Medtronic News

First-Ever Medtronic Harmony(TM) Transcatheter Pulmonary Valve Data Shows Positive Procedural Success In Early Feasibility Study

Encouraging Early Outcomes from Rigorously Designed Study Set the Stage for IDE

DUBLIN and CHICAGO - April 4, 2016 - Medtronic plc (NYSE: MDT) today announced first-ever clinical data on the Harmony(TM) Transcatheter Pulmonary Valve (TPV) from its early feasibility study, demonstrating positive initial outcomes at six-months in patients with an indication for pulmonary valve restoration. The initial results were presented during the 65th Annual Scientific Session of the American College of Cardiology (ACC). Following the positive initial data unveiled today, a pivotal Investigational Device Exemption (IDE) study is planned to start in late calendar year 2016, pending approval from the U.S. Food and Drug Administration (FDA).

The first-of-its-kind early feasibility study was initiated by Medtronic in close collaboration with the FDA in an effort to develop a minimally invasive alternative to open-heart surgery for patients with Congenital Heart Disease (CHD). Approximately one in five patients born with congenital heart disease have an abnormality of their right ventricular outflow tract (RVOT). In these patients, there are primarily two options currently used to facilitate blood flow from the heart to the lungs: an open surgical valve replacement (80 percent) or an open surgical valve-conduit implant (20 percent). In the latter case, when the conduit fails, a non-surgical valve such as the globally approved Melody® Transcatheter Pulmonary Valve (TPV) System-which helps restore pulmonary valve function and delays additional surgical intervention- may be an option. The Harmony TPV may prove to be a less invasive option for approximately 80 percent of patients who currently undergo initial open heart surgical valve replacement to restore normal valve function.

"Through precise patient selection, the early feasibility data enables the clinical community to gather several key insights that will help to determine the valve's therapeutic benefits in this patient population," said John Cheatham, M.D., director of cardiac catheterization and interventional therapy and co-director of The Heart Center at Nationwide Children's Hospital in Columbus, Ohio, as well as the presenter of the data at ACC. "Due to its unique design and ability to adapt to a wide variety of patient anatomies, the Harmony TPV and its future iterations may provide a broad range of CHD patients with a minimally invasive treatment option that allows for shorter procedural time and hospital stay."

The early feasibility study for the Harmony TPV is a non-randomized, prospective study at two sites in the United States and one in Canada. The study included a rigorous patient selection process to identify 20 patients for implant and follow-up out to five years. Due to the highly variable anatomy of the patient population, the study required careful screening to ensure the optimal fit.

Of the patients followed out to six months (N=18), severe pulmonary regurgitation improved from 95 percent pre-implant to 0 percent at six months. In addition, mean RVOT gradients were consistent and stable from 13.2 ± 5.1 mmHg at discharge and 15.4 ± 5.6 mmHg at six months. Some gradients are expected in this patient population due to the right side of the heart having free-blood flow before the valve is implanted.

"We are very encouraged by the positive early outcomes with the Harmony TPV. We look forward to partnering closely with the FDA to further continue our research with leading physicians to address an unmet need for this specific patient population," said Rhonda Robb, vice president and general manager of the Heart Valve Therapies business, part of the Cardiac and Vascular Group at Medtronic. "This clinical milestone underscores our commitment to broadening our congenital heart disease program as we bring new treatment solutions to this underserved patient group."

The Harmony TPV is not available in the United States and is available for investigational use only. The minimally invasive

congenital heart disease technology builds off of the proven Melody TPV platform, the first transcatheter heart valve available anywhere in the world.

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 85,000 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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