

# New Fantom Data Demonstrates Safety at 2 Years

# **REVA** Announces Next Generation Scaffold with 95 Micron Strut Thickness

**San Diego, California** (Tuesday, October 31, 2017, PDT) – The Fantom bioresorbable scaffold from REVA Medical, Inc. (ASX: RVA) shows continued positive clinical outcomes according to an interim data set from the FANTOM II clinical trial presented this week at the Transcatheter Therapeutics Conference ("TCT") in Denver, Colorado. The Company also revealed plans for its next generation scaffold, named Fantom Encore, which will have a market-leading 95 micron strut thickness for the 2.5 mm diameter scaffold.

Clinical outcomes were reported for an interim data set of 125 patients followed through 24 months. Findings included a low rate of Major Adverse Cardiac Events ("MACE") of 5.6% and a single very late scaffold thrombosis event. REVA previously reported a MACE rate of 4.2% through 12 months for the complete 240-patient data set with a single scaffold thrombosis event in the sub-acute time frame. The 24-month outcomes demonstrate a sustained safety profile for Fantom.

In addition to clinical follow up, a 25-patient subset in the trial underwent angiographic imaging to determine late lumen loss ("late loss") at 24 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-scaffold late loss of 0.25 mm, which is in the desired range of 0.2 mm to 0.4 mm. This range historically corresponds with positive long-term outcomes for stents and scaffolds.

The data were presented in a moderated poster session by trial investigator, Dr. Ricardo A. Costa, from Institute Dante Pazzanese of Cardiology in Sao Paulo, Brazil, and in an oral presentation by Dr. James B. Hermiller Jr., from the Heart Center of Indiana in Indianapolis, Indiana.

"This preliminary data set from the FANTOM II trial provides physicians with an early look at two-year clinical results for the Fantom scaffold," said Dr. Costa. "The low MACE rate and inscaffold late lumen loss measurement are encouraging as they demonstrate sustained safety and performance of Fantom out to 24 months in this group of patients."

The FANTOM II trial is evaluating the safety and performance of the Fantom sirolimus-eluting bioresorbable coronary scaffold in 240 patients outside of the United States. Six-month data from the FANTOM II trial was used as the basis for European CE Marking for Fantom, which was granted in April of this year.

REVA also announced plans for a 95 micron strut thickness scaffold. The new scaffold, named Fantom Encore, will utilize the same polymer as Fantom called Tyrocore, REVA's proprietary tyrosine-derived polymer designed specifically for vascular scaffold applications. Tyrocore is inherently radiopaque, making Fantom and Fantom Encore visible under fluoroscopy. Additionally, Tyrocore is strong, enabling thinner struts while retaining radial strength. Fantom

Encore will be available in 2.5, 3.0 and 3.5 mm diameters. The 95 micron struts will be available on the 2.5 mm diameter scaffold.

"REVA's announcement of 95 micron strut thickness for Fantom Encore in the 2.5 mm diameter is a promising development for bioresorbable scaffold technology," stated Dr. Hermiller. "Bioresorbable scaffolds have the potential to offer patients short term benefits of metallic stents without the long-term complications. Thinner struts have been associated with improved deliverability and vessel healing."

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

### **About Fantom**

Fantom is a sirolimus-eluting bioresorbable scaffold developed as an alternative to metallic stents for the treatment of coronary artery disease. Scaffolds provide restoration of blood flow, support the artery through the healing process, and then disappear (or "resorb") from the body over a period of time. This resorption is intended to allow the return of natural movement and function of the artery. Fantom is the only bioresorbable scaffold made from Tyrocore, REVA's proprietary tyrosine-derived polymer designed specifically for vascular scaffold applications. Tyrocore is inherently radiopaque, making Fantom the first and only bioresorbable scaffold that is visible under fluoroscopy. Fantom is designed with thin struts while maintaining strength and with distinct ease-of-use features such as expansion with one continuous inflation.

### About REVA Medical

REVA Medical is a medical device company focused on the development and commercialization of bioresorobable polymer technologies for vascular applications. The Company's lead product, the Fantom bioresorbable scaffold, received European CE Mark on April 3, 2017 for the treatment of coronary artery disease. REVA is located in San Diego, California, USA and employs over 50 people in the United States and Europe.

Fantom, Fantom Encore, and Tyrocore are trademarks of REVA Medical, Inc.

## **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 plans or performance and events or developments that may occur in the future, are forward-looking statements, such as those statements regarding the projections and timing surrounding commercial operations and sales, clinical trials, pipeline product development, and future financings. No undue reliance should be placed 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 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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