Medtronic News

Medtronic IN.PACT Admiral DCB Maintains Durable, Consistent and Safe Outcomes in Challenging Peripheral Cases

New Rigorous Analyses Presented at Charing Cross Reinforce Efficacy in Females, Chronic Total Occlusions and Patients with Diabetes; Data Details Unique, Sustained Benefit with IN.PACT Admiral DCB

DUBLIN and LONDON - April 26, 2016 - Medtronic plc (NYSE: MDT) today added to its robust body of clinical evidence supporting the IN.PACTTM AdmiralTM drug-coated balloon (DCB) with several new presentations that showed durable and consistent clinical outcomes in the most challenging patients with peripheral artery disease (PAD). The new data, presented at the 2016 Charing Cross Symposium in London, included the one-year results from the chronic total occlusion imaging cohort from the IN.PACT Global Study and the two-year gender and diabetic subgroup analyses from the pivotal IN.PACT SFA Trial.

"The IN.PACT Admiral drug-coated balloon's unique coating delivers paclitaxel in a solid state which results in durable tissue levels of drug leading to prolonged anti-restenotic effect. We have first-of-its-kind data that shows it continues to do so even in the more challenging cases and patient populations," said Peter Schneider, M.D., of Kaiser Medical Center in Honolulu, and a principal investigator of the IN.PACT SFA Trial. "These data continue to position the IN.PACT Admiral drug- coated balloon as a durable treatment option for femoropopliteal interventions."

CHRONIC TOTAL OCCLUSION ANALYSIS

New data from the chronic total occlusion (CTO) imaging cohort of the real-world, IN.PACT Global Study were presented today at Charing Cross by Gunnar Tepe, M.D., chief of radiology at RoMed Klinikum in Rosenheim, Germany. CTOs are typically characterized by calcified plaque, which often result in complete (or nearly complete) obstruction of blood flow through the artery.

As part of the 1,535 patients enrolled across 27 countries in the rigorous, first-of-its-kind IN.PACT Global Study, 126 patients with an average lesion length of 22.9 cm were included in the pure CTO imaging cohort analysis. The primary patency rate was 84.4 percent and the clinically-driven target lesion revascularization (CD-TLR) rate was 12.2 percent at one year. Additional safety and efficacy outcomes included low rates of all-cause mortality (4.3 percent), thrombosis (4.3 percent) and no occurrences of major target limb amputation (0.0 percent). Previous reports from the IN.PACT Global Study demonstrated effectiveness in complex in-stent restenosis (ISR) lesions and long lesions in the SFA through one year.

"Despite the complexity of these challenging and complex long chronic total occlusion lesions, the outcomes were excellent and remarkably consistent to that of the overall cohort. These results show the effectiveness of the IN.PACT Admiral drug-coated balloon as a primary treatment in this complex lesion subset," concluded Dr. Tepe.

GENDER AND DIABETES ANALYSIS

IN.PACT SFA Trial investigators sought to better understand the treatment effect of the IN.PACT Admiral DCB compared to balloon angioplasty in females and patients with diabetes, patient populations whose outcomes have historically not fared as well as males and non-diabetic patients, respectively. Dr. Schneider presented outcomes from the IN.PACT SFA Trial gender and diabetes subgroups, which showed superior and durable outcomes for the IN.PACT Admiral DCB compared to balloon angioplasty across both subgroups at two years.

The IN.PACT SFA Trial enrolled 331 patients, 113 of which were female, at 57 sites across Europe and the United States. At two years, females who were treated with the IN.PACT Admiral DCB demonstrated a higher primary patency rate compared to balloon angioplasty arm (76.7 percent versus 42.3 percent, $p<0.001$). Similarly, females in the IN.PACT Admiral DCB arm had a lower CD-TLR rate compared to the balloon angioplasty arm (13.2 percent versus 38.2 percent, $p=0.005$). The beneficial

treatment effect seen in female patients who were treated with the IN.PACT Admiral DCB was consistent with the male population, who had a primary patency rate of 80.2 percent in the IN.PACT Admiral DCB arm, compared to 53.7 percent in the balloon angioplasty arm ($p<0.001$), and a 6.9 percent CD-TLR rate versus 23.6 percent ($p=0.002$), respectively. These positive DCB outcomes in the female population are unique to IN.PACT Admiral DCB.

In a separate evaluation of patients with or without diabetes, the IN.PACT Admiral DCB group continued to demonstrate consistently favorable results at two years regardless of whether a patient had diabetes. Among patients with diabetes, those treated with an IN.PACT Admiral DCB had significantly higher rates of primary patency (73.3 percent versus 45.8 percent, $p<0.001$) and CD-TLR (10.7 percent versus 29.4 percent, $p=0.010$) compared to balloon angioplasty. Similarly, in the non-diabetes subgroup, the IN.PACT Admiral DCB arm showed consistent and significant improvements in primary patency (82.5 percent versus 54.5 percent, $p<0.001$) and CD-TLR (8.1 percent versus 27.3 percent, $p=0.002$).

DATA CONFIRMS IN.PACT ADMIRAL DCB CLINICAL BENEFIT

These sustained and consistent results across complex anatomy and patient subsets may be partly attributed to IN.PACT Admiral DCB's unique coating. New pre-clinical data presented at Charing Cross today by Renu Virmani, M.D., a cardiovascular pathologist and president of CVPATH Institute in Gaithersburg, Md., demonstrated that IN.PACT Admiral DCB's proprietary coating demonstrates sustained paclitaxel in tissue over time, facilitating an extended retention of drug in tissue available for a sustained anti-restenotic effect.

"The rigor, volume and cadence of strong clinical data along with the consistency of data for the IN.PACT Admiral drug-coated balloon are among the best for any anti-restenotic therapy available for the treatment of symptomatic superficial femoral artery disease," said Dr. Mark Turco, medical director of the Aortic & Peripheral Vascular Business within Medtronic's Cardiac and Vascular Group. "When evaluating quality of study data, it's important to consider the clinical rigor built into the study design. This is why Medtronic has made a significant investment in rigorous independent core lab adjudication for the IN.PACT clinical program to deliver unquestionable results. "

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 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 was 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 has been studied in more than 20 individual clinical trials demonstrating durable safety and clinical benefits. To date, more than 100,000 patients have been treated with IN.PACT Admiral DCB.
See: www.Medtronic.com/dcbresultsCX

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.

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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