The FANTOM Scaffold

Expanding the use of Fantom BRS in worldwide markets: REVA's global clinical trial programme and beyond

Gregg W. Stone MD

Columbia University Medical Center

The Cardiovascular Research Foundation

Potential conflicts of interest

Speaker's name: Dr. Gregg W. Stone

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

Consultant to REVA Medical, Inc.

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Clinical Programs & Beyond

- Clinical Trials that have Reached Their Primary Endpoint
- New Clinical Programs: Now Enrolling
- Planned Future Clinical Programs
- New Product Advancements
- Potential Product Applications

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Clinical Trials that have Reached Their Primary Endpoint

- **FANTOM I**
  - 7 patient single center pilot study
  - Primary endpoint
    - Ischemic-driven target lesion revascularization (TLR) at 6 months
  - Outcomes

MACE @ 12 months	OCT imaging @ 4 months	Scaffold Thrombosis @ 24 months
0% MACE No ID-TLR Primary endpoint met	99% strut coverage	0% ST

  - Status
    - All patients now beyond 24-month follow-up; data analysis in process
    - Continued follow-up through 60 months ongoing

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Clinical Trials that have Reached Their Primary Endpoint

- **FANTOM II (cohorts A and B)**
  - 240 patient multi-center safety and performance study
  - Primary endpoints
    - Major Adverse Cardiac Events (MACE) and Late Lumen Loss at 6 Months
  - Outcomes

Primary Endpoints / OCT Imaging	Secondary Endpoints
2.1% MACE through 6-month follow-up	4.2% MACE through 12-month follow-up
Late Lumen Loss 0.17 mm in-segment (0.25 mm in-scaffold) at 6 months	0.4% Scaffold Thrombosis (1 event) with more than 150 patients through 18-month follow-up
> 98% scaffold coverage at 6 months by OCT	

  - Status
    - All patients now beyond 12-month follow-up
    - Serial imaging sub-study analysis ongoing (cohort A: 24M, cohort B: 48M)
    - Continued follow-up through 60 months ongoing

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New Clinical Programs: Enrolling More Complex Patients

- **FANTOM II (Cohort C) – Long Lesions / Multiple Vessels**
  - 50 patient multicenter study
  - Population
    - Patients with lesions >20 mm in length requiring two or more scaffolds in the same vessel, and patients requiring treatment of multiple lesions in more than one vessel
  - Primary Endpoints
    - Major Adverse Cardiac Events (MACE) at 6 Months
    - Late Lumen Loss at 6 Months
  - Status
    - Initiated April 2017, enrollment ongoing

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New Clinical Programs: Enrolling AMI Patients

- **FANTOM AMI**
  - 20 patient single center pilot study
  - Primary Endpoint
    - Procedural success defined as acute angiographic success without in-hospital MACE
  - Secondary Endpoints
    - QCA and OCT serial imaging assessments at 6, 18 and 36 months
  - Status
    - Initiated May 2017, enrollment ongoing

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Planned Future Clinical Programs

- **FANTOM III (US Pivotal Trial)**
  - Randomized controlled multicenter study
    - Sample size: 1800 – 2200 patients
    - Control: Metallic drug-eluting stent
  - Primary Endpoint:
    - Target Lesion Failure (TLF) at 12 months (non-inferiority)
  - Secondary Endpoints (tentative):
    - QCA & OCT derived parameters at 3 years
  - Status
    - Currently in active discussions with FDA on study design
  - Planned Initiation: Q1/Q2 2018

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Planned Future Clinical Programs

- **FANTOM Japan**
  - Trial design currently in early planning phase
  - Typical pivotal trial design
    - Randomized controlled multi-center study
      - Sample size: 350 - 400 patients
      - Control: Metallic drug-eluting stent
    - Primary Endpoint: Target Lesion Failure at 12 Months
  - Status
    - Actively evaluating trial design options

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New Product Advancements

- **Fantom Gen 2**
  - Advanced Fantom scaffold with sub-100 micron strut thickness
  - Designed for use in smaller vessels (≤2.5 mm)
    - First product size 2.5 mm diameter in multiple lengths
  - Status
    - Actively qualifying design enhancements
  - Planned introduction
    - Q1/Q2 2018; pending regulatory approval

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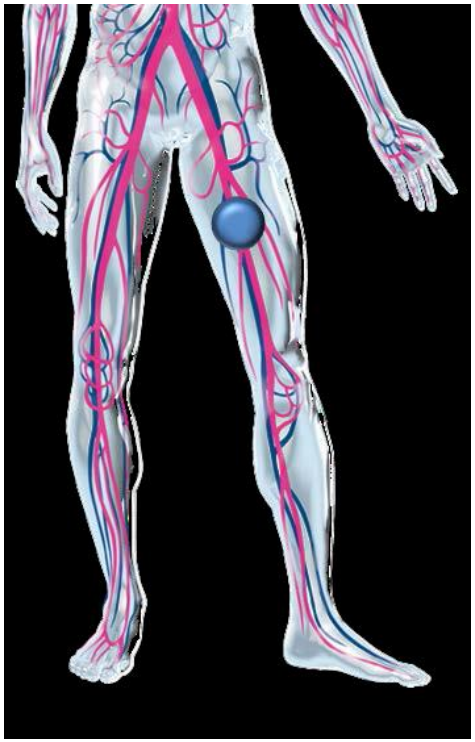
Potential New Product Applications

- **FANTOM Peripheral**
  - Fantom scaffold with design features needed for peripheral applications
  - Design Considerations
    - Evaluating potential use in SFA application
    - Evaluating potential use in BTK application
  - Status
    - Actively qualifying design enhancements



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Global Clinical Trial Programme and Device Development

Conclusions

- **Fantom has demonstrated initial device safety through 12 months**
  - 4.2% MACE
  - 0.4% scaffold thrombosis
- **Good late lumen loss, with excellent strut coverage at 6 months**
  - 0.17 mm in-segment, 0.25 mm in-scaffold
  - >98% scaffold coverage at 6 months by OCT
- **Fantom clinical program & product development expanding**
  - Expanding geographical approvals
  - Evaluating coronary and non-coronary indication expansion
  - Evaluating design enhancements (e.g. thinner struts)