Medtronic Drug-Coated Balloon Receives U.S. FDA Approval to Treat Arteriovenous Fistula Lesions

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Clinical Data Demonstrates IN.PACT™ AV DCB Is Safe, Reduces Reinterventions, and Maintains Access for End-Stage Renal Disease Patients Undergoing Dialysis

DUBLIN, Nov. 21, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced U.S. Food and Drug Administration (FDA) approval of the IN.PACT™ AV drug-coated balloon (DCB), a paclitaxel-coated balloon indicated for the treatment of failing arteriovenous (AV) access in patients with end-stage renal disease (ESRD) undergoing dialysis.

AV fistulae are created and used to enable hemodialysis for patients with ESRD. Over time, vessel restenosis limits the ability to use AV fistulae effectively. In order to restore function, patients often undergo one to three maintenance procedures per year,[1] which can result in significant disruptions to critical hemodialysis care and increased costs to the healthcare system. Pivotal randomized trial results from the IN.PACT AV Access trial have shown IN.PACT AV DCB can extend the time between reinterventions by maintaining AV access site patency, therefore maximizing a patient's uninterrupted access to lifesaving dialysis care.

"In many cases, AV fistula are considered lifelines for patients with ESRD as they are the primary access point for life-saving dialysis treatment. When these access sites fail, patients experience delays in their dialysis treatment and require multiple reinterventions to keep the site functioning," said Vincent Gallo, M.D., interventional radiologist at Holy Name Medical Center in Teaneck, New Jersey and an investigator for the IN.PACT AV Access trial. "With this approval physicians now have access to a safe and extremely effective therapy to slow the progression of restenosis, which results in fewer reinterventions and disruptions in care for these patients."

The FDA approval is based on data from a prospective, global, multicenter, blinded, randomized (1:1), investigational device exemption (IDE) study, which enrolled 330 subjects, and evaluated the safety and effectiveness of the IN.PACT AV DCB at 29 sites in the United States, Japan, and New Zealand. Early data presented at the Cardiovascular Interventional Radiological Society of Europe (CIRSE) met the primary endpoints in demonstrating the comparable safety and the superior effectiveness of IN.PACT AV DCB compared to percutaneous transluminal angioplasty (PTA). Patients treated with IN.PACT AV DCB maintained patency longer and required 56% fewer reinterventions compared to those treated with standard PTA through six months. Through 12 months the data also showed no difference in mortality rates between the IN.PACT AV DCB group and the PTA control group. Finally, data presented at VIVA 2019 demonstrated superior patency was achieved with IN.PACT AV DCB versus PTA in both de novo and restenotic lesions, and all studied types of AV access.

"Until now, there were virtually no therapies available to treat AV fistulae lesions that had demonstrated an ability to maintain primary patency and reduce reinterventions over time," said Robert Lookstein, M.D., national principal investigator in the U.S. and professor of radiology and surgery, vice-chair of interventional services, and medical director of clinical supply chain at Mt. Sinai Healthcare System in New York, New York. "In the largest AV DCB pivotal study to-date, IN.PACT AV DCB demonstrated the highest primary patency rate through six months and significantly lowered the rate of reinterventions required to maintain patency. With this evidence and approval in hand, we now have a technology that provides a significant clinical benefit of a 56% reduction in repeat interventions, which I believe is a huge win for the hemodialysis community and the patients we treat."

IN.PACT AV DCB, leveraging technology from Medtronic's IN.PACT™ Admiral™ platform, increases blood flow and reduces thickening of the vessel wall by delivering the proven anti-proliferative drug paclitaxel. This drug penetrates deep into the vessel wall to prevent restenosis and has the potential to extend time between reinterventions. In 2016, the CE Mark indication for IN.PACT Admiral DCB was expanded for the treatment of failing arteriovenous (AV) access in patients with end-stage renal disease undergoing dialysis.

"The FDA approval of IN.PACT AV DCB marks a significant step forward for paclitaxel-coated devices. Importantly, it allows us to expand our proven IN.PACT DCB platform beyond the superficial femoral artery," said Mark Pacyna, vice president and general manager of the Peripheral Vascular business in the Medtronic Cardiac & Vascular Group. "We are excited to bring this technology to physicians in the U.S. and to help improve the lives of patients living with ESRD."

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 and end-stage renal disease. 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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