Medtronic Starts U.S. Launch of IN.PACT Admiral Drug-Coated Balloon for Treatment of Peripheral Arterial Disease in Upper Leg

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First Uses of New Medical Device Following FDA Approval Take Place at Hospitals Nationwide

DUBLIN - Feb. 4, 2015 - U.S. hospitals this week began using a new medical device from Medtronic plc (NYSE: MDT) called the IN.PACT Admiral drug-coated balloon (DCB) to treat patients with peripheral arterial disease (PAD) in the upper leg, a common cardiovascular condition that causes leg pain and increases the risk of heart attack and stroke.

Recently approved by the U.S. Food and Drug Administration, 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 first uses of the new medical device following FDA approval took place at NewYork-Presbyterian Hospital/Columbia University Medical Center by William Gray; Detroit Medical Center's Harper Hospital in Michigan by Mahir Elder; Yuma Regional Medical Center in Arizona by Joseph Cardenas of the Heart Center of Yuma; and Terrebonne General Medical Center in Houma, Louisiana by Craig Walker of Cardiovascular Institute of the South.

"As an investigator in the clinical trial that contributed to this device's FDA approval, I have seen firsthand how well the IN.PACT Admiral drug-coated balloon works as a treatment for peripheral arterial disease in the upper leg," said Dr. Gray. "Based on the trial results, which were recently published in the journal *Circulation*, I see the IN.PACT Admiral DCB fast becoming a first-line therapy option for patients with this condition."

The U.S. launch of the IN.PACT Admiral DCB begins about a week after Medtronic completed its acquisition of Covidien. This acquisition significantly expands Medtronic's peripheral vascular sales force, which will facilitate access to the new device.

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 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.

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.

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.

Defined as atherosclerosis (hardening of the arteries) outside the heart and brain, peripheral arterial 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.

ABOUT MEDTRONIC

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, 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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[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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