Medtronic Drug-Coated Balloon for Treatment of Peripheral Arterial Disease Shows Strong Results in Long Lesions

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First Report of Findings from IN.PACT Global Study's Imaging Cohort Presented at EuroPCR

PARIS -- May 20, 2015 -- Presented for the first time today at EuroPCR during the "Hot line" session on "Peripheral interventions," new clinical data from two different studies show that the IN.PACT Admiral drug-coated balloon from Medtronic plc (NYSE: MDT) successfully treated long lesions in the superficial femoral and popliteal arteries.

Prof. Dierk Scheinert, chairman of the division for interventional angiology at University-Hospital Leipzig in Germany, presented 12-month results for 157 patients enrolled in the IN.PACT Global Study's long lesion imaging cohort. The average lesion length in this subset was 26.4 ± 8.61 cm -- nearly three times longer than the average lesion length of 8.9 ± 5.07 cm in the randomized controlled IN.PACT SFA Trial.

The IN.PACT Admiral drug-coated balloon (DCB) received approval from the U.S. Food and Drug Administration (FDA) in December 2014 for percutaneous transluminal angioplasty (PTA), after pre-dilitation, of de novo or restenotic lesions up to 18 cm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm. It received the CE *(Conformité Européene)* mark in 2009 for PTA in patients with obstructive disease of peripheral arteries -- a broader indication that does not specify lesion length or reference vessel diameter.

The 157 patients from the IN.PACT Global Study's long lesion imaging cohort had a total of 164 lesions of at least 15 cm in length. In addition to long lesion length, they also featured other challenging characteristics: 71.8 percent had calcified lesions, 60.4 percent had total occlusions and 41.0 percent had diabetes.

Despite these challenges, treatment with the IN.PACT Admiral DCB delivered excellent outcomes at 12 months, including a 6.0 percent rate of clinically-driven target lesion revascularization (CD-TLR) and primary patency of 91.1 percent according to Kaplan Meier analysis at 360 days post-procedure.

Prof. Scheinert also highlighted key safety data in his presentation -- specifically, 94.0 percent freedom from major adverse safety events and no major target limb amputations through 12-month follow-up.

"For patients with peripheral arterial disease in the lower extremities, long lesions pose a notoriously difficult treatment challenge," explained Prof. Scheinert, who is an investigator in the IN.PACT Global Study. "That's why the 12-month results in this long-lesion subset are so impressive. The results are also remarkably consistent with those from similar studies of the IN.PACT Admiral drug-coated balloon, irrespective of lesion length."

The IN.PACT Global Study is the largest and most rigorous post-market evaluation of any peripheral artery intervention ever undertaken. It has enrolled more than 1,500 patients at 64 sites worldwide to characterize the performance of the IN.PACT Admiral DCB in the context of routine clinical practice.

The IN.PACT Global Study's imaging cohort consists of three sub-groups, each with at least 150 patients: de novo in-stent restenosis; long lesions (at least 15 cm); and chronic total occlusions (at least 5 cm). All patients in the imaging cohort were required to undergo duplex ultrasound at 12-months post-procedure and at the time of a reintervention (if one occurred) to assess for patency.

Outcomes for patients in the in-stent restenosis and chronic total occlusion subgroups are expected to be presented at medical meetings over the next 12 months, as are two-year results from the IN.PACT SFA Trial, including the economic outcomes analysis.

The other study of the IN.PACT Admiral DCB's performance in long lesions presented today at EuroPCR, the DEB SFA-LONG Study, was conducted at six sites in Italy and enrolled 105 patients with an average lesion length of 25.2 cm. The 12-month results were presented by Dr. Antonio Micari, director of GVM Care & Research at Maria Cecilia Hospital in Palermo, and were consistent with those from the long-lesion subset of the IN.PACT Global Study's imaging cohort.

Using the same definitions, the CD-TLR rate in this independent, multicenter Italian study was 4.0 percent, and primary patency was 89.3 percent according to Kaplan Meier analysis at 360 days post-procedure.

"The latest data on the IN.PACT Admiral drug-coated balloon adds to the growing body of evidence that supports the device's use as a treatment for atherosclerotic lesions in the superficial femoral and popliteal arteries," said Dr. Mark Turco, medical director of the Aortic and Peripheral Vascular business at Medtronic. "It's especially encouraging to see such concordant results across company-sponsored and physician-initiated studies. We look forward to sharing additional data from the IN.PACT SFA Trial and IN.PACT Global Study as follow-up in our robust clinical program continues."

In collaboration with leading clinicians, researchers and scientists, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular diseases and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

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