Medtronic News

Medtronic IN.PACT Admiral DEB Receives CE Mark for Treatment of AV Access In Patients with End-Stage Renal Disease

IN.PACT Admiral DEB with 40 Centimeter Catheter Enables Physicians to Maintain Arteriovenous (AV) Access in Patients Undergoing Hemodialysis

DUBLIN - January 11, 2016 - Medtronic plc (NYSE:MDT), a global leader in medical technology, services and solutions, today announced that the IN.PACT® Admiral® drug eluting balloon (DEB) (also known as the IN.PACT Admiral drug-coated balloon (DCB) in non-European markets) has received CE (Conformité Européene) Mark for arteriovenous (AV) access to help maintain hemodialysis access in patients with end-stage renal disease.

Globally, more than 2.5 million end-stage renal disease patients are undergoing hemodialysis, 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. However, thickening of the vessel walls and restenosis, due to repeated access for needed dialysis, can limit the ability to use and eventually shut down the dialysis access site. IN.PACT Admiral DEB aids in preventing restenosis, by opening the artery and delivering paclitaxel, an anti-proliferative agent, to the vessel wall. A new 40 centimeter catheter shaft will also be made commercially available in Europe under the expanded indication, which is specifically designed for AV access. In the United States, IN.PACT Admiral DEB is approved to treat superficial femoral and popliteal arteries.

"For patients with hemodialysis, maintaining AV access is their lifeline to receiving the care they need to filter waste from their system. In the past, when the access site became stenosed, the only option was the use of a standard percutaneous transluminal angioplasty (PTA), which can result in the need for repeat procedures," said Konstantinos Katsanos, M.D., Ph.D., Guy's and St. Thomas' Hospital, London, UK. "The IN.PACT Admiral DEB, in my experience, provides a safe and more effective way of managing AV access by preventing vascular restenosis, improving patency of dialysis fistulas and grafts, and reducing the need of repeat PTA procedures."

"IN.PACT Admiral DEB, a best-in-class therapy for the treatment of superficial femoral artery (SFA) disease, is now indicated in Europe for the treatment of AV access, providing a durable primary intervention that aids in extending time to re-intervention while preserving future treatment options," said Brian Verrier, vice president and general manager of the Peripheral business, within the Aortic and Peripheral Vascular division at Medtronic. "Improving lives and alleviating pain is a core piece of Medtronic's mission, and through IN.PACT Admiral DEB, we can help physicians treat patients with end-stage renal disease."

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 IN.PACT Admiral Drug-Coated Balloon

The IN.PACT Admiral drug-coated balloon (DCB) is a clinically-proven, cost-effective primary endovascular therapy that enables physicians to treat claudication, restenosis and alleviate pain from superficial femoral artery (SFA) disease. The DCB's primary mode of action is physical dilatation of the vessel lumen by percutaneous transluminal angioplasty (PTA), and the proven paclitaxel drug is intended to prevent artery narrowing by minimizing scar tissue formation. See how it works, click here.

IN.PACT Admiral DCB received the CE (Conformité Européene) Mark in 2009 to treat peripheral artery disease (PAD) and approval by the U.S. Food & Drug Administration in December 2014 to treat superficial femoral and popliteal arteries. In 2016, the CE Mark indication was expanded for the treatment of failing arteriovenous (AV) access in patients with end-stage renal

disease undergoing dialysis. It is the most studied drug-coated balloon, with more than 20 individual studies demonstrating the durability, safety and clinical benefits. To date, more than 70,000 patients have been treated with IN.PACT Admiral DCB.

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.

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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