IN.PACT Admiral Demonstrates Consistent and Durable Outcomes in New Two-Year Japan Data and IN.PACT Global Critical Limb Ischemia Cohort Analysis

January 30, 2018 7:28 AM CT

Medtronic plc

Data Presented at LINC 2018 Highlight IN.PACT Admiral as Safe and Effective Treatment Option in PAD

DUBLIN and LEIPZIG - January 30, 2018 - Medtronic plc (NYSE: MDT) today added to its robust body of clinical evidence supporting the IN.PACT(TM) Admiral(TM) drug-coated balloon (DCB) with new presentations that demonstrated durable and consistent clinical outcomes in peripheral artery disease (PAD). The new data presented at the Leipzig Interventional Course (LINC) in Leipzig, Germany, included the two-year results from the MDT-2113 study (IN.PACT SFA Japan) and data from a critical limb ischemia (CLI) subgroup analysis from the IN.PACT Global Study.

Two-Year Japan Data
New data from the IN.PACT SFA Japan Study were presented by Osamu Iida, M.D., Kansai Rosai Hospital, Japan. The study enrolled 100 patients across 11 sites in Japan and randomized treatment to either DCB (n=68) or plain balloon angioplasty (PTA) (n=32). The results were consistent with two-year findings from the pivotal IN.PACT SFA Study, showing a low clinically-driven target lesion revascularization (CD-TLR) rate and high patency rate.

"Across SFA trials, IN.PACT Admiral has consistently demonstrated superior safety and efficacy compared to PTA," said Dr. Iida. "We are pleased to see comparable results in Japan at two-years with durable patency outcomes, low TLR, and no instances of thrombosis. There has been a critical unmet need in Japan for new technologies that safely and effectively treat PAD, and we believe IN.PACT Admiral is well-positioned to meet this need."

IN.PACT Admiral SFA Japan demonstrated 79.8 percent primary patency in the DCB group as compared to 46.9 percent in the PTA group at two years based on Kaplan-Meier Estimate ($p<0.001$). The two-year results also demonstrated a CD-TLR rate of 9.1 percent for the DCB group compared to 20.7 percent in the PTA group ($p=0.177$) and a freedom from CD-TLR based on Kaplan-Meier Estimate of 90.8 for the DCB group compared to 81.3 percent in the PTA group ($p=0.114$). In IN.PACT SFA Japan, major adverse events were also lower for the DCB at two years (15.2 percent compared to 24.1 percent in the PTA group; $p=0.384$), with no major target limb amputations. There were no additional safety concerns at two years.

Today's announcement follows the recent approval of IN.PACT Admiral from the Japanese Ministry of Health, Labor and Welfare (MHLW) for the treatment of peripheral artery disease (PAD) in the upper leg - specifically, in the thigh (superficial femoral arteries (SFA)) and behind the knee (popliteal arteries). The MHLW also granted reimbursement approval for the IN.PACT Admiral in December of 2017. IN.PACT Admiral is expected to commercially launch in Japan after completing the conditions associated with Shonin approval.

Critical Limb Ischemia Cohort Analysis
Michel Reijnen, M.D., vascular surgeon, Rijnstate Hospital, The Netherlands, presented the one-year results from the CLI subset of the IN.PACT Global Study, including data from 156 subjects with Rutherford Classification Categories (RCC)

four and five.

IN.PACT Admiral demonstrated consistent treatment effect among subjects with RCC four and five. Data showed comparable effectiveness with a freedom from CD-TLR based on Kaplan-Meier Estimate of 86.6 percent (RCC four) and 85.5 percent (RCC five) (p=0.6881). The rate of major target limb amputations remained low at 1.4 percent overall. Additionally, IN.PACT Admiral had a clear impact on improved quality of life as measured by the EQ-5D from baseline to 12-months (p<0.001).

"The treatment of CLI in PAD remains a challenge and has led to the need for more clinical evidence around the safety and efficacy of DCB in this population," said Dr. Reijnen. "The data presented today are very encouraging in that we were able to confirm IN.PACT Admiral's strong performance in this clinically complex patient subset, as well as improved quality of life."

"Our investment in clinical data is coupled with a commitment to working with the clinical community to provide timely access to new data that gives clinicians the information they need to determine treatment options for patients with this complex and chronic disease," said Mark Pacyna, vice president and general manager of the Peripheral business in the Medtronic Cardiac & Vascular Group. "The Japan two-year data presented today builds upon our global clinical data sets and shows that IN.PACT Admiral continues to be a durable, safe and effective option for the treatment of PAD. Additionally, the CLI analysis builds upon our growing body of evidence that demonstrates IN.PACT Admiral is effective in more complex patients. We look forward to continued opportunities to bring this therapy to more patients around the world."

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 that deliver clinical and economic value to healthcare consumers and providers around the world.

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.

-end-

Contacts:
Julia Baron
Public Relations
+1-858-692-2001

Ryan Weispfenning
Investor Relations
+1-763-505-4626