Positive Clinical Results for *Fantom*

**San Diego, California and Sydney, Australia** (Wednesday, 18 May 2016, AEST) – At the Paris Course on Revascularization (“EuroPCR”) being held this week in Paris, France, REVA Medical, Inc. (ASX: RVA) (“REVA” or the “Company”) announced positive six-month results from the first cohort of patients in the Company’s FANTOM II clinical trial. The Company had previously announced very good acute results from the trial. The FANTOM II trial is evaluating the safety and performance of the *Fantom®* sirolimus-eluting bioresorbable coronary scaffold, which was implanted in 240 patients in two cohorts between March 2015 and March 2016.

Clinical follow-up of the 117 patients in Cohort A showed a very low rate of Major Adverse Cardiac Events (“MACE”) through six months. MACE is a composite of cardiac death, myocardial infarction (“heart attack”), and clinically-driven revascularization. The reported preliminary six-month MACE rate of 1.71% demonstrates *Fantom’s* ability to effectively treat patients with coronary artery disease over this time frame.

An analysis of angiographic imaging of the first 100 patients at six months showed that the treated coronary arteries had a mean in-segment late lumen loss (“late loss”) of 0.21 mm. This low late loss is a desirable result that historically corresponds to positive long-term outcomes, and compares to permanent drug-eluting stents and competitive bioresorbable scaffolds that generally have late loss values in the range of 0.20 mm to 0.40 mm.

“The current results from the FANTOM II clinical trial are very encouraging,” stated Dr. Alexandre Abizaid, co-principal investigator for the trial and Director of Invasive Cardiology at Institute Dante Pazzanese of Cardiology in Sao Paulo, Brazil. “We look forward to continuing to follow our patients that have been treated with *Fantom* and providing longer-term data.”

The presentation materials delivered at the conference are attached hereto, and are available in the Investor Relations section of REVA’s website at [www.revamedical.com](http://www.revamedical.com).

**About REVA**

REVA is a clinical stage medical device company located in San Diego, California, USA, that is working to commercialize its proprietary bioresorbable stents, which are called “scaffolds.” The Company’s scaffolds have been developed as an alternative to metal stents, which are small tube-like devices permanently implanted into an artery to treat coronary artery disease. Scaffolds provide restoration of blood flow, support the artery through
the healing process, then disappear (or “resorb”) from the body over a period of time. This resorption allows the return of natural movement and function of the artery, a result not attainable with permanent metal stents. The Company’s initial product, the Fantom® scaffold, has been designed to offer an ideal balance of thinness and strength and distinct ease-of-use features including complete scaffold visibility under x-ray, expansion with one continuous inflation, and no procedural time limitations. REVA will require successful clinical trial results and regulatory approval before it can commercialize Fantom or any other product.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that are not statements of historical fact, including those statements that address future operating performance and events or developments that we expect or anticipate will occur in the future, are forward-looking statements, such as those statements regarding our ability to obtain regulatory approvals, timely and successfully complete our clinical trials, protect our intellectual property position, commercialize our products if and when approved, develop and commercialize new products, recruit and retain our key personnel, and estimates regarding our capital requirements and financial performance. You should not place undue reliance on forward-looking statements. Although management believes forward-looking statements are reasonable as and when made, forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to vary materially from those expressed in forward-looking statements, including the risks and uncertainties that are described in the “Risk Factors” section of our Annual Report on Form 10-K filed with the US Securities and Exchange Commission (the “SEC”) on March 10, 2016, and as may be updated in our periodic reports thereafter. Any forward-looking statements in this announcement speak only as of the date when made. REVA does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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Fantom®

Bioresorbable Sirolimus-Eluting Scaffold
Speaker's name: Dr. Alexandre Abizaid

☑️ I have the following potential conflicts of interest to report:
Consultant to REVA Medical, Inc.
Fantom Bioresorbable Scaffold

Key Scaffold Features

- Complete scaffold visibility under x-ray
- Single-step continuous inflation
- Clinically significant expansion range
- Optimal radial strength at 125 µm thickness
- Vasomotion restoration ~1 year
- No special storage or handling

Fantom® (REVA Medical)
Sirolimus-Eluting Bioresorbable Scaffold
Desaminotyrosine Polycarbonate

Visibility

Deliverability

Vessel Patency
• Fantom’s (x-ray) visibility

Allows for:

– Precise scaffold placement
– Accurate lesion coverage
– Full structural assessment after deployment
– Less reliance on invasive imaging compared to other BRS (IVUS/OCT)
Thin 125µm strut design enables:
- Reduced scaffold crossing profile
- Greater device flexibility
- Increased access to a greater number of lesions

Full blood flow restoration

Courtesy of A. Abizaid, Dante Pazzanese, Sao Paulo, Brazil
**Fantom**
Continuous Inflation

**Inflation process:**
- Continuous inflation to intended diameter
- Reduces arterial occlusion time for the patient
- Increases speed for scaffold delivery for the physician
- Eliminates the need to recall multiple inflation schemes

![Graph showing inflation pressure over time](image-url)

*Based upon manufactures instructions for use*
Fantom Bioresorbable Scaffold
Single Step Inflation

REVAs Advanced Polymer enables single step inflation
Fantom
Bioresorbable Scaffold Features

- **Post-dilation without compromise**
  - Substantial expansion safety margin
    - 0.75 to 1.0 mm depending upon device size
  - Able to adjust for vessel taper

- **Restoration of vasomotion**
  - Maintains radial strength during healing
  - Restoration of vasomotion approx. 1 yr.
    - > 80% molecular weight loss within 12 months
  - Eliminates undesirable shear stress induced by a permanent implant

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3.0mm Nominal Device

Polymer enables expansion to 4.0 mm without fracture

Degradation Profile
Molecular Weight Loss

![Degradation Profile Graph](image)
FANTOM II Trial

Safety & Performance Study for the Fantom Sirolimus-Eluting Bioresorbable Coronary 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. Brachman

• Netherlands
  – Dr. Amoroso, Dr. Wykrzykowska, Dr. Daemen

• Poland
  – Dr. Dudek, Dr. Kochman, Dr. Koltowski, Dr. Lesiak, Dr. Wojdyla
Study Design and Endpoints

- 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
  - Cohort B: 48 months

Study Population
N= 240 Patients
28 Clinical Centers Participating

Cohort A
(117 Patients)
6 Mo Clinical Follow-up (MACE)
6 Mo Angio Follow-up (LLL)
Includes OCT & IVUS Sub-study @ 24 months
Annual Clinical Follow-up (5 yrs)

Cohort B
(123 Patients)
6 Mo Clinical Follow-up (MACE)
9 Mo Angio Follow-up (LLL)
Includes OCT & IVUS Sub-study @ 48 months
Annual Clinical Follow-up (5 yrs)
FANTOM II – Cohort A
Study Overview and Baseline Characteristics

**Study Population**
N= 117 Patients
23 Clinical Centers

**Patient Characteristics (N=117)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Age (average years)</td>
<td>62.7 ± 9.7</td>
</tr>
<tr>
<td>Male</td>
<td>70.1%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>21.4%</td>
</tr>
<tr>
<td>Current/Former Smoker</td>
<td>50.4%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>76.9%</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>70.9%</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>40.2%</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>6.0%</td>
</tr>
<tr>
<td>Prior MI</td>
<td>26.5%</td>
</tr>
<tr>
<td>Recent LVEF &lt;40%</td>
<td>2.0% (N=113)</td>
</tr>
</tbody>
</table>
# FANTOM II – Cohort A
## Lesion Characteristics and Procedural Outcomes

### Target Lesion Location (n=117)

<table>
<thead>
<tr>
<th>Location</th>
<th>Percentage</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAD</td>
<td>49.6%</td>
<td>58</td>
</tr>
<tr>
<td>LCX</td>
<td>30.8%</td>
<td>36</td>
</tr>
<tr>
<td>RCA</td>
<td>19.7%</td>
<td>23</td>
</tr>
</tbody>
</table>

### ACC/AHA Lesion Class (n=115)*

<table>
<thead>
<tr>
<th>Class</th>
<th>Percentage</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type A</td>
<td>24.3%</td>
<td>28</td>
</tr>
<tr>
<td>Type B1</td>
<td>42.6%</td>
<td>49</td>
</tr>
<tr>
<td>Type B2</td>
<td>33.0%</td>
<td>38</td>
</tr>
<tr>
<td>Type C</td>
<td>0.0%</td>
<td>0</td>
</tr>
</tbody>
</table>

### Acute Procedural Outcomes

1. **Acute Technical Success (1)**: 96.6% (n=117)
2. **Acute Procedural Success (2)**: 99.1% (n=113)
3. **Clinical Procedural Success (3)**: 99.1% (n=112)

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(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.

*As assessed by an independent core lab*
## FANTOM II – Cohort A
### Angiographic – QCA Results*

<table>
<thead>
<tr>
<th>Analysis Type</th>
<th>Baseline (n=115)</th>
<th>Post Procedure (n=112)</th>
<th>6 Months (n=100)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In-Scaffold Analysis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RVD (mm)</td>
<td>2.68 ± 0.37</td>
<td>2.75 ± 0.40</td>
<td>2.69 ± 0.35</td>
</tr>
<tr>
<td>MLD (mm)</td>
<td>0.79 ± 0.29</td>
<td>2.47 ± 0.37</td>
<td>2.20 ± 0.39</td>
</tr>
<tr>
<td>Diameter Stenosis (%)</td>
<td>70.3 ± 10.4</td>
<td>10.7 ± 7.6</td>
<td>16.8 ± 11.5</td>
</tr>
<tr>
<td>Acute Gain (mm)</td>
<td></td>
<td>1.67 ± 0.41</td>
<td></td>
</tr>
<tr>
<td>Acute Recoil (%)</td>
<td></td>
<td>2.9 ± 8.8</td>
<td></td>
</tr>
<tr>
<td>Mean LLL (mm)</td>
<td></td>
<td></td>
<td><strong>0.29 ± 0.38</strong></td>
</tr>
<tr>
<td>Median LLL (mm)</td>
<td></td>
<td></td>
<td>0.22 (-0.43, 1.77)</td>
</tr>
<tr>
<td><strong>In-Segment Analysis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean LLL (mm)</td>
<td></td>
<td><strong>0.21 ± 0.32</strong></td>
<td></td>
</tr>
<tr>
<td>Median LLL (mm)</td>
<td></td>
<td>0.16 (-0.43, 1.67)</td>
<td></td>
</tr>
</tbody>
</table>

* Preliminary Results: Analyzed by an independent QCA core lab (Yale Cardiovascular Research Group, New Haven, US)
# FANTOM II – Cohort A
## MACE Results

### 6 Month MACE Results

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-Hospital</td>
<td>1 (Post Procedure MI)</td>
</tr>
<tr>
<td>30-Day Follow-up</td>
<td>1 (MI/TLR/SAT)</td>
</tr>
<tr>
<td>90-Day Follow-up</td>
<td>0</td>
</tr>
<tr>
<td>6-Month Follow-up</td>
<td>0</td>
</tr>
</tbody>
</table>

### Components of the Primary Endpoint (ITT): Hierarchical

<table>
<thead>
<tr>
<th>Component</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE(^1)</td>
<td>1.71%</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>0.0%</td>
</tr>
<tr>
<td>Target vessel MI</td>
<td>1.71%</td>
</tr>
<tr>
<td>Clinically Driven TLR</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

1) As adjudicated by an independent Clinical Events Committee
2) One event pending final adjudication review (non ischemic driven TLR)
FANTOM II Case Sample
Angiographic Assessment

Pre-Implant
> 95% occlusion

Post-Implant
Full vessel restoration

6-Month Follow-up
Vessel remains widely patent

For personal use only
FANTOM II Case Sample
OCT Assessment

Post-Implant

6-Month Follow-up
4-month Follow-up
4-month Follow-up
FANTOM Program
Clinical Summary

Fantom offers new and interesting features

– Radiopacity
– Enhanced deliverability
– Single-step inflation
– No special handling requirements

Initial clinical data demonstrates

– Good acute performance
  • Excellent device deliverability
  • Minimal residual stenosis and acute recoil

– Sustained performance and safety through 6 months
  • Low MACE Rate
  • Low late lumen loss
Thanks!