Medtronic News

Medtronic IN.PACT(TM) Admiral(TM) Drug Coated Balloon Receives FDA Approval to Treat Long SFA Lesions

New Indication Expands DCB Treatment for Patients with SFA Lesions Up to 360mm

DUBLIN - April 23, 2018 - Medtronic plc (NYSE: MDT) today announced that it has received U.S. Food and Drug Administration (FDA) approval for the IN.PACT(TM) Admiral(TM) Drug-Coated Balloon (DCB) to treat long superficial femoral artery (SFA) lesions up to 360mm in patients with peripheral artery disease (PAD).

Approval was based on clinical data from the complex lesion imaging cohorts of the IN.PACT Global Study, including long lesion, in-stent restenosis, and chronic total occlusion (CTO) groups with lesion lengths >180mm. Across these groups, a total of 227 subjects with mean lesion lengths of 28.7 ± 7.1 cm were analyzed. Data showed a one-year patency rate of 89.1 percent by Kaplan Meier estimate at day 360, and a clinically-driven target revascularization (CD-TLR) rate of 7.1 percent.

"Data from the IN.PACT Global Study demonstrate that IN.PACT Admiral DCB is a safe and effective treatment option in real-world patients with lesions beyond 180 mm, frequently comprised of in-stent restenosis and chronic total occlusions," said Daniel Clair, M.D., chair of the Department of Surgery for University of South Carolina (USC) and the Palmetto Health-USC Medical Group. "More specifically, these results show maintenance of strong clinical outcomes, including a high primary patency rate and limited need for reintervention in patients exhibiting these complex, long lesions - among the most prevalent cases we see. The FDA's approval of this expanded indication now offers U.S. physicians a clinically-proven endovascular therapy to address this critical patient need."

PAD is a serious, chronic condition that affects more than 200 million people worldwide.1 In PAD, arteries in the legs become narrowed or blocked by plaque. This narrowing of the blood vessel reduces blood flow to the leg, which can result in severe pain and limit physical mobility.2 Complex lesions, including those over 150mm, remain a significant treatment challenge for physicians.

"In conversations with physicians, a key clinical challenge raised is the ability to provide a sustainable treatment option for longer length, complex lesions. With this approval, IN.PACT Admiral is now indicated to treat the longest lesions of any commercially-available DCB or peripheral stent in the U.S., providing physicians with additional confidence in using this DCB as part of their treatment algorithm," said Mark Pacyna, vice president and general manager of the Peripheral business, which is part of the Aortic & Peripheral Vascular division at Medtronic. "In partnership with the clinical community, we look forward to continued collaboration as we work to address additional treatment challenges in PAD with this device."

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. It was the first DCB to have received approval by the U.S. Food and Drug Administration (FDA) for the treatment of in-stent restenosis. The DCB's primary mode of action is physical dilatation of the vessel lumen by PTA, and the proven paclitaxel drug, with a unique dose and excipient, is intended to prevent artery narrowing by minimizing scar tissue formation.

IN.PACT Admiral received the CE (*Conformité Européene*) Mark in March 2009 to treat PAD and was approved by the FDA 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 200,000 patients have been treated with IN.PACT Admiral. It is the only DCB to have published three-year data and the first to have presented four-year data from a pivotal randomized trial.

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 84,000 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 Fowkes, F. G., et al. (2013). Lancet 382(9901): 1329-1340.

2 Roberts, D., et al. (2014). Catheter Cardiovasc Interv 84(2): 236-244.

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