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Medtronic Harmony™ Transcatheter Pulmonary Valve Only System of its Kind to Present Successful Outcomes for Congenital Heart Disease Patients at Two Years

SCAI 2023 Scientific Sessions: Harmony™ Transcatheter Pulmonary Valve System Demonstrates Strong Clinical and Hemodynamic Outcomes at Two Years

Medtronic today announced two-year results of their Harmony™ Transcatheter Pulmonary Valve (TPV) System, which treats severe pulmonary regurgitation (PR) in the native or surgically repaired right ventricular outflow tract (RVOT). The analysis demonstrates strong clinical and hemodynamic outcomes for patients with a congenital heart defect of the RVOT and was presented at the Society for Cardiovascular Angiography & Interventions (SCAI) 2023 Scientific Sessions.

“Sharing these longer-term outcomes for the Harmony Transcatheter Valve is an important milestone to help offer more streamlined treatment options for patients living with congenital heart disease,” Mary Hunt Martin, MD, FSCAI, director of Adult Congenital Intervention at University of Utah and Primary Children’s Hospital in, Salt Lake, Utah. “The strong safety profile reflected in these findings is especially encouraging since prior to Harmony, many of these patients would have to undergo multiple surgeries early on in their life.”

Congenital heart disease (CHD) is the most common type of birth defect in the United States, affecting an estimated 40,000 infants each year[1] and 1.6 million 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[3], 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.

Harmony TPV was 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. The Harmony TPV provides these patients with a minimally invasive treatment alternative.

Patients received a commercially available Harmony valve – a 22 mm valve (TPV22 device) or a 25 mm valve (TPV25 device) – as part of the Harmony Native Outflow Tract Early Feasibility Study (EFS), Harmony TPV Pivotal Trial, and Continued Access Study (CAS). Eligible patients had severe PR by echocardiography or PR fraction ≥30% by cardiac magnetic resonance imaging and a clinical indication for pulmonary valve replacement. In the study, 86 patients were implanted with a TPV22 (n=42) or TPV25 (n=44) device, all of whom remained implanted for >24 hours.

Key findings include 0% vascular injury requiring intervention, 98% freedom from major stent fracture (TPV22), and 97% with none/trace or mild PR at 2- years.

“These findings help deepen our long-term evidence for Harmony TPV and underscore our commitment to providing solutions for congenital patients with complex anatomies,” said Nina Goodheart, SVP and President of the Structural Heart & Aortic business at Medtronic. “Providing a system designed to reliably treat pulmonary regurgitation is an important way Medtronic innovations positively impact this vulnerable patient population.”

The Harmony TPV System received U.S. FDA approval in 2021 based on the Harmony TPV clinical study that demonstrated safety and effectiveness. The Harmony TPV device is commercially available for use in the United States and Japan, and has received regulatory approval in Canada and Saudi Arabia. Earlier this year, Medtronic relaunched the Harmony TPV system following a voluntary recall of the Harmony Delivery Catheter System (DCS) in March 2022. Medtronic worked collaboratively with the FDA to remediate the issue and earn FDA approval to return the device to market.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, 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 90,000+ 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 @Medtronic on Twitter and 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] Hoffman JL, Kaplan S. The incidence of congenital heart disease. *J Am Coll Cardiol*. 2002;39(12):1890-1900.

[2] Adult Congenital Heart Association (ACHA).

[3] McElhinney DB, Hennesen JT. The Melody® valve and Ensemble® delivery system for transcatheter pulmonary valve replacement. *Ann NY Acad Sci.* 2013; 1291: 77-85.

https://news.medtronic.com/harmony-two-year-outcomes