Medtronic News

IN.PACT™ AV Drug-Coated Balloon Is First and Only to Show Superior and Sustained Results Through Two Years Compared to PTA in Treating Arteriovenous Fistulae Lesions

IN.PACT AV Access Trial 24 Month Results Presented as a Podium First at Charing Cross Symposium

DUBLIN and LONDON, April 20, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced the safety and effectiveness results through 24 months for the IN.PACT AV Access clinical study. The data, which were presented virtually as a podium first at the 2021 Charing Cross Symposium, demonstrated that the IN.PACT™ AV drug-coated balloon (DCB) is the first and only DCB to show sustained and superior effectiveness through two years compared to standard percutaneous transluminal angioplasty (PTA) in end-stage renal disease (ESRD) patients with de novo or non-stented restenotic native arteriovenous fistulae (AVF) in the upper extremity.[1,2]

"A patient who receives hemodialysis will often need to have several reinterventions each year to maintain patency and keep critical access sites open and functioning properly," said Andrew Holden, MBChB, FRANZCR, director of interventional radiology at Auckland Hospital and associate professor of radiology at Auckland University. "Being able to show these results at two years will ultimately impact standard of care for patients undergoing dialysis. For my patients, these durable results translate into fewer reinterventions and a better quality of life."

AV fistulae are created and used to deliver hemodialysis to 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 AV fistula maintenance procedures per year.[3] 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.

Over two years, the IN.PACT AV DCB group demonstrated a continued clinical benefit compared to the PTA control group. Key data highlights per Kaplan-Meier estimates for this dataset include:

- Target lesion primary patency through 24 months was 52.2% in the IN.PACT AV DCB group compared to 36.2% in the PTA control group (log-rank $p<0.001$).
- Access circuit primary patency through 24 months was 39.5% in the IN.PACT AV DCB group compared to 25.4% in the PTA control group (log-rank $p<0.001$).
- Freedom from all-cause mortality through 24 months was 82.4% in the IN.PACT AV DCB study group and 82.8% in the PTA control group (log-rank $p=0.829$).

"Medtronic is committed to providing physicians and patients with technology to improve dialysis access maintenance outcomes and reduce disruptions to care. Both our investment in this study as well as its results are a clear testament to this," said Dave Moeller, president of the Peripheral Vascular Health business, which is part of the Cardiovascular Portfolio at Medtronic. "These results are significant not only because IN.PACT AV is the only DCB to meet both safety and effectiveness endpoints through six months, but also because it demonstrates that at two years, IN.PACT AV does better than PTA in helping to keep critical lifelines open and reduce the number of times a patient needs to return to their physician for a reintervention."

About the IN.PACT AV Access Study

The IN.PACT AV Access study is a prospective, global, single-blinded, randomized controlled trial (RCT), which enrolled 330 subjects at 29 sites in the United States, Japan and New Zealand. Results of the six-month pivotal IN.PACT AV Access study were presented at CIRSE in September 2019 and also published in *The New England Journal of Medicine* in August 2020.[4]

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.

[1] Holden, A., Charing Cross 2021

[2] Trerotola SO, Saad TF, Roy-Chaudhury P; Lutonix AV Clinical Trial Investigators. The Lutonix AV Randomized Trial of Paclitaxel-Coated Balloons in Arteriovenous Fistula Stenosis: 2-Year Results and Subgroup Analysis. J Vasc Interv Radiol. January 2020;31(1):1-14.e5.

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

[4] Lookstein et al. Drug-Coated Balloons for Dysfunctional Dialysis Arteriovenous Fistulas. N Engl J Med 2020; 383:733-742.

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