Medtronic News

Medtronic IN.PACT Admiral DCB Global Two Year Data and IN.PACT SFA Four Year Data Presented in VIVA Late Breaking Clinical Trials

Data Further Reinforce IN.PACT Admiral DCB as Frontline Option to Address Treatment Challenges in PAD

DUBLIN and LAS VEGAS - September 12, 2017 - Medtronic plc (NYSE: MDT) data announced today reinforce the durability and safety of the IN.PACT(TM) Admiral(TM) drug-coated balloon (DCB) in patients with peripheral arterial disease (PAD). The two-year, real-world results from the full clinical cohort of the IN.PACT Global Study and four-year results from the pivotal IN.PACT SFA Study were presented in two late-breaking clinical trial presentations at the Vascular Interventional Advances (VIVA) 2017 conference in Las Vegas.

IN.PACT Global Study

Professor Thomas Zeller, M.D., director of the Department of Angiology at Universitaets-Herzzentrum, Freiburg-Bad Krozingen, Germany, presented the new, two-year results from the full clinical cohort of the IN.PACT Admiral DCB Global Study. The results are the first two-year, real-world, fully adjudicated DCB data to be presented in a scientific congress, which showed consistent performance in both safety and efficacy for IN.PACT Admiral DCB.

The data were calculated using Kaplan-Meier survival estimates and revealed a freedom from clinically-driven target lesion revascularization (CD-TLR) rate of 83.3 percent in a real-world patient cohort with a mean lesion length of 12.09 ± 9.54 cm, 18.0 percent in-stent restenosis lesions, 35.5 percent occluded lesions and 39.9 percent diabetes subjects. Additional safety and effectiveness outcomes also included low rates of thrombosis (4.5 percent), occurrences of major target limb amputation (0.7 percent), and CD-TLR (16.9 percent) within two years.

"At two years, the IN.PACT Admiral DCB continues to confirm positive outcomes from the IN.PACT randomized trials, demonstrating efficacy, safety, and durability, despite the complexity of these lesions," said Prof. Zeller. "These results also highlight the clinical utility of the IN.PACT Admiral DCB as a primary therapy in treating patients with some of the most challenging PAD cases."

The IN.PACT Global Study is the largest and most rigorous real-world evaluation of any peripheral artery intervention ever undertaken. It has enrolled over 1,500 patients across 24 countries, including the 1,406 patients in the full clinical cohort presented today, to characterize the performance of the IN.PACT Admiral DCB in treating real-world patients with challenging and complex lesions. The study included adjudication of events by an independent clinical events committee.

IN.PACT SFA Study

Dr. Peter Schneider, chief of the vascular therapy division at Kaiser Foundation Hospital and Hawaii Permanente Medical Group in Honolulu also presented the first, four-year data outcomes for a DCB, further demonstrating the safety and efficacy of IN.PACT Admiral DCB in patients with PAD. Of the patients who received a repeat procedure within four years, those in the IN.PACT Admiral DCB group showed that time to reintervention was approximately double that of those in the percutaneous transluminal angioplasty (PTA) group (739.2 ± 384.0 days for IN.PACT Admiral DCB on average versus 302.9 ± 213.0 days for PTA ($p<0.001$)).

Using Kaplan-Meier survival rate estimates, IN.PACT Admiral DCB continued to outperform in freedom from CD-TLR compared to PTA with a 76.8 percent compared to 70.4 in PTA ($p= 0.0399$). The data also showed the long-term safety benefits of the IN.PACT Admiral DCB, with no major target limb amputations, a low rate of thrombosis, and no major adverse events from years three to four in the IN.PACT Admiral DCB group.

"With the IN.PACT Admiral DCB, pre-clinical studies have demonstrated that the drug remains in the tissue for approximately

six months. Therefore, at four years, we would expect to see some catch up effect and at least some late progression of atherosclerosis," said Dr. Schneider. "However, in the four-year data from IN.PACT SFA, we are still seeing sustained durability and clinical benefit. For patients suffering with this chronic condition, these findings are not only encouraging from a therapeutic perspective, but are also suggestive of improved quality of life, with patients requiring fewer reinterventions over time compared to PTA and leaving future treatment options open."

The IN.PACT SFA Trial enrolled 331 patients at 57 sites across Europe and the United States who were randomized to treatment with either the IN.PACT Admiral DCB or PTA. The four-year data includes a total of 284 patients (184 DCB and 103 PTA).

"PAD is a chronic condition associated with disease progression and often requires repeat interventions to manage the disease," said Mark Pacyna, vice president and general manager of the Peripheral business in the Medtronic Cardiac & Vascular Group. "In partnership with the clinical community, our objective has been to develop a safe, effective, and sustainable treatment option for these patients. The data presented today reflects this goal and our commitment to timely and transparent data releases. We are excited to see consistency in real-world patients and fewer interventions out to four years, which was statistically significant."

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. It was the first DCB to have received approval by the U.S. Food and Drug Administration (FDA) for the treatment of in-stent restenosis. The DCB's primary mode of action is physical dilatation of the vessel lumen by PTA, and the proven paclitaxel drug, with a unique dose and excipient, 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 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, approximately 200,000 patients have been treated with IN.PACT Admiral DCB. It is the only DCB to have published two-year data from a pivotal randomized trial, as well as the first to have presented three- and four-year data.

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 84,000 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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