Medtronic News

Medtronic Announces Japanese Regulatory Approval for the IN.PACT(TM) Admiral(TM) Drug-Coated Balloon

Clinically-Proven, Durable, Consistent, and Safe Market-Leading DCB Poised to Improve Outcomes for PAD Patients in Japan

DUBLIN - September 8, 2017 - Medtronic plc (NYSE: MDT) today announced that the IN.PACT(TM)Admiral(TM) Drug-Coated Balloon (DCB) received approval from the Japanese Ministry of Health, Labour 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). Before Medtronic can begin commercialization, it must partner with Japanese MHLW to gain reimbursement to ensure broader access to this innovative and clinically-proven therapy.

"The IN.PACT Admiral DCB has demonstrated superior one-year clinical outcomes in Japan and across Medtronic IN.PACT SFA clinical trials, providing patients with an improved restoration of blood flow and reduced need for additional revascularization compared to plain balloon angioplasty, a current standard of care," said Hiroyoshi Yokoi, M.D., at Fukuoka Sannou Hospital, Japan. "In the IN.PACT SFA Japan Trial, the DCB demonstrated superior patency and lower reintervention rates. I look forward to treating PAD patients in Japan with this durable, consistent, and safe DCB technology."

The MHLW granted approval for the IN.PACT Admiral DCB based on the robust clinical data from the IN.PACT SFA Japan Trial (MDT-2113 SFA Japan Trial) led by Osamu Iida, M.D. of Kansai Rosai Hospital, Japan and Dr. Yokoi.

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 one-year findings from the pivotal IN.PACT SFA Trial, showing a consistently 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 demonstrated 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.

"Medtronic has long been committed to providing life-saving therapies to the more than 200 million patients suffering from PAD worldwide," said Mark Pacyna, vice president and general manager of the Peripheral business in the Medtronic Cardiac & Vascular Group. "IN.PACT Admiral was launched more than seven years ago in Europe. Now, with more than 200,000 patients treated, we are excited to bring IN.PACT Admiral DCB to patients in Japan."

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 prevent artery narrowing by minimizing scar tissue formation.

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.

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