Terumo Completes U.S. Patient Enrollment in the OSPREY Trial to Evaluate the MISAGO Self-expanding Stent

The Associated Press

Terumo Interventional Systems, a strategic business unit of Terumo Medical Corporation, a U.S. subsidiary of Terumo Corporation, today announced the completion of U.S. patient enrollment in the Occlusive/Stenotic Peripheral Artery REvascularization StudY (OSPREY) designed to evaluate the safety and effectiveness of the MISAGOT Self-expanding Stent System. OSPREY is a single-arm, multi-center, non-randomized prospective clinical trial for the treatment of atherosclerotic stenoses and occlusions of the superficial femoral artery that included 200 patients in 31 centers in the U.S. and 100 patients in seven centers in Japan.

(Photo: http://photos.prnewswire.com/prnh/20120711/NY37622) A unique feature of this landmark study is that it simultaneously enrolled patients in the U.S. and Japan as part of the larger Harmonization by Doing (HBD) pilot program, a cooperative effort led by the U.S. Food & Drug Administration, the MHLW/PMDA (Japan's regulatory body), Terumo Corporation, based in Tokyo, Japan, and Terumo Medical Corporation, based in Somerset, New Jersey. The HBD initiative is intended to shorten the gap between product approvals in these two significant world healthcare markets.

"OSPREY is Terumo Medical Corporation's first U.S. clinical trial for a premarket approval (PMA) device and we are exceptionally pleased with its progress. Terumo is greatly appreciative of the tremendous support given by our U.S. clinical investigators, which helped us meet the critical enrollment goal in this landmark HBD initiative," said James Rushworth, President of Terumo Interventional Systems and Onset Medical Corporation. "The OSPREY trial and the MISAGO Stent truly speak to our three strategic pillars of introducing innovative technologies that create Clinical, Economic, and Quality of Life Benefits." The MISAGO Self-expanding Stent consists of a nitinol stent pre-mounted on the distal portion of a rapid-exchange delivery catheter system. The stent has three radiopaque markers located on each end of the stent to help ensure accurate placement in the lesion. The stent is currently available for sale in Europe.

The first U.S. patient implant in the OSPREY trial occurred in September 2010. The primary endpoints of the U.S. arm of the OSPREY study are: -- Primary stent patency rate at one year as confirmed by duplex ultrasound or angiography.

-- Freedom from major adverse events within 30 days of the procedure, which would result in target lesion revascularization, amputation of the treated limb or death.

"Peripheral vascular disease is a leading cause of disability in the U.S., affecting

between 8 and 12 million Americans. It is critical that physicians, and their patients, have faster access to the latest technologies in order to maximize treatment options," said J. Fritz Angle, MD, Professor of Radiology, University of Virginia, and U.S.

Principal Investigator in the OSPREY trial. "I look forward to analyzing and discussing the OSPREY data with all of the trial investigators. The international experience and testing efficiencies obtained from our collective participation in this HBD initiative could have a dramatic effect on the way important medical devices reach the market in the future." For more information about the OSPREY trial, contact Joanna Murray, Clinical Project Manager, Terumo Interventional Systems, 732-302-4900, extension 7210.

Terumo Interventional Systems Terumo Interventional Systems (TIS) is a strategic business unit of Terumo Medical Corporation. As a market leader in entry site management and lesion access, TIS is committed to pursuing unique technologies designed to enhance treatment of coronary and peripheral endovascular diseases as well as driving strategic initiatives focused on Critical Limb Ischemia, Complex Coronary Intervention and Transradial Access. TIS directly markets a full line of guidewires, catheters, introducer sheaths, guiding sheaths and embolization products for use in a multitude of different interventional procedures.

Terumo Medical Corporation Founded in 1972 as a Terumo Corporation subsidiary, Terumo Medical Corporation (TMC) develops, manufactures, and markets a complete, solutions-based portfolio of high-quality medical devices used in a broad range of applications for numerous areas of the healthcare industry. TMC is comprised of two business divisions: Terumo Interventional Systems and Terumo Medical Products.

The company places a premium on providing customers with world-class products, training and education programs that drive clear economic value, better clinical outcomes and improved Quality of Life for patients.

Terumo Corporation Tokyo-based Terumo Corporation is one of the world's leading medical device manufacturers with $5 billion in sales and operations in more than 160 nations. Founded in 1921, the company develops, manufactures, and distributes world-class medical devices including products for use in cardiothoracic surgery, interventional procedures, and transfusion medicine; the company also manufactures a broad array of syringe and hypodermic needle products for hospital and physician office use. Terumo contributes to society by providing valued products and services to the healthcare market and by responding to the needs of healthcare providers and the people they serve.

Terumo Corporation's shares are listed on the first section of the Tokyo Stock Exchange (No. 4543, Reuters symbol <4543.T>, or Bloomberg 4543: JP) and is a component of the Nikkei 225, Japan's leading stock index.

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