Medtronic News

World's First Transcatheter Valve, Medtronic Melody® Transcatheter Pulmonary Valve Shows Positive Clinical Outcomes in Real-World Study

Has Repaired Hearts of 6,000+ Patients; More Than Half Are Children

MINNEAPOLIS and WASHINGTON - March 30, 2014 - Medtronic, Inc. (NYSE: MDT), today announced the one-year results of the Melody® Transcatheter Pulmonary Valve (TPV) U.S. Post-Approval Study, which found that real-world use of the Melody TPV was associated with high procedural success, excellent valve function and few repeat procedures at the primary endpoint of six months. These results were sustained out to one year.

The Melody TPV was the first transcatheter valve to be approved by the U.S. Food and Drug Administration (FDA) and the first transcatheter valve available anywhere in the world. The therapy has treated more than 6,000 patients worldwide to date, more than half of whom are children with congenital heart disease (CHD).

Presented as a late-breaking clinical trial at the American College of Cardiology (ACC) 63rd Annual Scientific Session, the study results demonstrated a procedural success rate of 98.0 percent and showed that nearly all patients were free from major stent fracture (99.0 percent), transcatheter pulmonary valve dysfunction (98.0 percent) and reintervention (100.0 percent) at six months.

Following FDA approval in 2010 of the Melody TPV under a Humanitarian Device Exemption (HDE), the device equivalent of regulations for "orphan" drugs, the post-approval study prospectively enrolled 120 patients at 10 U.S. sites not included in the U.S. Melody TPV Investigational Device Exemption (IDE) Clinical Trial. The patients had a mean age of 20 years (ranging from ages 5 to 45). The post-approval study results confirm the positive findings of the original Melody TPV U.S. IDE Clinical Trial, reinforcing the device's ability to safely prolong the time between open-heart surgeries for patients with a dysfunctional right ventricular outflow tract (RVOT) caused by CHD.

"The positive results garnered in this real-world setting mirror those seen in other studies of the Melody valve," said Aimee K. Armstrong, M.D., associate director, University of Michigan C.S. Mott Children's Hospital Cardiac Catheterization Laboratories. "The one-year results show strong performance of the valve, which is intended to delay the time until open-heart surgery is needed. Decreasing the number of open-heart surgeries that our patients need has a significant impact on their lives and quality of life."

Adverse events seen in the post-approval study ranged from fever to arrhythmia; and endocarditis (n=3) to confined conduit tear (n=6), the latter of which were all resolved with the use of a covered stent.

CHD is the most common birth defect in the United States; it affects an estimated 40,000 U.S. babies each year.1,2,3 Approximately 20 percent of those infants have deformities that disrupt the blood flow from their RVOT to the pulmonary arteries.4 A subset of these children will receive a connecting conduit early in life to improve that blood flow. If a patient's RVOT conduit fails later in life but is still of adequate size to address the patient's needs (i.e., the patient has not outgrown the conduit), then a Melody TPV may be implanted to help delay a surgical pulmonic valve replacement, which is a much more invasive procedure than transcatheter valve replacement.

"Open-heart surgery can come with significant risks, not to mention pain and discomfort, so the quality of life for these children with CHD can be compromised given the number of surgeries they typically have to endure over their lifetime," said John Liddicoat, M.D., senior vice president, Medtronic, and president of the Medtronic Structural Heart Business. "The Melody TPV is making a big difference in the lives of these young patients, and we're committed to continuing to provide successful therapies for this underserved patient group."

Following the late-breaking trial, a moderated poster, titled "Current Results of the MELODY Registry - an International Multicenter Registry of Transcatheter Pulmonary Valve Implantation (TPVI)," also was presented today at the ACC Scientific Session by the German Heart Center, Berlin. The multicenter MELODY Registry represents the largest patient series after TPV implantation to date and further confirmed the safety of the Melody TPV in more than 1,000 CHD patients in real-world clinical practice.

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, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

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.

-end-

---

1 Congenital heart disease. National Institutes of Health's MedlinePlus. Accessed on February 26, 2014. Available at: http://www.nlm.nih.gov/medlineplus/ency/article/001114.htm.

2 Hoffman JL, Kaplan S. The incidence of congenital heart disease. *J Am Coll Cardiol*. 2002;39(12):1890-1900.

3 Reller MD, Strickland MJ, Riehle-Colarusso T, Mahle WT, Correa A. Prevalence of congenital heart defects in metropolitan Atlanta, 1998-2005. *J Pediatrics*. 2008;153:807-813.

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

Contacts:

Tracy McNulty
Public Relations
+1-763-526-2492

Jeff Warren
Investor Relations
+1-763-505-2696

---

https://news.medtronic.com/2014-03-30-Worlds-First-Transcatheter-Valve-Medtronic-Melody-R-Transcatheter-Pulmonary-Valve-Shows-Positive-Clinical-Outcomes-in-Real-World-Study