Medtronic News

First Patient Treated in Landmark Transcatheter Mitral Valve Replacement (TMVR) Pivotal Trial

Global Medtronic APOLLO Trial Now Underway with the Intrepid(TM) TMVR System for Patients with Severe Mitral Regurgitation

DUBLIN - October 23, 2017 - Medtronic plc (NYSE:MDT) today announced the first patient implant in the APOLLO Trial - the pivotal trial designed to evaluate the Intrepid(TM) TMVR system following receipt of an investigational device exemption (IDE) from the U.S. Food and Drug Administration (FDA). As the first-ever pivotal trial for transcatheter mitral valve replacement therapy, the study will evaluate the safety and efficacy of the Intrepid TMVR system in up to 1,200 patients with severe, symptomatic mitral valve regurgitation.

The first patient in the APOLLO trial was implanted by the team at Aurora St. Luke's Medical Center in Milwaukee.

"This is the beginning of an important journey to establish a truly less invasive approach to treat severe mitral valve regurgitation in patients who are appropriate candidates for mitral valve replacement with a transcatheter technology that eliminates the need for open-heart surgery," said David H. Adams, M.D., surgeon-in-chief of Mount Sinai Health System, and national co-principal investigator of the APOLLO Trial.

The APOLLO Trial Design

The APOLLO Trial design consists of two cohorts and will be conducted at up to 60 sites to evaluate two distinct patient populations. The primary endpoint in both cohorts of the trial is a composite endpoint rate of all-cause mortality, all-stroke, reoperation (or reintervention) and cardiovascular hospitalization at one year with secondary endpoints that measure quality of life and valve performance in patients with severe symptomatic mitral regurgitation.

The randomized cohort will enroll up to 650 patients who are candidates for conventional open-heart mitral valve replacement surgery and not eligible for mitral repair. These patients will be evenly randomized to receive either the Intrepid TMVR system or conventional mitral valve surgery. The primary endpoint is designed to demonstrate the Intrepid TMVR system is statistically non-inferior to conventional surgery at one year.

The single arm cohort will enroll up to 550 patients who are considered too high a risk for conventional open-heart mitral valve surgery as determined by a multi-disciplinary heart team and will be assigned to undergo the TMVR procedure with the Intrepid system. The primary endpoint of this cohort is designed to demonstrate statistical non-inferiority to a performance goal at one year.

"We worked closely with the FDA and leading physicians to design a trial that will compare the Intrepid TMVR system with the current standard of care for patients with mitral regurgitation," said Sean Salmon, senior vice president and president of the Coronary and Structural Heart division, which is part of the Cardiac and Vascular Group at Medtronic. "We are excited to investigate whether this technology holds promise for the large number patients suffering from the debilitating symptoms of severe mitral regurgitation."

Mitral Regurgitation and the Intrepid TMVR System

Mitral regurgitation occurs when blood flows backward through the mitral valve and into the atrium each time the left ventricle contracts. If left untreated, mitral regurgitation can lead to heart failure or death. Due to the complexity of the mitral valve anatomic structure and multiple comorbidities typically present in such patients, limited medical therapies are available to clinicians and their patients.

The Intrepid TMVR system integrates self-expanding, dual-stent technology with a replacement tissue heart valve to facilitate a catheter-based implantation. The Intrepid valve is compressed inside a hollow delivery catheter and is inserted between the ribs to enter the heart. The new replacement valve is expanded directly into the malfunctioning mitral valve. The outer stent frame is designed to attach and conform to the native valve without the need for additional sutures, tethers, or anchors to secure the prosthesis. The inner stent houses the valve, which is made from bovine tissue and is intended to maintain blood flow.

"The Intrepid system features a truly innovative dual-stent design and the trial will investigate its safety and efficacy in addressing severe symptomatic mitral regurgitation replacing the need for an open-heart procedure," said Martin Leon, M.D., director of the Center for Interventional Vascular Therapy at Columbia University Medical Center/New York-Presbyterian Hospital, and national co-principal investigator of the APOLLO Trial. "We look forward to working with the APOLLO Trial clinical sites in the U.S. and around the world."

The Intrepid TMVR system is available for investigational use only and it is not approved for use outside of clinical studies.

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 84,000 people worldwide, serving physicians, hospitals and patients in approximately 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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