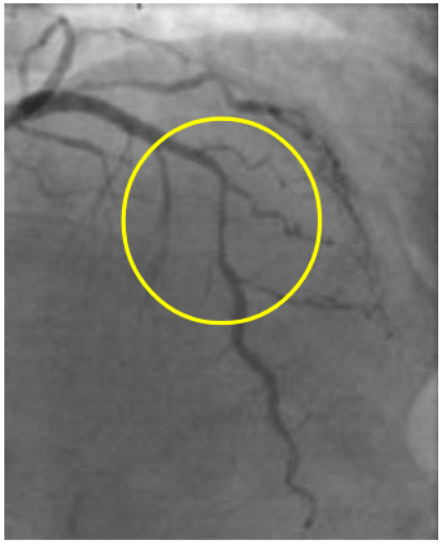
(1) Baseline angiographic data was not available for two enrolled patients

(2) N = 156 patients available for recoil analysis

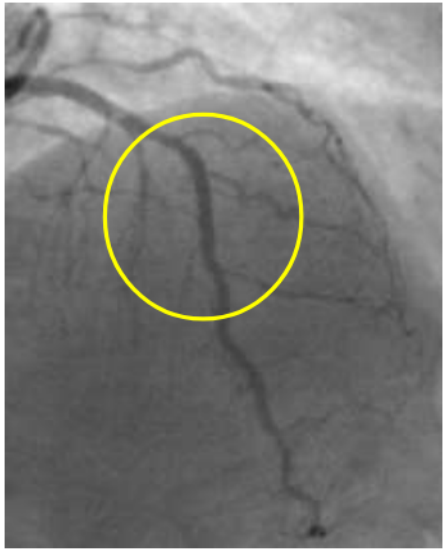
(3) Average follow up days=744

FANTOM II
Long Term Follow-up Case Sample

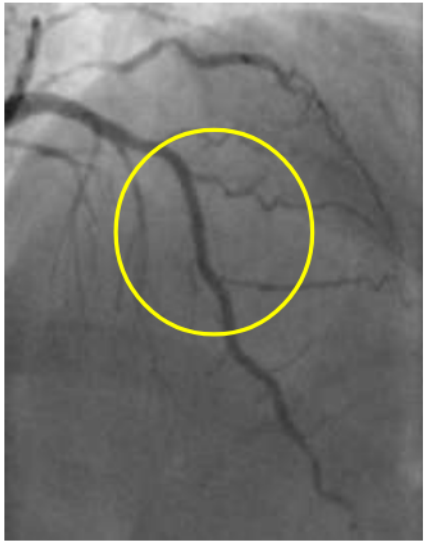
Index - Pretreatment



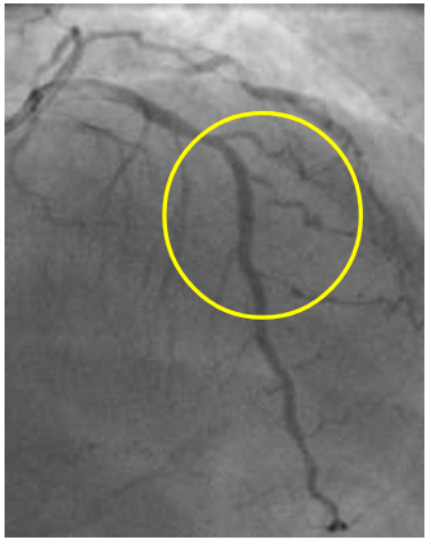
Index – Post Implant



Follow-up 6 Mo.



Follow-up 24 Mo.



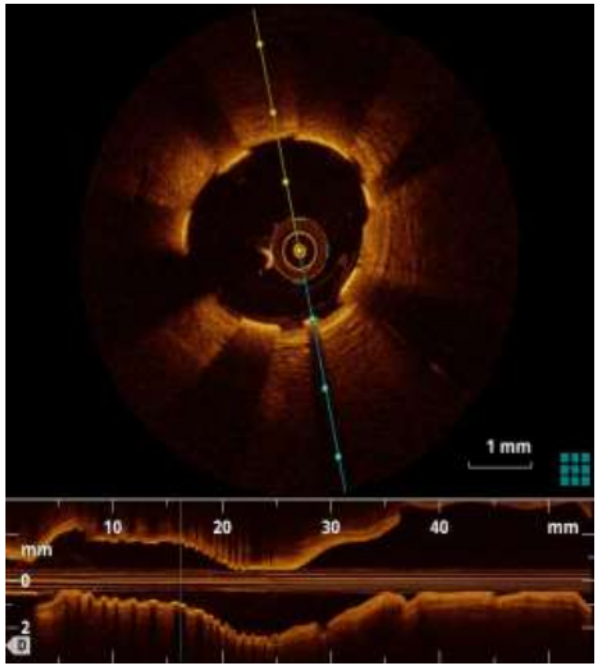
Procedure Details

- Pre-dilation performed
  - BSC Maverick 2.5 x 15mm balloon
- Fantom Scaffold implant
  - 3.0 x 18mm Fantom deployed at 14atm
- Post Dilation Performed
  - 3.25 x 6mm NC Sprinter to 16atm

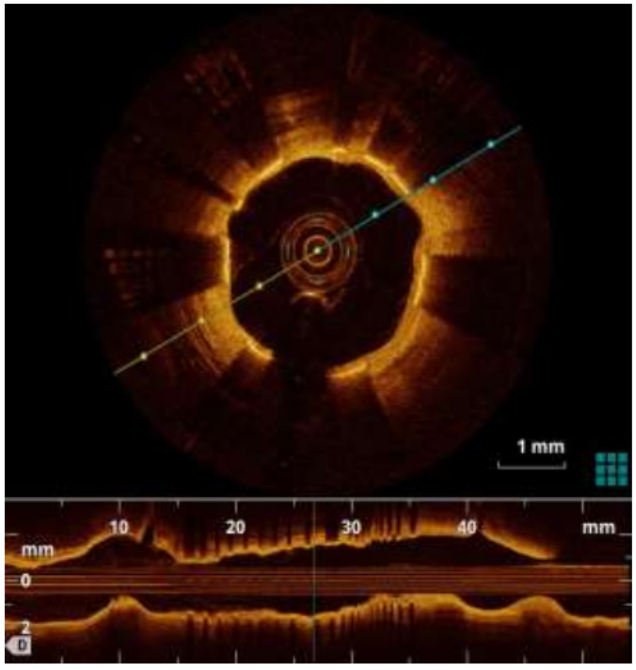
FANTOM II

Long Term Follow-up Case Sample

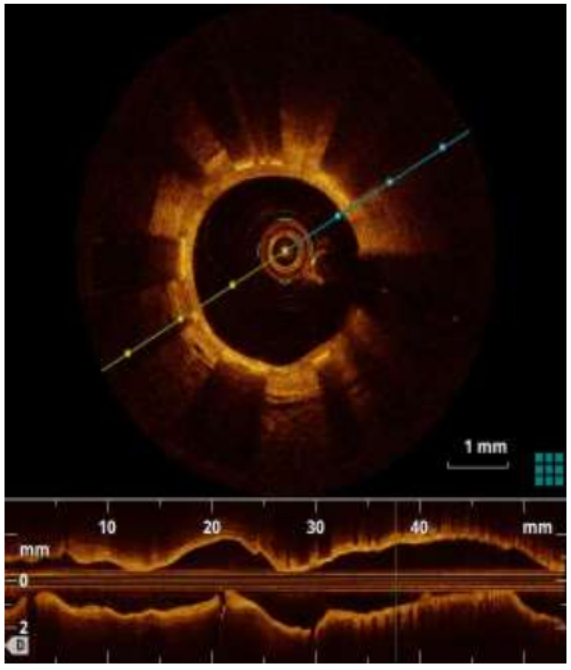
Index – Post Implant



Follow-up 6 Mo.



Follow-up 24 Mo.



Fantom Global Clinical Trial Program

Enrollment Complete – In Follow Up		
FANTOM I	First-in-human safety study (n=7)	Year 3
FANTOM II Cohorts A&B	Multi-center safety and performance study (n=240)	Year 2
Enrolling		
FANTOM II Cohort C	Long lesion and multiple vessel study (n=30-50)	enrolling
FANTOM STEMI	Single center pilot study in STEMI (n=20)	enrolling
FANTOM Post Market Trial	European post-market trial (n=1,500)	enrolling
Planning		
FANTOM III (US pivotal trial)	Multi-center RCT vs. metallic DES (n=1,800-2,200)	planning
FANTOM Asia	Multi-center RCT vs. metallic DES (n=350-400)	planning

FANTOM Program Clinical Summary

- **Only BRS with unique Tyrocore polymer**
  - Thin struts, radiopaque, enhanced radial force, biocompatible
- **Sustained safety and efficacy through 24-months:**
  - Low MACE Rate (5.0%)
  - Low rate of VLST (0.4%)
- **Vessel lumen is maintained through 24 months:**
  - No change in average late lumen loss
  - No evidence of chronic scaffold recoil

Thank you!