Medtronic News

First Drug-Coated Balloon (DCB) Study Results in Japan Demonstrate Consistent Clinical Outcomes with Other Medtronic DCB Studies

New Data Recently Presented at LINC 2017 Represents the First Presentation of Clinical Results Comparing a DCB to Angioplasty in Japan

DUBLIN - Feb. 9, 2017 - Medtronic plc (NYSE: MDT) today announced the one-year clinical outcomes from the MDT-2113 IN.PACT SFA Japan Trial. The data was recently presented by Osamu Iida, M.D., Kansai Rosai Hospital, Hyogo, Japan at the Leipzig Interventional Course (LINC) 2017 conference, and reinforced the consistent clinical outcomes obtained using Medtronic's drug-coated balloon (DCB).

The IN.PACT SFA Japan Trial enrolled 100 patients at 11 sites in Japan who were randomized to treatment with either the DCB (n=68) or plain balloon angioplasty (percutaneous transluminal angioplasty, or PTA) (n=32). Per protocol, primary patency rates were assessed at 12 months of follow-up and demonstrated: 89.2 percent for the DCB group and 48.4 percent for the PTA group ($p<0.001$). Primary patency at 360 days was also calculated by Kaplan-Meier survival estimates; at this specific time point, it was 93.9 percent for the DCB group and 49.9 percent for the PTA group ($p<0.001$). Primary patency means a restoration of adequate blood flow through the treated segment of the diseased artery. Clinically-driven target lesion revascularization was 2.9 percent for the DCB group, compared to 18.8 percent in the PTA group ($p=0.012$).

The data also showed lower major adverse events for the DCB at one year (4.4 percent compared to 18.8 percent in the PTA group; $p=0.028$), with no major target limb amputations.

"This study builds on the previous Medtronic DCB clinical studies, reinforcing the consistent clinical performance in terms of primary patency and re-intervention rates of this device across patient populations," said Dr. Iida. "We are pleased to see such substantive DCB clinical data from a patient cohort in Japan."

These results are consistent with prior findings from the pivotal IN.PACT SFA Trial one-year outcomes, and further reinforce the real-world results from the full clinical cohort of the IN.PACT Global Study.

"The MDT-2113 IN.PACT SFA Japan Trial represents our global commitment to deliver robust clinical evidence to aid in the choice of treatment options for patients with PAD," said Mark Pacyna, vice president and general manager of the Peripheral business, which is part of the Cardiac and Vascular Group at Medtronic. "We are pleased to be the first to present data comparing a DCB to angioplasty in Japan."

The Medtronic DCB is an investigational device in Japan and not available for sale.

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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