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Medtronic enrolls first patient in global trial for its Prevail™ drug-coated balloon

St. Francis Hospital in New York performs the first patient procedure in clinical trial for coronary artery disease

Medtronic today announced that the first patient has been enrolled in its pivotal trial of the Prevail™ paclitaxel-coated balloon catheter (also known as a drug-coated balloon) for in-stent restenosis (ISR) and *de novo* small vessel disease. The first procedure was performed by Dr. Ziad Ali, director of DeMatteis Cardiovascular Institute at St Francis Hospital & Heart Center in New York. Data from the Prevail Global study is intended to support approval of the Prevail drug-coated balloon (DCB) in the United States and Japan.

“Coronary artery disease (CAD) is a chronic condition affecting over 315 million people globally, highlighting the importance of developing innovative and long-lasting solutions to assist patients in maintaining blood flow, whether they have new heart blockages or have been previously treated,” said Dr. Ali. “In the U.S., drug-coated balloons have been used for more than a decade in patients with peripheral artery disease. This trial will not only bring the use of this innovative DCB technology to patients with previously treated blockages - where stents have failed - but it will also bring use to new blockages in small vessels - where stents might not perform as well in the coronary arteries. We are proud to be enrolling patients in the Prevail Global study.”

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 an anti-restenotic effect.

The multi-center, dual cohort clinical trial will enroll up to 1,205 patients with CAD 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 for the primary endpoint of target lesion failure at 12 months post procedure.

The Prevail Global study will build upon the extensive commercial 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 first patient enrollment in the Prevail Global study is a pivotal milestone as we look to provide clinicians with innovation in complex PCI procedures," said Jason Weidman, senior vice president and president of the Coronary and Renal Denervation business within the Medtronic Cardiovascular Portfolio. "As a leader in coronary drug eluting stents and peripheral drug-coated balloons, Medtronic is committed to delivering this new evidence to support future regulatory submissions for Prevail DCB in the U.S. and Japan."

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, visit www.Medtronic.com and follow us on LinkedIn.

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