Medtronic News

New Data Presented in VIVA Late Breaking Clinical Trials Demonstrate Durability, Safety and Efficacy for the Medtronic In.Pact Admiral DCB

Multiple, Rigorous Analyses Reinforce the Excellent Outcomes of IN.PACT Admiral Drug Coated Balloon and Differentiate it as Best-in-Class Treatment Option for PAD

DUBLIN and LAS VEGAS - September 19, 2016 - Medtronic today reinforced the superior durability, consistency, and safety of the IN.PACT Admiral drug-coated balloon (DCB) in patients with peripheral arterial disease (PAD). The new data, presented in a series of late-breaking clinical trial presentations at the Vascular Interventional Advances (VIVA) 2016 conference in Las Vegas, included three-year results from the pivotal IN.PACT SFA Trial and one-year, real-world results from the full clinical cohort of the IN.PACT Global Study.

IN.PACT SFA Trial

The three-year outcomes from the IN.PACT SFA Trial were presented today by Prakash Krishnan, M.D., assistant professor of medicine and director of endovascular intervention at Mount Sinai Heart in New York. The results demonstrated the sustained, long-term clinical benefits of IN.PACT Admiral DCB compared to plain balloon angioplasty.

"The IN.PACT Admiral is the only DCB to-date with superior performance supported by three-year data," said Dr. Krishnan. "In line with the one- and two-year data, we saw a consistently low clinically-driven target lesion revascularization rate and high patency rate. These durable, long-term outcomes reinforce the shift we are seeing in adoption of IN.PACT Admiral DCB as the primary treatment option for SFA treatment."

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 plain balloon angioplasty (percutaneous transluminal angioplasty, or PTA). The data demonstrate strong durability through three years with superior performance in both primary patency (69.5 percent compared to 45.1 percent in the PTA group ($p<0.001$)) and clinically-driven target lesion revascularization (CD-TLR) (15.2 percent compared to 31.1 percent in the PTA group ($p=0.002$)).

Additionally, of the patients who received a repeat procedure within three years, those in the IN.PACT Admiral DCB group did not require a second procedure as soon as those in the PTA group (542.9 days for IN.PACT Admiral DCB on average versus 302.9 days for PTA, $p<0.001$). The data also continue to demonstrate the long-term safety benefits of the IN.PACT Admiral DCB, with no major target limb amputations in the IN.PACT Admiral DCB group.

IN.PACT Global Study

In a separate session, Michael R. Jaff, D.O., medical director, Mass General Vascular Center at the Massachusetts General Hospital and professor of medicine at Harvard Medical School in Boston, presented new one-year results from the full clinical cohort of the IN.PACT Global Study. The results continue to underscore the consistent performance in both safety and efficacy for the IN.PACT Admiral DCB.

The IN.PACT Global Study is the largest and most rigorous post-market evaluation of any peripheral artery intervention ever undertaken. It has enrolled over 1,500 patients across 27 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 external monitoring and adjudication of events by an independent clinical events committee. Additionally, it included core lab evaluations for pre-specified imaging subsets for subjects with long lesions (>=15 cm) (n=157), chronic total occlusions (CTO) (>= 5 cm) (n=126) and in-stent restenosis (ISR) lesions (n=131), as recently

presented at international conferences.

"Despite the complexity of these challenging lesions and patients, the outcomes were consistent across all patients, including the imaging subsets," said Dr. Jaff. "Complex lesion types, including long lesions, chronic total occlusions and ISR, remain challenging to treat with no clearly superior treatment options. These results demonstrate the effectiveness of the IN.PACT Admiral DCB as a primary therapy in treating these challenging patients who we routinely see in clinical practice."

The one-year data demonstrated a low CD-TLR rate of 7.5 percent in a population with a mean lesion length of 12.09 cm, 18.0 percent in-stent restenosis lesions, and 35.5 percent occluded lesions. Additional safety and efficacy outcomes also included low rates of thrombosis (2.9 percent), occurrences of major target limb amputation (0.2 percent), and clinically-driven target vessel revascularization (8.1 percent) within one year.

"When evaluating quality of data, it's important to consider the clinical rigor built into the study design," said Mark Turco, M.D., medical director of the Aortic & Peripheral Vascular Business within Medtronic's Cardiac and Vascular Group. "This is why Medtronic has made significant investments in independent adjudication for the IN.PACT clinical program to deliver unquestionable results that clinicians have come to expect in our DCB. The three-year IN.PACT SFA data and the one-year IN.PACT Global data continue to demonstrate consistency, durability, and safety of the IN.PACT Admiral DCB. We look forward to sharing additional outcomes when other data sets mature."

IN.PACT DEB Long Study
Additionally, Dr. Antonio Micari of Maria Eleonora Hospital in Palermo, Italy performed an independent study evaluating treatment of long lesion lengths with the IN.PACT Admiral DCB. His data will be presented in the late-breaking clinical trial session at VIVA on Tuesday, September 20, 2016.

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 is the only 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 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, more than 150,000 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 and also the first to have presented three 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 88,000 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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