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Medtronic receives CE Mark for leading transcatheter pulmonary valve replacement system for congenital heart disease

Harmony™ Transcatheter Pulmonary Valve system approval expands minimally invasive treatment options for patients with congenital heart disease across European Union

Medtronic plc, a global leader in healthcare technology, today announced it received CE (*Conformité Européenne*) Mark for the Harmony™ Transcatheter Pulmonary Valve (TPV) System, a minimally invasive alternative to open-heart surgery for congenital heart disease patients with native or surgically repaired right ventricular outflow tract (RVOT). The Harmony TPV system has already been implanted in over 2,200 patients and now has access to help many more patients across the European Union.

The Harmony TPV system is designed to treat patients with RVOT anomalies with severe pulmonary valve regurgitation (PR), a condition where blood leaks back into the right lower chamber of the heart after being pumped into the lungs. Harmony TPV system clinical trials demonstrate ease of implant, conformability to the anatomy, and strong clinical and hemodynamic outcomes for congenital heart disease patients up to three years.

“The expansion of the Harmony TPV system enables a critical new solution, ensuring that more patients can have access to cutting-edge transcatheter technology and potentially lessen the need for multiple surgeries,” said Nina Goodheart, senior vice president and president of the Structural Heart & Aortic business, which is part of the Cardiovascular Portfolio at Medtronic. “This significant milestone underscores our unwavering commitment to delivering minimally invasive treatment options with excellent safety and effectiveness to patients and physicians worldwide.”

Congenital heart disease (CHD) is the most common type of birth defect in Europe, affecting an estimated 40,000 infants each year[1] and 2.3 million adults who live with the disease[2]. Approximately one in five patients born with CHD have structural malformations that disrupt the connection between the heart and the lungs, or the RVOT. The current standard of care is open-heart surgery or other interventions early in life to address these malformations. For the 80% of CHD patients who require a native or surgically repaired RVOT at birth, many will need a pulmonary valve replacement later in life, which often requires another open-heart surgery.

“Receiving CE Mark for the Harmony TPV system helps advance options for minimally invasive solutions for

physicians to treat this vulnerable patient population and optimize their outcomes," said Professor Peter Ewert, MD, PhD, director of the Department of Congenital Heart Defects and Pediatric Cardiology at the German Heart Center in Munich, Germany. "Clinicians across Europe are in need of solutions to fill this gap, and this milestone will be a potential turning point for patients who want to avoid multiple surgeries and minimize medical disruptions in their daily lives."

CE Mark follows U.S. Food and Drug Administration approval of the system in 2021. Harmony TPV U.S. mid-term (three-year) data results demonstrated superior patient outcomes with positive sustained RV remodeling, effective valve function, and a strong safety profile, all contributing to significant improvement in patient quality of life. The device is expected to be commercially available across Europe later this month.

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 Medtronic 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.

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[1] Hoffman JL, Kaplan S. The incidence of congenital heart disease. J Am Coll Cardiol. June 19, 2002;39(12):1890-1900

[2] Chessa M, Tutarel O. Adults with congenital heart disease - we need more Europe for a better care. Eur J Heart Fail. 2021;23(3):454-455.

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