IN.PACT AV Access Trial Meets Primary Safety and Effectiveness Endpoints

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IN.PACT AV Drug-Coated Balloon Shows Promise in Treating Arteriovenous Fistulae Lesions in End-Stage Renal Disease Patients

DUBLIN and BARCELONA, Spain, Sept. 07, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) announced the first-ever results from the IN.PACT AV Access clinical study comparing the investigational IN.PACT™ AV™ drug-coated balloon (DCB) to percutaneous transluminal angioplasty (PTA) in patients with de novo or non-stented restenotic arteriovenous (AV) fistulae lesions. The study met primary safety and effectiveness endpoints and data were presented today at the Cardiovascular and Interventional Radiology Society of Europe (CIRSE) annual meeting in Barcelona, Spain.

“Maintaining patency and limiting the frequency of reinterventions needed to keep AV access sites functioning properly remain significant treatment challenges for physicians treating AV fistulae lesions,” said Andrew Holden, M.D., director of interventional radiology at Auckland Hospital and associate professor of radiology at Auckland University. “These results demonstrate the promise of IN.PACT AV DCB to not only address these critical issues, but to potentially improve the quality of life of patients undergoing dialysis.”

AV fistulae, otherwise known as AV access sites, are created and used to deliver hemodialysis to patients with end-stage renal disease (ESRD). Over time, vessel restenosis limits the ability to use AV fistulae effectively. In order to restore function, patients often undergo one to three AV fistula maintenance procedures per year.[1] The need for frequent reinterventions can result in significant disruptions to critical hemodialysis care and increased costs to the healthcare system. Drug-coated balloons have the potential to extend the time between reinterventions by maintaining AV access site patency, therefore maximizing a patient’s uninterrupted access to lifesaving dialysis care.

The IN.PACT AV Access study is a randomized controlled trial (RCT), which has enrolled 330 subjects at 29 sites in United States, Japan, and New Zealand. The primary effectiveness endpoint was defined as freedom from clinically-driven target lesion revascularization (CD-TLR) or access circuit thrombosis measured through six months post-procedure and the primary safety endpoint was defined as the serious adverse event rate involving the AV Access circuit through 30 days post-procedure. Additional endpoints include but are not limited to: access circuit primary patency, cumulative target lesion revascularizations, and number of interventions required to maintain target lesion patency.

The study enrolled a challenging patient population who had been undergoing dialysis for an average of 4.3 years. Overall, the IN.PACT AV DCB group demonstrated clinical benefit compared to the PTA control group. Key data highlights include:

- Per Kaplan-Meier estimates, the primary patency rate of the target lesion at 180 days was 86.1% in the IN.PACT AV DCB group compared to 68.9% in the PTA control group ($p<0.001$).
- Per Kaplan-Meier estimates, the primary patency rate of the target lesion at 210 days was 81.4% in the IN.PACT AV DCB group compared to 59.0% in the PTA control group ($p<0.001$).
- Patients in the IN.PACT AV DCB group required 56.0% fewer reinterventions to maintain target lesion patency through 210 days compared to those in the PTA control group.
- A low rate of access circuit-related serious adverse events, with 4.2% in the IN.PACT AV DCB study group compared to 4.4% in the PTA control group through 30 days.

Additionally, the Kaplan-Meier estimated freedom from all-cause death through 360 days was 90.6% in the IN.PACT AV DCB study group and 90.4% in the PTA control group. This data adds to the initial safety data presented at U.S. Food and Drug Administration's Advisory Committee meeting of the Circulatory System Devices Panel in June, showing no difference in mortality rates in this patient population.

“The data presented today at CIRSE demonstrate the potential of IN.PACT AV DCB to address restenosis in high-risk patients who currently have few long-term treatment options available to them,” said Mark Pacyna, vice president and general manager of the Peripheral Vascular business, which is part of the Aortic, Peripheral, and Venous division at Medtronic. “As part of our commitment to improving outcomes, we look forward to generating further clinical evidence in support of this therapy.”

In the U.S., IN.PACT AV DCB is an investigational device and not yet approved for commercial use. In January 2016, the CE (Conformité Européene) indication for the IN.PACT™ Admiral™ DCB was expanded for the treatment of failing arteriovenous access in patients with end-stage renal disease undergoing dialysis.

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 90,000 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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[1]*THE USRDS Special Study Center. Transition of care in CKD. Prelude to Dialysis: Trends and Timely Transitions. Kalantar-Zadeh K. Et Al. 2016*

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