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REVA MEDICAL ANNOUNCES INITIATION OF ENROLLMENT IN THE MOTIV IDE CLINCIAL TRIAL

San Diego, California (September 27, 2022) – REVA Medical, LLC, a leader in bioresorbable polymer technologies for vascular applications, today announced that enrollment in the MOTIV pivotal trial has been initiated at clinical centers in both the U.S. and Europe. The study will evaluate the use of the MOTIV® Sirolimus-Eluting Bioresorbable Vascular Scaffold for treatment in patients suffering from chronic limb-threatening ischemia (CLTI). CLTI is an advanced stage of peripheral artery disease (PAD), often affecting the below-the-knee (BTK) artery bed and associated with an impaired quality of life due to a high risk of serious health concerns, including amputation, adverse cardiovascular events and mortality.

The MOTIV study is a global, randomized controlled trial (RCT) that was designed to evaluate the safety and efficacy of the MOTIV scaffold for the treatment of infrapopliteal lesions in patients with CLTI by randomized comparison with standard balloon angioplasty. The study, led by co-principal investigators, Dr. Ehrin Armstrong from Adventist Health in St. Helena, California, and PD Dr. med. Andrej Schmidt from Universitätsklinikum Leipzig, will follow up to 292 patients at approximately 35 clinical centers in the U.S. and Europe.

"The absence of an approved device as a dedicated treatment option for the estimated 20 million patients[1] worldwide suffering from CLTI is a significant unmet need," commented Dr. Jason Ricci of Bellin Health Cardiology Associates in Green Bay, Wisconsin, and the physician who enrolled the first U.S. patient. "I'm delighted to play a role in this important trial and evaluate its potential to advance the science and therapies available to this highly complex patient population."

MOTIV is a fully bioresorbable sirolimus-eluting scaffold that is designed to dissolve over time, leaving the artery free from a permanent implant and, thereby, allowing it to return to its natural movement, or vasomotion. MOTIV is made from REVA's proprietary polymer, Tyrocore®, which was developed specifically for scaffold performance. The novel properties of Tyrocore provide for enhanced scaffold strength in a thin-strut design; are intended to improve ease of use, including single-step inflation; and enable visibility of the entire device under fluoroscopy, an attribute unique to MOTIV among bioresorbable scaffolds.

"The initiation of our MOTIV clinical trial is an exciting and important milestone for REVA, as well as the global medical community," said Jeffrey Anderson, President and CEO, REVA Medical, LLC. "We are focused on addressing the need for more durable treatment options for this debilitating disease and committed to finding the best possible therapies to improve patient outcomes."

The MOTIV scaffold has been approved for use in Europe since 2018 when the device became the first bioresorbable scaffold to receive CE Mark for use below the knee. PD Dr. med. Schmidt recently recorded a live case using MOTIV scaffolds that was shown at the 2022 Transcatheter Cardiovascular Therapeutics (TCT) conference. During the procedure, PD Dr. med. Schimdt implanted three 60-millimeter MOTIV scaffolds in a patient with CLTI below the knee, and the patient has demonstrated positive post-operative results.

[1] [1] Duff S, Mafilios MS, Bhounsule P, Hasegawa JT. The burden of critical limb ischemia: a review of recent literature.Vasc Health Risk Manag. 2019; 15:187–208. doi: 10.2147/VHRM.S209241

"The MOTIV scaffold has a demonstrated history of positive clinical results, and I am honored to have performed the first procedures with the device in this trial," stated Dr. med. Henrik Schröder, who enrolled the first European patients in the trial at Ihre Radiologien MVZ in Berlin. "The scaffold was easily delivered, and the procedure was aided by visibility of the device under fluoroscopy, which is beneficial to confirm proper placement."

In August, REVA announced the closing of a $45 million Series B equity financing in support of its clinical program for the MOTIV scaffold. That funding was led by Boston Scientific and existing investors.

Additional information can be found at REVA's website: www.revamedical.com

About REVA Medical

REVA Medical is a medical device company focused on the development and commercialization of bioresorbable polymer technologies for vascular applications. The Company's products include MOTIV bioresorbable scaffolds for the treatment of peripheral artery disease, Fantom and Fantom Encore bioresorbable vascular scaffolds for the treatment of coronary artery disease, and TyroSphere embolic beads. REVA is based in San Diego, California. More information can be found at REVA's website: www.revamedical.com.

Fantom, Fantom Encore, and MOTIV have CE Mark only. Fantom, Fantom Encore, and MOTIV are available in select countries in Europe and the Middle East. Fantom, Fantom Encore, MOTIV, and TyroSphere are not available in the U.S. or other countries that do not accept CE Mark. Fantom, Fantom Encore, MOTIV, TyroSphere, and Tyrocore are trademarks of REVA Medical, LLC.

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. 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.