Medtronic News

Medtronic Receives FDA Approval for "Breakthrough" Transcatheter Pulmonary Valve Replacement for Patients with Congenital Heart Disease

Harmony™ Transcatheter Pulmonary Valve is First Minimally Invasive Alternative for Patients with Severe Pulmonary Regurgitation Who Have a Native or Surgically-Repaired Right Ventricular Outflow Tract

DUBLIN, March 26, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced it has received U.S. Food and Drug Administration (FDA) approval for its Harmony™ Transcatheter Pulmonary Valve (TPV), the first minimally invasive therapy created to treat patients with a specific type of congenital heart defect of the right ventricle (RV), one of the four chambers of the heart, which makes it difficult for blood to travel from the heart to the lungs. The Harmony TPV, which is placed inside a patient's native anatomy during a catheter-based procedure, was designated as a Breakthrough Therapy under FDA's Breakthrough Device Designation (BDD) program, an approval pathway intended to help patients receive more timely access to certain life-saving technologies.

Congenital heart disease (CHD) is the most common type of birth defect in the United States, affecting an estimated 40,000 infants each year[1] and about 1.6 million adults currently living with congenital heart disease[2].

"The typical congenital heart disease patient will face a multitude of open-heart surgeries over their lifetime, to continually address issues with their pulmonary valve. Furthermore, congenital heart disease patients require lifelong monitoring, preventive care and specialized treatment all the way from childhood to adulthood," said Matthew J. Gillespie, M.D., attending interventional cardiologist, co-director of the Pediatric Valve Center and director of the Cardiac Catheterization Laboratory at Children's Hospital of Philadelphia, and investigator in the Harmony TPV Clinical Study.

Approximately one in five patients born with CHD have structural malformations that disrupt the connection between the heart and the lungs[3], called the right ventricular outflow tract (RVOT). The standard of care today in the U.S. requires that these patients receive open-heart surgery or other interventions early in life to address these malformations. Some of these patients may become candidates for the Medtronic Melody® TPV later in life, the first transcatheter heart valve shown to effectively delay open-heart surgery. For the 80% of CHD patients who require a native or surgically repaired RVOT at birth, many will need a pulmonary valve replacement later in life, which historically has required another open-heart surgery. The Harmony TPV provides these patients with an alternative to the more invasive open-heart surgical approach; instead, the valve is loaded onto a catheter and delivered via a small incision in the femoral vein or in the neck and placed directly inside the heart.

"The availability of the Harmony TPV will allow a broader range of congenital heart disease patients access to transcatheter technology," said Nina Goodheart, president of the Structural Heart & Aortic business, which is part of the Cardiovascular Portfolio at Medtronic. "Harmony TPV's novel attributes make it the only non-surgical solution designed to adapt to a wide variety of anatomies for this specific patient population living with congenital heart disease."

The FDA approval is based on clinical data from the Harmony TPV clinical study that showed excellent safety (freedom from mortality) and effectiveness (acceptable hemodynamic function) at 30 days and six months, respectively. Data from the study also showed patients treated with Harmony TPV experienced no significant reinterventions, reoperations or endocarditis at six months.

The Harmony TPV qualified as a proof of concept product for the Harmonization by Doing (HBD) for Children program. The HBD for Children program was established as a partnership among stakeholders of academia, industry and regulatory agencies in Japan and the United States, with a primary focus on the development of pediatric devices as the development of medical devices for pediatric use lags behind that of medical devices for adults in both countries. The Harmony TPV device is available

for use in the United States. Outside of the U.S., Harmony TPV is limited to investigational use and not approved for sale or distribution.

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 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 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.

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

[2] Adult Congenital Heart Association (ACHA).

[3] 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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