Medtronic News

Medtronic Receives FDA Approval of First Drug-Coated Balloon for Treatment of In-Stent Restenosis (ISR)

IN.PACT Admiral DCB Indication Expansion to Treat Patients with ISR

DUBLIN - Sept. 13, 2016 - Medtronic plc (NYSE: MDT) today announced that the U.S. Food and Drug Administration (FDA) approved the IN.PACT(TM) Admiral(TM) drug-coated balloon (DCB) as a treatment for in-stent restenosis (ISR) in patients with peripheral artery disease (PAD). This is the first DCB that has gained approval to treat ISR in the U.S. FDA approval was based on ISR data from the IN.PACT Global Study compared to a standard percutaneous balloon angioplasty (PTA) control.

"We are experiencing a paradigm shift in treating patients with complex PAD," said John Laird, M.D., interventional cardiologist at U.C. Davis Medical Center and co-principal investigator for the IN.PACT SFA Trial. "Until now physicians have had limited treatment options to address patients with ISR. The FDA's approval of IN.PACT Admiral DCB allows us to treat patients with a durable, proven, and safe technology."

ISR occurs when a stent is placed in the artery to restore blood flow but over time plaque can form in and around the stent. This condition is estimated to occur in up to 40 percent of all stents placed in the superficial femoral artery (SFA).1,2

"Prior to the FDA approval of IN.PACT Admiral DCB for ISR, physicians were challenged to find a durable treatment for PAD patients, considering the complexity of the disease," said Mark Pacyna, vice president and general manager of the Peripheral business, which is part of the Aortic & Peripheral Vascular division at Medtronic. "Together, in collaboration with physicians in the vascular clinical community, we designed the IN.PACT Global Study to look at challenging lesions in real-world patients. Today, the IN.PACT Admiral DCB has demonstrated consistent outcomes across all patient morphologies, and it is the only DCB approved to treat patients with ISR in the U.S."

Real-world data from the IN.PACT Global Study demonstrating safe and effective treatment of complex ISR lesions was first presented on the scientific podium at VIVA 2015. The one-year primary patency rate for this difficult to treat patient subgroup in the IN.PACT Global ISR Imaging Cohort was 88.7 percent, and the clinically-driven target revascularization (CD-TLR) rate was 7.3 percent. The mean length of lesions was 17.2 ± 10.5 cm, with 34.0 percent occluded ISR lesions. Additional ISR data from the IN.PACT Global Study and a PTA control were used to gain FDA approval of the ISR indication.

About IN.PACT Admiral Drug-Coated Balloon

The IN.PACT Admiral drug-coated balloon is a clinically-proven, cost-effective primary endovascular therapy that enables physicians to treat claudication and restenosis for patients with superficial femoral artery (SFA) disease. The DCB's primary mode of action is physical dilatation of the vessel lumen by PTA, and the proven paclitaxel drug is intended to prevent artery narrowing by minimizing scar tissue formation.

IN.PACT Admiral DCB received the CE (Conformité Européene) Mark in 2009 to treat PAD and was approved by the U.S. Food & Drug Administration in December 2014 to treat superficial femoral and popliteal arteries. It has been studied in more than 20 individual clinical trials demonstrating durable safety and clinical benefits. To date, more than 150,000 patients have been treated with IN.PACT Admiral DCB.

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 of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

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 88,000 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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1 Laird, J.R., et al., *Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: twelve-month results from the RESILIENT randomized trial.* Circ Cardiovasc Interv, 2010. 3(3): p. 267-76.

2 Armstrong, E.J., et al., *Nitinol self-expanding stents vs. balloon angioplasty for very long femoropopliteal lesions.* J Endovasc Ther, 2014. 21(1): p. 34-43.

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