Medtronic News

Medtronic Receives IDE Approval to Initiate Study of IN.PACT® Admiral® Drug-Coated Balloon for a New Indication in Patients with End-Stage Renal Disease

DUBLIN - Jan. 26, 2017 - Medtronic plc (NYSE: MDT) today announced receipt of an investigational device exemption (IDE) from the U.S. Food and Drug Administration (FDA) to initiate a study of the IN.PACT® Admiral® drug-coated balloon (DCB) for a potential new indication in patients with end-stage renal disease. The randomized study will evaluate the IN.PACT Admiral DCB as a treatment for failing arteriovenous (AV) fistulas in these patients as compared to plain balloon angioplasty. The IDE approval enables Medtronic to initiate the study and gain safety and effectiveness data for the device in this investigational indication.

Globally, more than 2.5 million patients with end-stage renal disease are undergoing dialysis,1 a procedure that filters waste and removes extra fluid from the blood when the kidneys are no longer healthy. AV access sites are used to provide hemodialysis to patients. Over time, thickening of the vessel walls limits the ability to use a dialysis access site, requiring repeat interventions, which increase health care utilization and reduce quality of care. Repeated procedures are also associated with high technical failure rates and reduced quality of life for patients.2,3

"In the past, when the AV access site became narrowed, the only option was use of a standard percutaneous transluminal angioplasty (PTA) balloon to re-open and regain access for dialysis. This would often result in restenosis and high rates of reintervention," said Andrew Holden, M.D., director of interventional radiology at Auckland Hospital and associate professor of radiology at Auckland University. "Patients on dialysis need alternatives to help reduce and manage stenoses of their AV access sites. It is important to effectively evaluate options such as this DCB, which already has clinical evidence in patients with peripheral artery disease (PAD) in the upper leg. "

The IDE study will evaluate the safety and efficacy of the IN.PACT DCB for up to two years at approximately 30 sites in United States, Japan, and New Zealand. Principal Investigators include: Dr. Holden, Robert Lookstein, M.D., professor of radiology and surgery, vice-chair of interventional services, and medical director of clinical supply chain at Mt. Sinai Healthcare System, and Hiroaki Haruguchi, M.D., clinic director at Haruguchi Vascular Clinic. The study will aim to enroll 330 patients with a 1:1 randomization to either treatment with IN.PACT Admiral DCB or standard balloon angioplasty. The primary efficacy endpoint is patency of dialysis fistulas through six months and the primary safety endpoint is major adverse events through 30 days. Additional endpoints include reducing access circuit related events including repeat procedures.

"IN.PACT Admiral DCB has demonstrated superior clinical outcomes in patients with PAD in the upper leg. Through our IN.PACT clinical program, we are looking at ways this DCB technology can address challenging lesions, and we have specifically designed the DCB with extended sizes for use in AV access," said Mark Pacyna, general manager of the Peripheral business, which is part of the Aortic & Peripheral Vascular division at Medtronic. "Following receipt of the CE Mark for this indication last year, the IDE approval and study initiation reflects our commitment to innovation and, most importantly, to our patients. This is an exciting new opportunity for our unique DCB with the potential to reduce rates of repeat procedures, while improving patient quality of life and quality of care in the healthcare system."

About IN.PACT Admiral Drug-Coated Balloon

IN.PACT Admiral DCB received the CE (*Conformité Européene*) Mark in 2016 for AV access and in 2009 to treat PAD. It was approved by the U.S. FDA in December 2014 for percutaneous transluminal angioplasty, after appropriate vessel preparation, of restenotic lesions with lengths up to 180 mm in superficial femoral or popliteal arteries with diameters of 4-7 mm. It is also the

only DCB technology with FDA approval to treat in-stent restenosis (ISR). IN.PACT Admiral has been studied in more than 20 individual clinical trials demonstrating durable safety and clinical benefits in the superficial femoral artery (SFA). It is the only DCB to have published two year data from a pivotal randomized trial and also the first to have presented three year data. To date, more than 200,000 patients have been treated with IN.PACT Admiral DCB.

The use of IN.PACT Admiral DCB as a treatment for patients with end-stage renal disease is investigational use only in the U.S.

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 European Renal Care Provider Association. Facts and Figures. http://ercpa.eu/facts-figures/

2 Maya, I. D. and M. Allon (2008). "Vascular access: core curriculum 2008." Am J Kidney Dis 51(4): 702 708.

3 Maya, I. D., et al. (2009). "Outcomes of brachiocephalic fistulas, transposed brachiobasilic fistulas, and upper arm grafts." Clin J Am Soc Nephrol 4(1): 86-92

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