Medtronic News

Medtronic Receives FDA Approval for 200mm & 250mm IN.PACT(TM) Admiral(TM) Drug Coated Balloons

GLOBE NEWSWIRE via COMTEX) --New, Extended Balloon Lengths Enable Physicians to Efficiently Treat Long SFA Lesions

DUBLIN - June 15, 2018 - Medtronic plc (NYSE: MDT) today announced that it has received U.S. Food and Drug Administration (FDA) approval for 200mm and 250mm lengths of the IN.PACT(TM) Admiral(TM) Drug-Coated Balloon (DCB) to treat long superficial femoral artery (SFA) lesions in patients with peripheral artery disease (PAD).

"As SFA disease progresses, we tend to see patients present with longer, more complex lesions. As a result, these lesions become incredibly challenging to treat and often require interventions with multiple technologies to effectively treat the entire segment," said Gary Ansel, M.D., system medical director for Vascular Services at OhioHealth Riverside Methodist Hospital in Columbus, Ohio. "The approval of the IN.PACT Admiral 200mm and 250mm balloons provides physicians with a solution to treat these long, complex lesions with fewer devices, potentially leading to shorter procedure times and reduced procedural cost."

Complex lesions, including those over 150mm, are commonly encountered in clinical practice and remain a significant treatment challenge for physicians. In April of this year, IN.PACT Admiral received approval to treat SFA lesions up to 360mm in length. 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.

"In our IN.PACT Global Study, IN.PACT Admiral demonstrated safety and effectiveness in real-world patients with complex lesions, including long lesions," said Mark Pacyna, vice president and general manager of the Peripheral business in Medtronic's Cardiac & Vascular Group. "Our new long lesion indication - coupled with the approval of the 200mm and 250mm balloons -furthers our commitment to the clinical community by equipping them with the tools and evidence needed to effectively treat complex cases."

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 SFA disease. It was the first DCB to receive approval by the U.S. FDA for the treatment of in-stent restenosis and lesions up to 360mm in length. The DCB's primary mode of action is physical dilatation of the vessel lumen by PTA, followed by the delivery of paclitaxel. With a unique dose and excipient, IN.PACT Admiral 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 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 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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