

## FDA Grants Pre-Market Approval for Medtronic Melody® Transcatheter Pulmonary Valve

February 3, 2015 12:00 PM CT



*Previously Approved Under Humanitarian Device Exemption (HDE), Melody Valve Shows Safety and Effectiveness in Patients with Congenital Heart Disease*

**DUBLIN and MINNEAPOLIS - February 3, 2015** - Medtronic plc (NYSE: MDT), today announced that its Melody® Transcatheter Pulmonary Valve (TPV) received Pre-Market Approval (PMA) from the United States Food and Drug Administration (FDA) based on strong clinical evidence from three clinical studies demonstrating the valve's effectiveness in delaying open-heart reoperation.

The first transcatheter heart valve available anywhere in the world, the Melody TPV was originally approved in 2010 under a Humanitarian Device Exemption (HDE), a regulatory approval for treatments intended for fewer than 4,000 U.S. patients per year. HDEs are granted for medical devices that have demonstrated reasonable safety and probable benefit, but do not have evidence of clinical effectiveness. PMA approval has been issued based on the robust evidence now available that supports both safety and effectiveness of the Melody TPV.

Melody TPV is a minimally invasive therapy shown to effectively prolong the time between open-heart surgeries for patients with a dysfunctional right ventricular outflow tract (RVOT) conduit caused by congenital heart disease (CHD). More than 7,300 patients worldwide have received the therapy to date, more than half of whom are children with CHD.

"The Melody valve has been a reliable option for patients suffering from CHD, and these data reinforce its strong performance since it was first introduced," said William E. Hellenbrand, M.D., chief of pediatric cardiology at the Yale School of Medicine. "This approval underscores the valve's importance in treating this small patient population, who over their lifetime will face several open heart surgeries."

The PMA approval is based on accumulated data from three clinical studies that followed a total of 310 patients implanted with Melody TPV - the Melody U.S. IDE Study, the Melody U.S. Post Approval Study (PAS) and the Melody European and Canadian Post-Market Surveillance Study (PMSS). Data showed strong valve performance in all three studies in patients implanted with the Melody valve as approximately 98 percent of patients were free from conduit reoperation (open-heart surgery) at one year post-implant. Additionally, 91 percent of patients in the IDE cohort were free from conduit reoperation at five years post-implant.

"The transition from HDE to PMA is an important regulatory milestone, which truly emphasizes the significant clinical benefit that the Melody TPV can bring to people with CHD by providing a therapy option that may reduce the number of open heart surgeries they need throughout their lifetime," said Rhonda Robb, vice president and general manager of Heart Valve Therapies at Medtronic. "Today's approval reinforces Medtronic's ongoing commitment to a congenital heart disease program by providing innovative and successful therapies to this underserved patient group."

CHD is the most common birth defect in the United States; it affects an estimated 40,000 U.S. babies each year.<sup>1,2,3</sup> Approximately 20 percent of those infants have deformities that disrupt the blood flow from their RVOT to the pulmonary arteries.<sup>4</sup> 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.

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](http://www.medtronic.com)), headquartered in Dublin, Ireland, 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.**

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<sup>1</sup> 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>.

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

<sup>3</sup> 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.

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

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