Medtronic News

Medtronic Drug-Coated Balloon (DCB) Demonstrates Consistent Results in Two New Analyses of Complex PAD Patients

DUBLIN and LONDON - April 25, 2017 - Medtronic plc (NYSE: MDT) today reinforced consistent results for its IN.PACT(TM) Admiral(TM) drug-coated balloon (DCB) with two new sub-analyses from the IN.PACT Global Study in patients with peripheral artery disease (PAD). The new data were reported at the annual 2017 Charing Cross Symposium (CX) in London, one of the world's largest educational meetings specializing in vascular and endovascular disease management.

Sub-Analysis in Patients with Complex Lesions

In a "Podium First" presentation at the conference, Gary Ansel, M.D., system medical director for Vascular Services at OhioHealth Riverside Methodist Hospital in Columbus, Ohio, presented one-year results analyzing outcomes in patients from the IN.PACT Global Study with complex lesions. The analysis compared standard usage patients (n=281) who met similar inclusion criteria for the IN.PACT SFA pivotal trial,1 an investigational device exemption (IDE) study, compared with use in a broader spectrum of patients (n=1125) who had wider inclusion criteria reflecting more real-world patients.2

Results in both groups demonstrated consistent and positive outcomes with IN.PACT Admiral at one year. In the standard IN.PACT Global Study group, clinically-driven target lesion revascularization (CD-TLR) was 3.4 percent, which was comparable to 2.4 percent in a similar population in the IN.PACT SFA pivotal trial. CD-TLR for the group with complex lesions was 8.5 percent, despite the disease complexity observed in these patient types. These results were also consistent with the full clinical cohort for the IN.PACT Global Study (n=1406), in which one-year CD-TLR was 7.5 percent.

Results of the primary safety endpoint were generally consistent across the cohorts and no safety signals were observed.

"These sub-analyses show that IN.PACT Admiral continues to deliver durable and consistent results across our more typically treated patient populations," commented Dr. Ansel. "Notably, the data in this study highlight that the IN.PACT Admiral DCB can be safe and effective when used in our patients with complex PAD, such as those with challenging calcified lesions and with significant co-morbidities."

Sub-Analysis of Patients with Calcified Lesions

Additionally, Fabrizio Fanelli, M.D., EBIR, professor of radiology at the Sapienza University in Rome, Italy, shared results of a new subset analysis of patients with complex, calcified lesions from the long lesion and chronic total occlusion (CTO) imaging cohort of the IN.PACT Global Study.

The analysis included long lesion and CTO patients defined as having moderately severe or severely calcified lesions (n=72).3 Calcium levels were assessed by the site according to protocol and confirmed by core laboratory assessment. At one year, patients achieved primary patency rates of 88.8 percent as calculated by Kaplan-Meier analysis. Primary patency is the ability for the treated artery to remain open over time. The analysis also demonstrated a CD-TLR rate of 8.5 percent. Consistent with other data sets, no safety signals were observed. In 51.4 percent of subjects, provisional stenting occurred.

Calcium remains a challenge within endovascular procedures and has historically been linked to higher provisional stenting rates, greater complications and poor outcomes. Directional atherectomy and specialty

balloons, while not evaluated in this study, are commonly used to debulk or predictably dilate calcified lesions, which may minimize the need for provisional stents.4

"Through our investments in the IN.PACT clinical program and ongoing studies, Medtronic is committed to partnering with clinicians to develop evidence-based treatments for complex PAD," said Mark Pacyna, general manager of the Peripheral business, which is part of Medtronic's Aortic & Peripheral Vascular division. "The adoption of IN.PACT Admiral as a frontline treatment option has been driven by its unparalleled clinical profile, which continues to demonstrate durability, safety, and efficacy across PAD patient populations."

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 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 femoropopliteal disease. It has been studied in 21 individual clinical trials demonstrating durable safety and clinical benefits. To date, more than 200,000 patients have been treated with the 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 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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1 Patients with single lesions less than or equal to 18 cms, total occlusions less than or equal to 10 cms, no in-stent restenosis (ISR), and none to mild calcification.

2 Patients with bilateral/multiple lesions, and moderate-to-severe calcification.

3 Dattilo, R; J Invasive Cardiol 2014;26(8):355360.

4 McKinsey, J. F., et al. (2014). JACC Cardiovasc Interv 7(8): 923-933.

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