Medtronic News

REALITY Study to Evaluate Use of Directional Atherectomy and Drug Coated Balloon in Patients with Peripheral Arterial Disease

VIVA Physician Sponsored Study to Determine the Benefits of Debulking Plaque and Maximizing Luminal Gain Prior to Drug Coated Balloon Therapy

DUBLIN and LAS VEGAS - Nov. 2, 2015 - Medtronic plc (NYSE: MDT) announced today the initiation of the REALITY Study (DiRectional AthErectomy + Drug-coAted BaLloon to Treat Long, Calcified FemoropopliTeal ArterY Stenoses) to evaluate patient outcomes following adjunctive use of directional atherectomy and drug-coated balloon (DCB) treatment of patients with symptomatic peripheral arterial disease (PAD) in long, calcified lesions in the superficial femoral artery (SFA) and/or popliteal artery. The study is sponsored and will be managed by VIVA Physicians, and will have multidisciplinary representation in leadership.

The REALITY Study is a multi-center, prospective, single-arm observational angiographic and duplex ultrasound core lab adjudicated study that will enroll 250 subjects at up to 20 sites across the U.S. with primary patency assessed by duplex ultrasound at 12-months. Patients will be followed to 24 months to determine CD-TLR. Medtronic's directional atherectomy systems and IN.PACT® Admiral® drug-coated balloon will be studied in REALITY. The study also includes several important core lab adjudicated sub-analyses including the intravascular ultrasound assessment of the efficiency of directional atherectomy to debulk various plaque morphologies including severe calcium in long lesions prior to DCB deployment and the validation of the Peripheral Arterial Calcium Scoring Scale (PACSS) to assess the impact of severe vessel calcification on Major Adverse Clinical Events (MACE) from the procedure through 12 months. Importantly, a health economics and Quality of Life assessment will also be included as part of REALITY.

"As standalone treatments for peripheral arterial disease, directional atherectomy and DCBs have demonstrated strong clinical results. However, challenges in treating long and severely calcified femoropopliteal lesions remain including the associated provisional stent rate with DCB and reintervention rates with directional atherectomy over the long-term," said Dr. Krishna Rocha-Singh, chief scientific officer, Prairie Heart Institute at St. John's Hospital; Springfield, Ill. "The REALITY study was driven by the need to look at a viable treatment paradigm that combines the use of directional atherectomy and DCB therapy to address these challenges."

At VIVA 2014, Covidien (now Medtronic) presented the one-year results from the DEFINITIVE AR pilot study, which showed early promise in calcified and long lesions for PAD patients treated with directional atherectomy prior to DCB use.

"DEFINITIVE AR was the first, and only randomized pilot study to determine the outcome differences between patients who were treated with directional atherectomy and DCB and DCB alone. While the data demonstrated positive, early trends towards combination therapy in some lesion subsets, further investigation is needed to determine the effectiveness of debulking a lesion with directional atherectomy prior to DCB," said Dr. Mark Turco, medical director of the Aortic & Peripheral Vascular Business within Medtronic's Cardiac and Vascular Group. "It is an honor for Medtronic to partner with VIVA and a multi-disciplinary team of clinicians in the study. We are pleased to support research in advancing therapy options for patients with PAD."

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

About Directional Atherectomy Devices

Medtronic's directional atherectomy portfolio includes the HawkOne(TM), TurboHawk(TM) and SilverHawk(TM) systems. The systems are designed to remove a variety of plaque morphologies from the peripheral vessels in patients with PAD, and permit the restoration of blood flow known as revascularization.

Medtronic's directional atherectomy portfolio is backed by more than 15 peer-reviewed studies. Recent published data from the DEFINITIVE LE study in the *Journal of American College of Cardiology, Cardiovascular Interventions* demonstrated 95 percent limb salvage in patients with critical limb ischemia (CLI) and 78 percent overall patency (the ability for the treated artery to remain open) in claudicant patients at 12 months following standalone treatment with directional atherectomy (SilverHawk and TurboHawk).i

About IN.PACT Admiral Drug-Coated Balloon

IN.PACT Admiral drug-coated balloon (DCB) is designed to reopen superficial femoral and popliteal arteries that have been narrowed or blocked by plaque. Once deployed in the artery, the balloon delivers a proven, safe and effective dose of the anti-restenotic drug paclitaxel to the artery walls. The drug aims to prevent the artery from narrowing again by minimizing scar tissue formation.

IN.PACT Admiral DCB received the CE (Conformité Européene) mark in 2009 and approval by the U.S. Food & Drug Administration in December 2014. It is the most studied drug-coated balloon to date. Medtronic is conducting four Medtronic-sponsored studies which include IN.PACT SFA, IN.PACT Global, IN.PACT Japan and IN.PACT China to assess the safety and effectiveness of the IN.PACT Admiral DCB. In addition, Medtronic is supporting approximately 20 physician-initiated DCB studies. In total, data on more than 4,000 patients treated with the IN.PACT Admiral DCB will be available.

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. The world renowned faculty emphasizes unbiased and critically evaluated educational content that highlights multidisciplinary perspectives and collaboration.

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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i McKinsey J, Zeller T, Rocha-Singh K, Jaff M, Garcia L, DEFINITIVE LE Investigators. Lower Extremity Revascularization Using Directional Atherectomy: 12-Month Prospective Results of the DEFINITIVE LE Study. JACC: Cardiovascular Interventions 2014; 7(8):923-33.

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