Medtronic News

Medtronic Launches Below-The-Knee Clinical Study in Europe for Treatment of PAD Using New Drug-Coated Balloon Technology

First Procedure in Prospective, Randomized, Multi-Center Study Performed at Maria Cecilia Hospital in Italy

DUBLIN - Mar. 9, 2017 - Medtronic plc (NYSE: MDT) today announced the launch of the IN.PACT(TM) BTK study to evaluate the effectiveness of using a drug-coated balloon (DCB) in patients with below-the-knee (BTK) peripheral arterial disease (PAD). This study will evaluate the IN.PACT 0.014 paclitaxel-coated percutaneous transluminal angioplasty (PTA) balloon catheter. This is an investigational device, which uses Medtronic's unique IN.PACT(TM) Admiral(TM) drug coating technology.

Dr. Antonio Micari of Maria Cecilia Hospital in Cotignola, Italy performed the first procedure on a patient with critical limb ischemia (CLI). Dr. Micari reports the first patient is doing well post-treatment.

"The first patient enrollment in the IN.PACT BTK study marks a landmark milestone in identifying a treatment option for below-the-knee PAD," said Dr. Micari. "Given the chronic nature and co-morbidities of this disease, there is a critical need for treatment options that are safe and durable. I look forward to continuing patient enrollment to evaluate the use of this DCB in treating this challenging disease state."

CLI with PAD below-the-knee is associated with risk of non-healing wound ulcers and amputation. This complex disease is one of the most significant clinical challenges for physicians in the clinical vascular community.

"Patency rates after conventional balloon angioplasty can be challenging in BTK disease, and we believe that a sustained patency could improve healing and reduce the need of target lesions revascularization (TLR) and major amputation," said Francesco Liistro, M.D., chief of Cardiovascular Intervention at San Donato Hospital, Arezzo, Italy. "Multiple studies have evaluated DCBs in the superficial femoral arteries (SFA), but the need for clinically supported treatment options for below-the-knee PAD still remains. We look forward to participating in this significant trial to evaluate the IN.PACT 0.014 DCB in a complex CLI patient population, particularly given the strong evidence for use of IN.PACT Admiral in the SFA."

The IN.PACT BTK study is a unique, prospective, randomized, multi-center study that will enroll approximately 60 patients at four sites in Europe. The study's primary endpoint is late lumen loss at nine months, an important angiographic measure of drug effectiveness, in patients who received treatment with the IN.PACT 0.014 DCB compared to standard PTA. The study also includes a wound care protocol, which provides additional safety controls and ensures patients will routinely undergo routine and standard monitoring by qualified wound care professionals.

Medtronic partnered closely with the clinical community to further understand the complexity of this disease state and build on the emerging body of scientific knowledge regarding use of DCBs below-the-knee. This includes findings from Medtronic's IN.PACT DEEP trial, which used an earlier balloon technology. Additionally, at TCT 2016, Dr. Juan F. Granada presented pre-clinical data on wound healing in a porcine model. The findings indicated that the use of the IN.PACT Admiral drug-coated balloon in the SFA territory does not delay wound healing despite measureable concentrations of paclitaxel in the adjacent cutaneous tissue.

"Peripheral artery disease below the knee is complex. With these prior analyses, we have developed an unmatched knowledge around the treatment of below-the-knee disease and CLI," said Mark Pacyna, vice president and general manager of the Peripheral business in Medtronic's Aortic & Peripheral Vascular division. "Together with our clinical investigators, we look forward to launching the IN.PACT BTK study to evaluate the effect of the IN.PACT 0.014 in patients with below-the-knee PAD."

The IN.PACT 0.014 DCB is an investigational device being evaluated in Europe and does not have an approved Investigational

Device Exemption in the United States.

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 of the highest quality 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 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.

-end-

Contacts:
Krystin Hayward Leong
Public Relations
+1-508-261-6512

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

---

https://news.medtronic.com/2017-03-09-Medtronic-Launches-Below-The-Knee-Clinical-Study-in-Europe-for-Treatment-of-PAD-Using-New-Drug-Coated-Balloon-Technology