Medtronic Receives FDA Approval for IN.PACT Admiral DCB 150 mm Lengths

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Medtronic

Expanded Treatment Options for Patients with Longer SFA Lesions with Best-In-Class Drug-Coated Balloon Technology Now Available

DUBLIN - July 13, 2016 - Medtronic plc (NYSE: MDT) has received U.S. Food and Drug Administration (FDA) approval for the IN.PACT(TM) Admiral(TM) drug-coated balloon (DCB) in longer, 150 mm lengths. The new 150 mm length balloon, available in four, five, and six mm diameters, will provide greater treatment options for long lesions in patients with peripheral artery disease (PAD).

"The long lesion (10-18 cm) sub-group outcomes from the IN.PACT SFA Trial at one year demonstrated superiority over balloon angioplasty," said John Laird, M.D., interventional cardiologist at U.C. Davis Medical Center and co-principal investigator for the IN.PACT SFA Trial. "The availability of the 150 mm length sizes will expand proven treatment options to more patients."*

The IN.PACT SFA Trial, a prospective, multi-center, randomized, controlled pivotal trial demonstrated, in a subgroup of patients with lesions >=10 cm and <18 cm, a clinically-driven target lesion revascularization (CD-TLR) rate of 5.3 percent for the IN.PACT Admiral DCB arm (n=79) and 32.4 percent for the PTA arm (n=36) ($p<0.001$). There were no device or procedure-related deaths, no occurrences of major target limb amputation, and a 3.9 percent thrombosis rate in the IN.PACT Admiral DCB arm versus 5.9 percent in the PTA arm through 12 months ($p=0.326$) in this subgroup.

"The expansion of IN.PACT Admiral DCB to 150 mm lengths demonstrates our commitment to providing meaningful technology to improve patient outcomes in a value-based healthcare environment," said Mark Pacyna, vice president and general manager of the Peripheral business, which is part of the Aortic & Peripheral Vascular division at Medtronic. "The IN.PACT Admiral platform continues to show durable, consistent, and safe outcomes."

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. See: http://www.medtronic.com/dcbresults

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 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 85,000 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.

** Cited clinical results from Medtronic IN.PACT Admiral DCB studies did not include the 150 mm lengths.*

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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Contacts:
Kena Hudson
Public Relations
+1-510-246-0163

Ryan Weispfenning
Investor Relations
+1-763-505-4626

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