TCT 332: FANTOM II Trial: Safety & Performance Study of the Fantom Sirolimus-Eluting Bioresorbable Coronary Scaffold – First Report on Initial 24 Month Outcomes

Fantom II Clinical Trial Investigators

Fantom®

Sirolimus Eluting Bioresorbable Coronary Scaffold

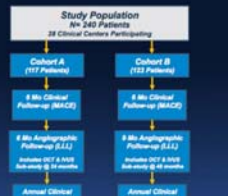
1st and Only BRS Made with Tyrocore™:

- Uniquely designed for vascular scaffolds
- Derived from naturally occurring tyrosine amino acid
- Bound Iodine for radiopacity
- Proprietary, patent protected, and manufactured by REVA Medical

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 – Cohort A & B

Safety Results

Components of 6-Month Primary Endpoint (modified ITT): non-Hierarchical	6 Month (n = 240)	12 Months (n = 240)	Preliminary Interim Data set: 24 Month Ongoing (N = 123)
MACE	2.1% (5)	4.2% (10)	5.6% (7)
Cardiac Death	0.4% (1)[1]	0.8% (2)[1,2]	0.8 (1)[2]
MI	1.3% (3)	1.3% (3)	2.4 (3)
Clinically Driven TLR	0.8% (2)	2.5% (6)	3.2 (4)

* As adjudicated by an Independent Clinical Events Committee

(1) One patient died between 6-9 months. Exact cause of death not determined. Patient died at home 4 weeks after subsequent TAVI procedure.
(2) One death occurred between 9-12 months. Patient was reported to have died of COPD by treating physician but cardiac relation could not be excluded.

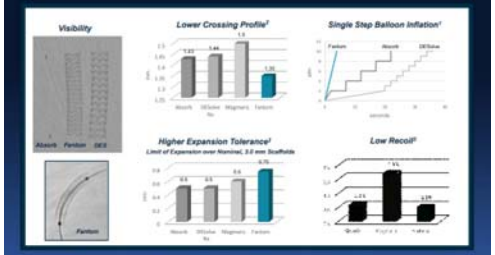
FANTOM Program

Clinical Summary

- **Fantom offers new and clinically important features**
  - Ease-of-use
    - Radiopacity with complete scaffold visibility
    - Low crossing profile with high flexibility
    - Single-step inflation, no special handling requirements
  - Thin struts and radial strength to facilitate vessel healing
- **Data demonstrates continued safety through 24 mo.**
  - Low MACE Rate (5.6%)
- **Imaging sub-study shows sustained results**
  - No change in average late lumen loss from 6 to 24 months
  - No evidence of late or chronic scaffold recoil

Fantom Ease of Use Features

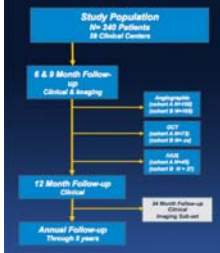
Makes the Implant Procedure Easier



1. Product Instructions for Use. 2. Manufacturer reported data on file at Reva Medical. 3. Tests performed by and data on file at Reva Medical.

FANTOM II – Cohorts A & B

Study Overview 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)

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Angiographic – QCA Results

In-Scaffold Analysis	Baseline (n=238)[1]	Cohort A – 6 Mo. (n=100)	Preliminary Interim Data Set: Cohort A – 24 Mo. (Subset n=25)
RVD (mm)	2.71 ± 0.37	2.70 ± 0.36	2.64 ± 0.35
MLD (mm)	0.82 ± 0.31	2.23 ± 0.41	2.14 ± 0.55
Diameter Stenosis (%)	69.5 ± 11.0	15.3 ± 15.2	16.9 ± 20.3
Acute Gain (mm)	1.68 ± 0.41		
Acute Recoil (%)	4.0 ± 8.3[2]		
Mean LLL (mm)		0.25 ± 0.40	0.25 ± 0.56
In-Segment Analysis			
Mean LLL (mm)		0.17 ± 0.34	0.21 ± 0.52

(1) Baseline angiographic data was not available for two enrolled patients
(2) N = 155 patients available for recoil analysis

Fantom Global Clinical Program

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. Klocke, Dr. Ince, Dr. Brachmann
- **Netherlands**
  - Dr. Amoroso, Dr. Wykrzykowska, Dr. Daemen
- **Poland**
  - Dr. Dudek, Dr. Kochman, Dr. Koltowski, Dr. Lesiak, Dr. Wojdyla

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

Initial 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.

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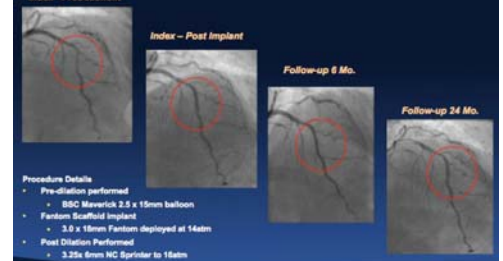
Long Term Follow-up Case Sample



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
  - 3.25x 6mm NC Sprinter to 16atm

Fantom Product Evolution

Next Generation: Fantom Encore

- Thinner struts without compromising radial strength
  - 95 micron on 2.5 mm diameter
- No changes to Tyrocore™ polymer composition or scaffold design
- Improved polymer processing and manufacturing technique
- European approval and launch anticipated in 2018

Diameter	Fantom	Fantom Encore
2.5 mm	125 µm	→ 95 µm
3.0 mm	125 µm	→ to be announced
3.5 mm	125 µm	→ to be announced