



REVA Announces Positive 12-Month Clinical Results

4.2% rate of MACE equivalent to best-in-class drug-eluting stents

San Diego, California (Tuesday, May 16, 2017, PDT) – At the Paris Course on Revascularization (“EuroPCR”) being held this week in Paris, France, REVA Medical, Inc. (ASX: RVA) (“REVA” or the “Company”) announced sustained positive clinical results from the FANTOM II clinical trial. The trial is evaluating the safety and performance of the Company’s *Fantom* sirolimus-eluting bioresorbable coronary scaffold in 240 patients outside the United States. Six-month data from the trial was used as the basis for European CE Marking for *Fantom*, which was granted last month. The current data release showcases safety data through 12 months in all patients, as well as imaging data on subsets of patients from the trial.

Clinical follow-up on the 240 patients showed a very low 4.2% rate of Major Adverse Cardiac Events (“MACE”) through 12 months. MACE is a composite of cardiac death, myocardial infarction (“heart attack”), and clinically-driven revascularization. The 12-month MACE rate demonstrates a strong safety profile for *Fantom* over a sustained timeframe. In addition to the low MACE rate, there have been no reported cases of late or very late scaffold thrombosis to date.

Subsets of patients in the trial underwent angiographic imaging to determine late lumen loss (“late loss”) at six and nine months. Late loss is the difference between the diameter of a stented segment immediately after treatment compared with the follow-up angiogram. The clinical data showed a final in-segment late loss of 0.17 mm (± 0.34 mm) at six months, and 0.29 mm (± 0.41 mm) at nine months, which is in the desired range of 0.20 mm to 0.40 mm. This range historically corresponds with positive long-term outcomes for stents and scaffolds.

REVA also released nine-month Optical Coherence Tomography (“OCT”) results on a subset of patients from the trial. The OCT imaging results demonstrated continued vessel patency and sustained healing with greater than 99% strut coverage at nine months.

“Data from the FANTOM II clinical trial through 12 months continues to demonstrate a positive safety profile for *Fantom*,” 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. “These results, sustained through an extended timeframe, provide additional confidence about the future outlook for this next-generation bioresorbable scaffold.”

The presentation materials delivered at the conference are available in the Investor Relations section of REVA’s website at www.revamedical.com.

About REVA

REVA is a medical device company located in San Diego, California, USA, that has developed a proprietary bioresorbable scaffold, as an alternative to metal stents, 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 *Fantom*[®] scaffold has been designed to offer an ideal balance of thinness and strength, with distinct ease-of-use features including complete scaffold visibility under x-ray, expansion with one continuous inflation, and no procedural time limitations.

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 the projections and timing surrounding our plans to commence commercial operations and sell products, conduct clinical trials, develop pipeline products, incur losses from operations, list our securities for sale on a U.S. stock exchange, and assess and obtain future financings for operating and capital requirements. Readers 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 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 February 28, 2017, 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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