



Submission of CE Mark Application

Sydney, Australia and San Diego, California (Wednesday, 3 August 2016 AEST) – REVA Medical, Inc. (ASX: RVA) (“REVA” or the “Company”) is pleased to announce that it has submitted an application for CE Marking of its *Fantom* scaffold, following completion of clinical data analyses and required testing. The regulatory approval process generally spans several months and includes evaluation of the clinical, preclinical, and bench test data submitted, as well as audits of the Company’s quality assurance system and related processes. Accordingly, the Company expects it would receive CE Mark approval, or notice of any issues with the application, prior to 31 December 2016. This regulatory approval would allow commercial sales in Europe and other countries that recognize the CE Mark.

The clinical data used in the application was obtained from the 117 patients in Cohort A of the FANTOM II clinical trial, which is being conducted in 28 hospitals in eight countries outside the United States. The primary endpoint in the trial was a combined clinical assessment of Major Adverse Cardiac Events (“MACE”) and an invasive imaging assessment of Late Lumen Loss (“LLL”) at six months. The adjudicated clinical data showed a MACE rate of 2.56%, which is consistent with the low preliminary rates previously reported for these patients. Additionally, the clinical data showed a final in-scaffold LLL of 0.25mm (± 0.35 mm) and an in-segment LLL of 0.17 mm (± 0.29 mm), which compare favorably to the rates of commercially available competitive bioresorbable scaffolds and drug-eluting stents.

The Company will continue to follow and evaluate patients in the trial for five years. The 123 patients enrolled in Cohort B of the trial will undergo clinical safety evaluations at six months and invasive imaging assessments at nine months. As these patients completed enrollment in March 2016, the imaging evaluations will be ongoing into the first quarter of 2017.

The clinical data and any additional data from Cohort A, as well as any available data from Cohort B patients in the trial, are planned to be reported at the Transcatheter Cardiovascular Therapeutics (“TCT”) conference, which will be held October 29th through November 2nd in Washington D.C.

About REVA

REVA is a clinical stage medical device company located in San Diego, California, USA, that is working to commercialize its proprietary bioresorbable scaffolds, 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. REVA will require 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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