The FANTOM Scaffold

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

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Potential conflicts of interest

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✓ 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

<table>
<thead>
<tr>
<th>MACE @ 12 months</th>
<th>OCT imaging @ 4 months</th>
<th>Scaffold Thrombosis @ 24 months</th>
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</thead>
<tbody>
<tr>
<td>0% MACE</td>
<td>99% strut coverage</td>
<td>0% ST</td>
</tr>
<tr>
<td>No ID-TLR</td>
<td></td>
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<tr>
<td>Primary endpoint met</td>
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- Status
  - All patients now beyond 24-month follow-up; data analysis in process
  - Continued follow-up through 60 months ongoing
### Fantom
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
      | 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)