Medtronic News

Medtronic Drug-Coated Balloon Receives FDA Approval for Treating Peripheral Artery Disease in Upper Leg

Pivotal Study Shows New Medical Device Provides Exceptional Clinical Outcomes and Reduces Need for Costly Repeat Procedures

MINNEAPOLIS -- Jan. 5, 2015 -- Medtronic, Inc. (NYSE: MDT) announced today that the U.S. Food and Drug Administration (FDA) has approved the company's IN.PACT Admiral drug-coated balloon (DCB) for the interventional treatment of peripheral artery disease (PAD) in the upper leg, a serious and common cardiovascular condition that causes pain in the legs and is known to be associated with a four- to five-fold increase in risk for heart attack and stroke.

The IN.PACT Admiral DCB offers patients a new therapy option that has demonstrated the best clinical outcomes ever reported for this disease state and has been proven to reduce the need for costly repeat procedures that are commonly associated with other available interventional therapies.

The IN.PACT Admiral DCB is designed to reopen arteries located in the upper leg, specifically the superficial femoral and popliteal arteries, when they 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.

"The introduction of drug-coated balloons represents a significant breakthrough that might establish a new standard of care with its potential to change the way we treat peripheral artery disease in the leg," according to Dr. Michael R. Jaff, Paul and Phyllis Fireman Chair in Vascular Medicine at the Massachusetts General Hospital and professor of medicine at Harvard Medical School in Boston, Mass., who participated in the studies that led to the new device's FDA approval as the medical director of VasCore, the Vascular Ultrasound Core Laboratory. "Data from clinical trials evaluating this new drug-coated balloon have consistently demonstrated improved patient outcomes."

The DCB arm of the IN.PACT SFA Trial demonstrated the lowest clinically-driven target lesion revascularization (CD-TLR) rate ever reported for an interventional treatment of PAD in the superficial femoral artery (SFA), with only 2.4 percent of patients treated with the IN.PACT Admiral DCB requiring a repeat procedure at one year, compared to one in five patients (20.6%) treated with percutaneous transluminal angioplasty (PTA).

The data also revealed the highest reported rates of primary patency, which measures sustained restoration of adequate blood flow through the treated segment of the artery. Based on Kaplan-Meier survival estimates for primary patency at 360 days, the data showed an 89.8 percent sustained restoration of blood flow in the DCB group compared to 66.8 percent for the PTA group. Using the trial's protocol definition, primary patency assessed at 12 months of follow up was 82.2 percent for the DCB group and 52.4 percent for the PTA group.

The exceptionally positive clinical data from the pivotal IN.PACT SFA Trial, which compared treatment with the IN.PACT Admiral DCB to standard balloon angioplasty, has been approved by the FDA without the use of an independent advisory panel.

By reducing the need for repeat procedures, the new device is also proving to be economically attractive. Results from an interim economic analysis of the IN.PACT SFA Trial revealed that treatment with the IN.PACT Admiral DCB is cost-effective compared to balloon angioplasty from discharge through one-year of follow-up, indicating the potential to lower overall healthcare costs over the longer term.

"Having shown success in Europe for several years, we are excited to bring the IN.PACT Admiral drug-coated balloon to patients and physicians in the U.S.," said Tony Semedo, senior vice president and president of Medtronic's Aortic and

Peripheral Vascular business. "In addition to being a key growth driver, the IN.PACT Admiral DCB delivers on our commitment to providing innovative technologies that not only provide clinical benefit, but also economic value."

The IN.PACT Admiral DCB received the CE (*Conformité Européene*) mark in 2009 and has been widely adopted by European physicians, leading the market with nearly 100,000 patients treated.

About the IN.PACT Admiral Drug-Coated Balloon

The IN.PACT Admiral DCB is the newest minimally-invasive treatment for PAD in the upper leg. It features a proprietary coating of the drug paclitaxel and a naturally occurring excipient called urea, which facilitates transfer of the drug from the balloon into the artery wall. Paclitaxel is delivered in a 3.5 µg/mm2 dose to maximize therapeutic benefit and remains at therapeutic levels for up to 180 days. The device is available in 40, 60, 80, and 120 mm lengths and can accommodate vessels ranging from 4-7 mm in diameter.

IN.PACT Admiral is the most studied drug-coated balloon to date, with more than 3,500 patients enrolled in ongoing clinical trials around the world that demonstrate positive, consistent results across a broad range of patient populations, both in randomized controlled and real-world settings. Reproducible, positive outcomes were observed in the IN.PACT Global single-arm study, the largest and most rigorous post-market evaluation of its kind, which enrolled a real-world patient population with more complex disease and more challenging lesions.

About Peripheral Artery Disease

Defined as atherosclerosis (hardening of the arteries) outside the heart and brain, peripheral artery disease (PAD) affects an estimated 8-12 million people in the U.S.1 The condition is caused by the build-up of plaque in the arteries that carry oxygenated blood from the heart to the rest of the body. The plaque can harden over time, narrowing the arteries and restricting blood flow. Complications related to PAD are heightened due to common co-morbidities: 63 percent of people with PAD also have coronary artery disease, and one in three people with diabetes over age 50 are also living with PAD.2,3,4

PAD most commonly affects arteries in the legs, and when present in the upper leg, greatly increases risk of a sudden heart attack or stroke.5 Blocked blood supply to the muscles and tissues in the legs can cause recurrent and painful muscle cramping in the thigh and/or upper calf while walking or climbing stairs that can be restrictive and impair quality of life. Experiencing pain, even while at rest or while sleeping, is a sign of a more severe disease. Without proper treatment, 30 percent of people with PAD are likely to die within five years from a PAD-related heart attack or stroke.3

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

Multimedia Release

A multimedia version of this release, with links to graphics and additional background information can be found at: https://medtronicmediacap.gcs-web.com/medtronic-drug-coated-balloon-receives-fda-approval-treating-peripheral-artery-disease

ABOUT MEDTRONIC

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology -- alleviating pain, restoring health and extending life for millions of people around the world.

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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1 National Heart Lung and Blood Institute (NHBLI). Facts About Peripheral Arterial Disease (P.A.D.) n.d. Web.

2 Bhatt DL, et al. REACH Investigation. Presented at: American College of Cardiology Annual Scientific Session; March 8, 2005; Orlando, FL. Abstract 1127-96.

3 Hirsch AT. Criqui MH. Treat-Jacobson D. et al. Peripheral arterial disease detection, awareness and treatment in primary care. JAMA. 2001;286(11), 1317-1324.

4American Diabetes Association. Facts About Peripheral Arterial Disease. n.d. Web.

5 Aboyans V. Desormias I. Lacroix P. Salazar J. Criqui MH. Laskar M. The General Prognosis of Patients With Peripheral Arterial Disease Differs According to the Disease Localization. J Am Coll Cardiol. 2010;55(9):898-903.

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