Medtronic News

Medtronic Announces Commercial Launch of the IN.PACT(TM) Admiral(TM) Drug-Coated Balloon in Japan

GLOBE NEWSWIRE via COMTEX) --DUBLIN - August 15, 2018 - Medtronic plc (NYSE:MDT) today announced full commercial launch of the IN.PACT(TM) Admiral(TM) Drug-Coated Balloon (DCB) in Japan. The news follows the completion of a post-market clinical trial, which enrolled 300 subjects.

IN.PACT Admiral received approval last year 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 Japan, there is a significant need for new technologies to safely and effectively treat PAD," said Tony Semedo, president, Medtronic Japan. "Earlier this year, we presented both one- and two-year results from the IN.PACT SFA Japan study, representing consistency in clinical data shared on IN.PACT Admiral to-date. Now with the completion of our post-market study, we will become the first company to bring DCB technology to Japanese physicians and their patients."

Approval for IN.PACT Admiral in Japan was based on data from MDT-2113 (IN.PACT SFA Japan), which enrolled 100 patients across 11 sites and randomized treatment to either DCB (n=68) or standard percutaneous transluminal angioplasty (PTA) (n=32). The results were consistent with one-year findings from the pivotal IN.PACT SFA Trial, showing a low clinically-driven target lesion revascularization (CD-TLR) rate and high patency rate.

IN.PACT Admiral SFA Japan demonstrated 93.9 percent primary patency in the DCB group as compared to 46.9 percent in the PTA group at one year based on Kaplan-Meier Estimate ($p<0.001$). Additionally, one-year results showed a CD-TLR rate of 2.9 percent for the DCB group compared to 18.8 percent in the PTA group ($p=0.012$). In IN.PACT SFA Japan, major adverse events were also lower 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 or all-cause death in both treatment groups.

Most recently, two-year data from IN.PACT SFA Japan were presented at the Leipzig Interventional Course (LINC) in Leipzig, Germany. Results were also consistent with two-year findings from the IN.PACT SFA Trial.

"We are incredibly proud to have paved the way for IN.PACT Admiral and DCB technology in Japan," said Mark Pacyna, vice president and general manager of the Peripheral business, which is part of the Aortic & Peripheral Vascular division at Medtronic. "We worked closely with regulatory bodies to obtain both product and reimbursement approvals for IN.PACT Admiral, and we have continued to demonstrate IN.PACT Admiral's superior safety and efficacy compared to PTA in a Japanese patient population. We look forward to bringing this proven technology to Japan and providing physicians with the tools they need to effectively treat PAD."

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 the IN.PACT Admiral Drug-Coated Balloon
The IN.PACT Admiral drug-coated balloon is a clinically-proven primary endovascular therapy. It has been approved in Japan to treat de novo and non-stented restenotic lesions with length <=200 mm in superficial femoral and popliteal arteries with reference vessel diameters of >=4 mm and <=7 mm. The DCB's primary mode of action is physical dilatation of the vessel

lumen by PTA, and the proven paclitaxel drug is intended to reduce restenosis.

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 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 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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