REALITY Trial Enrolls First Patient in Study Evaluating Medtronic Directional Atherectomy and Drug-Coated Balloon in PAD Treatment

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Medtronic

VIVA Sponsored REALITY Study Assessing Vessel Preparation and Treatment in Severe Calcified Lesions Expands to Germany; Principal Investigators Named; First Patient Enrolled

DUBLIN and SAN JOSE, Calif. -July 27, 2016 - Medtronic plc (NYSE: MDT) and VIVA Physicians today report the first patient enrolled in the REALITY Study. The VIVA sponsored study is assessing outcomes for patients with significantly calcified and symptomatic femoropopliteal peripheral artery disease (PAD), following adjunctive use of directional atherectomy and drug-coated balloon (DCB). Krishna Rocha-Singh, M.D., chief scientific officer, Prairie Heart Institute of Illinois, and Brian DeRubertis, M.D., FACS, associate professor of surgery, UCLA Division of Vascular Surgery, are co-principal investigators. The study will include investigative sites both within the U.S. and in Germany.

"PAD is a complex and progressive disease. The severity of the disease can often have an impact on treatment options for patients. Long lesion length and severe calcification are obstacles that challenge both our ability to gain acute luminal gain and to maintain long-term patency," said Dr. Rocha-Singh. "REALITY is driven by the need to look at a viable treatment paradigm that combines the use of directional atherectomy and DCB therapy to address the challenges of treating complex PAD."

Roger Gammon, M.D., interventional cardiologist at Austin Heart Central-Heart Hospital, treated the first patient enrolled in the study. "We know that directional atherectomy and DCB perform well as standalone treatments; and early data suggests that combined therapy may improve patient outcomes in more complex lesions. Through REALITY we hope to answer this critical question with rigorous clinical data in this well designed study," said Dr. Gammon.

The REALITY Study evaluates patient outcomes with adjunctive use of Medtronic HawkOne (TM) or Medtronic TurboHawk(TM) and Medtronic IN.PACT(TM) Admiral(TM) drug-coated balloon. The multi-center, international, prospective, single-arm study will enroll up to 250 subjects at up to 15 sites. The study includes angiographic and duplex ultrasound core lab adjudication. Primary patency is assessed by duplex ultrasound at 12-months. Patients are followed up to 24 months to determine clinically driven target lesion revascularization (CD-TLR). The study is sponsored and managed by VIVA Physicians with support from Medtronic through an external research project grant.

"Medtronic is committed to improving patient lives through unique clinical partnerships, exemplified by the REALITY Study," said Mark Pacyna, vice president and general manager of the Peripheral business, which is part of the Aortic & Peripheral Vascular division at Medtronic. "This study is designed to further refine the PAD treatment algorithm by providing greater evidence for vessel preparation with directional atherectomy prior to treatment with DCB."

About VIVA PHYSICIANS

VIVA Physicians is a not-for-profit organization dedicated to advancing the field of vascular medicine and intervention through education and research. Since 2003, VIVA Physicians has held an annual multidisciplinary vascular education conference for physicians and healthcare professionals dedicated to treating patients with vascular diseases. Attendees learn the most current diagnostic techniques and leading edge treatment strategies utilizing innovative technologies and creative learning platforms.

VIVA Physicians continues to advance the design, execution and publication of high quality, independently adjudicated clinical trials that promote the safe and effective use of novel medical devices in the treatment of patients with advanced peripheral artery disease.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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