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Medtronic receives expanded CE Mark indications for Prevail™ paclitaxel-coated PTCA balloon catheter, including complex bifurcation lesions

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Medtronic, a global leader in healthcare technology, announced today that it has received CE (Conformité Européenne) Mark approval for several expanded indications for the treatment of coronary artery disease (CAD) with the Prevail™ paclitaxel-coated percutaneous transluminal coronary angioplasty (PTCA) balloon catheter, also known as a drug-coated balloon (DCB). The Prevail DCB now has the broadest range of CE Mark indications including bifurcation and is the only DCB indicated for treatment in patients with multivessel disease, acute coronary syndrome, and diabetes.[1]

CE Mark approval follows the Prevail DCB's excellent performance in a large, real-world, complex patient population from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR). In a late-breaking clinical trial, presented at Cardiovascular Research Technologies, the Prevail DCB demonstrated low event rates* at two years including 6.1% new myocardial infarction, 7.4% target lesion revascularization, and 0.8% target lesion definite thrombosis. In hybrid percutaneous coronary intervention (defined as DCB and drug-eluting stent in the same vessel), the study showed the Prevail DCB demonstrated numerically lower new myocardial infarction rates versus other DCBs.

These results were confirmed for bifurcation patients in a subgroup analysis presented at EuroPCR this week. In bifurcation lesions, the Prevail DCB demonstrated low mortality and revascularization rates,[1] with 2.3% new myocardial infarction, 2.8% target lesion revascularization, and 0% target lesion definite thrombosis at one year. The event rates were consistently low across the different bifurcation strategies and suggest the Prevail DCB is an effective treatment option for a variety of complex coronary lesions.

"The Prevail DCB's acute performance, clinical data, and expanded indications support the needs of physicians who treat increasingly complex patients. We are taking the same approach we've taken over the years with our drug-eluting stents," said Jason Weidman, senior vice president and president of the Coronary & Renal Denervation business, part of the Cardiovascular Portfolio at Medtronic. "By bringing real world clinical data to the forefront, we can expand use of the

Prevail DCB in new patient populations. We look forward to helping even more physicians across the globe access the tools they need to give their patients best-in-class care."

CAD affects more than 315 million people worldwide and is a condition in which arteries that support blood and oxygen to the heart become narrowed or blocked, most often because of plaque buildup.[2] Drug-coated balloons are gaining traction globally as a treatment option for patients with CAD. As the clinical evidence landscape expands, physicians are using DCBs in a broader range of cases, including one of the fastest growing areas - bifurcation lesions.[3] DCBs can simplify bifurcation procedures, which are often considered more challenging, by potentially reducing the number of stents when treating side branch disease while also promoting positive vessel remodeling.[4]

Prevail DCB provides superior deliverability, an effective antirestenotic drug formulation (paclitaxel), and sustainable long-term outcomes.[5,6] It 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.[7] The Prevail DCB is commercially available in more than 80 countries globally and is limited to investigational use in the U.S. and 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 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 Securities and Exchange Commission. Actual results may differ materially from anticipated results.

[1] CE Mark approved for the treatment of the following patient and lesion subsets: De novo, In-stent restenosis, Small vessel, Diabetes mellitus, Acute coronary syndrome, ST-elevated myocardial infarction, Multivessel disease, Large vessel, Bifurcations, and Total occlusions/Chronic total occlusions, May 2025

[2] World Health Organization, Cardiovascular diseases fact sheet, 11 June 2021

[3]DCB tracking study in Europe. 2024

[4]Raban V. Jeger et al. J Am Coll Cardiol Intv 2020; 13:1391-1402.

[5]Data on File at Medtronic, reference D00178515 Preclinical acute performance testing. 2020

[6]Data on File at Medtronic, reference D00178518 Preclinical elution evaluation. 2019

[7]Data on file at Medtronic

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* The event rates are based on KM estimates

https://news.medtronic.com/Medtronic-receives-expanded-CE-Mark-indications-for-Prevail-TM-paclitaxel-coated-PTCA-balloon-catheter,-including-complex-bifurcation-lesions