**OCT 23, 2024**

# Medtronic received FDA approval for IDE Trial for its Prevail™ drug coated balloon

- *Data to support regulatory submissions for the treatment of coronary artery disease in the U.S. and Japan*
- *Prevail Global Study will include the first head-to-head randomized evaluation of two drug-coated balloons in the U.S.*
- *Trial will assess safety and effectiveness of the Prevail DCB for in-stent restenosis (ISR) and de novo small vessels*

Medtronic today announced it has received approval of a U.S. Food and Drug Administration (FDA) investigational device exemption (IDE), to initiate its pivotal clinical trial of the Prevail™ coronary paclitaxel drug-coated balloon (DCB) for in stent restenosis (ISR) and *de novo* small vessel disease. Data from the Prevail Global Clinical Program will be used to support approval of the Prevail DCB in Japan and the U.S.

The multi-center, dual cohort clinical trial will enroll up to 1,205 patients with coronary artery disease from approximately 65 global centers across the U.S., Europe and Asia Pacific. The trial will include a randomized controlled evaluation of ISR patients and a single arm evaluation of de novo small vessel disease patients to assess the safety and efficacy of the Prevail DCB.

“As physicians treat more patients with complex lesions, it is important to have a device that helps to maintain durable patency while preserving future treatment options,” said David Kandzari, M.D., chief, Piedmont Heart Institute and Cardiovascular Services in Atlanta and co-principal investigator of the Prevail Global Study. “Drug-coated balloons provide clinicians with an anti-restenosis solution, without the need of a permanent stent. This groundbreaking trial will include the first head-to-head randomized trial of two drug coated balloons in the U.S. and will provide important additional evidence for this growing therapy.”

The ISR Cohort will be led by Dr. Kandzari and Prof. Bruno Scheller, M.D., professor for Clinical and Experimental Interventional Cardiology at Saarland University, Germany and will randomize patients 1:1 with the Medtronic Prevail DCB and Boston Scientific AGENT™ DCB* to assess non-inferiority.

The *de novo* small vessel (DNSV) Cohort will be led by Azeem Latib, M.D., system director of Interventional Cardiology, Montefiore Health System and director of Structural Heart, Montefiore Medical Center & White Plains Hospital, and Darren Mylotte, M.D., consultant cardiologist, Galway University Hospital and School of Medicine, University of Galway, and will compare Prevail DCB against drug eluting stents, the standard of care for small

vessel treatment, using a historical control from the extensive body of evidence from the Resolute Onyx Clinical Program. The primary endpoint for both cohorts will be target lesion failure (TLF) at 12 months. Patients will be followed out to five years.

The Prevail DCB is intended to be used during percutaneous coronary intervention (PCI) procedures to treat narrowed or blocked coronary arteries in patients with coronary artery disease. During the catheter-based procedure, the balloon inflates within the artery, while the drug (paclitaxel) is delivered to the arterial tissue where it is absorbed and retained to provide a durable anti-restenotic effect.

"The launch of the Prevail IDE study underscores our commitment to pioneering advanced solutions for complex PCI," stated Jason Weidman, senior vice president and president of the Coronary and Renal Denervation business, which is part of the Cardiovascular Portfolio at Medtronic. "The Prevail DCB has the potential to be a significant advancement in the coronary market. Medtronic is proud to invest in the expansion of clinical evidence to bring Prevail to patients globally. As a leader in drug and device combination therapies for vascular diseases, we look forward to collaborating closely with study investigators and the FDA to initiate patient enrollment in the forthcoming months."

The Prevail Global Study will build upon the extensive experience from the use of Prevail DCB globally. Prevail DCB was launched in Europe in 2021 with indications for the treatment of de novo lesions, in-stent restenosis, and small vessel disease in the coronary arteries. Its differentiated FreePac™ coating has an extensive body of evidence in both coronary and peripheral artery disease with over 10 trials and 1,600 patients studied.

The Prevail™ DCB is commercially available in more than 79 countries globally. Within the Prevail Global Study, Prevail DCB is investigational. Prevail DCB is not approved or sold in the U.S. or Japan.

**About Medtronic**

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow us on LinkedIn.

**Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the U.S. Securities and Exchange Commission. Actual results may differ materially from anticipated results.**

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