Medtronic News

Medtronic Melody Transcatheter Pulmonary Valve First of Its Kind to Receive FDA Approval for Implantation in Failed Surgical Pulmonary Heart Valves

Newly Approved Indication in U.S. Expands Treatment Options to More Patients with Congenital Heart Disease

DUBLIN - March 14, 2017 - Medtronic plc (NYSE: MDT) today announced that its Melody(TM)Transcatheter Pulmonary Valve (TPV) received approval from the United States Food and Drug Administration (FDA) for implantation in patients whose surgical bioprosthetic pulmonary heart valves have failed. Designed specifically for the pulmonic position, Melody TPV is the first transcatheter pulmonary valve to receive this approval in the U.S.

When a surgical valve degenerates over time, patients may require another valve replacement, which would involve undergoing another open-heart surgery. Intended to prolong the time between open-heart surgeries for patients with a dysfunctional right ventricular outflow tract (RVOT) conduit caused by CHD, the Melody TPV may now provide these patients with a minimally invasive treatment option.

"As the first commercially available transcatheter heart valve, the Melody TPV brought a breakthrough non-surgical option to treat failing pulmonary valve conduits," Jeremy Asnes, M.D., associate professor of pediatric cardiology and director of the Congenital Cardiac Catheterization Laboratory at the Yale School of Medicine in New Haven, Conn. "Thousands of congenital patients globally have benefited from this therapy in the past decade. With this expanded indication, we can further reduce the need for obtrusive open-heart surgery and allow even more patients to benefit from this minimally invasive treatment option."

During the procedure, the Melody TPV is placed inside a failing pulmonic surgical heart valve through the recently launched Ensemble(TM) II Delivery System, a low-profile, delivery catheter, specifically designed to deliver the Melody TPV.

The first transcatheter heart valve available anywhere in the world-and now implanted in more than 10,500 patients worldwide-the Melody TPV first received CE Mark in September 2006 for the treatment of failing pulmonary valve conduits. It was introduced in the U.S. in 2010 following FDA approval. Over the last 10 years, clinical evidence from three Medtronic clinical studies has demonstrated the valve's effectiveness in delaying the need for open-heart reoperation.

"Unlike other transcatheter valves currently on the market, Melody TPV is uniquely designed for use in the pulmonic position and is thus well suited for implantation in failed surgical pulmonary heart valves," said Rhonda Robb, vice president and general manager of the Heart Valve Therapies business, which is part of the Cardiac and Vascular Group at Medtronic. "This approval further demonstrates our commitment to improving treatment options for congenital heart disease and we look forward to bringing this proven non-surgical option to congenital patients."

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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