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Medtronic’s DCB gets FDA nod 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

Medtronic plc has 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, 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."

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."