Medtronic News

Medtronic Harmony(TM) Transcatheter Pulmonary Valve Demonstrates Positive Early Clinical Outcomes at One Year

FDA Approves IDE Study Initiation Following Positive Results from First-of-its-Kind Early Feasibility Study Presented at TCT

DUBLIN and WASHINGTON, D.C. - Nov. 1, 2016 - Medtronic plc (NYSE: MDT) today announced new clinical data for the Harmony(TM) Transcatheter Pulmonary Valve (TPV) from its early feasibility study, showing improved hemodynamics from baseline and consistent valve performance at one year. Presented at the Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, the positive new data from the first-of-its-kind early feasibility study led the U.S. Food and Drug Administration (FDA) to also recently approve the initiation of a Pivotal Investigational Device Exemption (IDE) study to evaluate the valve's safety and effectiveness.

The Harmony TPV was designed in an effort to offer a treatment alternative for patients with Congenital Heart Disease (CHD), specifically the 80 percent of CHD patients born with right ventricular outflow tract anomalies who undergo a surgical repair early in life. For these patients, the Harmony TPV provides a less invasive option to restore normal valve function later in life. The minimally invasive TPV therapy builds off of the proven Melody TPV technology, the first transcatheter heart valve available anywhere in the world, which has been implanted in more than 10,000 patients worldwide.

"These outcomes are promising indicators that this technology can help patients who experience severe pulmonary regurgitation after repair of complex congenital heart disease," said Lee N. Benson, M.D., professor of pediatrics at the University of Toronto and director of the Cardiac Diagnostic and Interventional Unit at The Hospital for Sick Children in Toronto, Canada. "We look forward to further evaluating the clinical performance of the Harmony TPV in future studies and providing this growing patient population with a less invasive option to address pulmonary regurgitation, which can be adapted to different outflow tract morphologies," added Benson, who also presented the data at the meeting.

Patients enrolled in the Harmony TPV early feasibility study who were followed out to one year (N=18) experienced statistically significant improvements in hemodynamics, including RV end diastolic volume from 280.4 ± 74.0ml pre-implant to 195.1 ± 57.9 at one year (N=12, p= 0.001). Mean gradients were consistent and stable at one-year follow up and there were no clinically significant paravalvular leaks.

"We are excited to further study this device with the initiation of our Harmony TPV Pivotal IDE study, and ultimately, if the data are positive, enable more patients to have access to a less invasive non-surgical option following approval," said Rhonda Robb, vice president and general manager at the Heart Valve Therapies business, part of the Cardiac and Vascular Group at Medtronic. "Together with leading physicians, we look forward to expanding our heart valve therapy portfolio with innovative products that address the unmet lifetime needs of CHD patients."

The Harmony TPV is available for investigational use only.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 88,000 people worldwide, serving physicians, hospitals and patients in more than 160 countries.

The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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