

Medtronic Announces Early Feasibility Trial for Intrepid™ Transcatheter Mitral Valve Replacement System with Transfemoral Transseptal Approach

New Study Shows Momentum in Establishing a Less Invasive Approach to Treat Patients with Severe Mitral Valve Disease

DUBLIN, Sept. 27, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced it has received U.S. Food and Drug Administration (FDA) approval to begin an early feasibility study (EFS) for its Intrepid™ transcatheter mitral valve replacement (TMVR) system using a minimally-invasive transfemoral access approach. This announcement builds upon primary endpoint outcomes of the Intrepid TMVR pilot study using the transapical approach published in the *Journal of the American College of Cardiology*, the first-ever trial approved by the FDA to evaluate the safety and efficacy of a TMVR system.

The prospective, multi-center, non-randomized EFS will evaluate the safety and performance of the Intrepid TMVR System with the transfemoral approach in patients with severe, symptomatic mitral regurgitation (MR) who are ineligible for conventional mitral valve surgery. The study will enroll and treat up to 15 patients who require mitral valve intervention at up to six centers. Treated patients will be followed up at 1, 3, 6 and 12 months, and every 6 months thereafter through 5 years. The results from this EFS study will inform the development of next-generation transfemoral TMVR technologies.

"We are optimistic about the potential benefits of the transfemoral approach for mitral valve replacement – which is less invasive than the transapical technologies currently in pivotal trials," said national co-principal investigator Martin B. Leon, M.D., director of the Center for Interventional Vascular Therapy at New York-Presbyterian/Columbia University Medical Center and professor of medicine at the Columbia University College of Physicians and Surgeons. "The early clinical results we have seen with Intrepid and this early feasibility study advances the TMVR field as we look for less invasive ways to treat this patient population, of which a large proportion are considered too high risk for surgery."

Mitral regurgitation (MR) is the most common heart valve disease in the United States, affecting an estimated four million people. If left untreated, MR may lead to chronic heart failure (HF), the leading cause of hospitalization in the United States and Europe. Despite the prevalence of MR, there are limited procedural treatment options for this complex patient population.

"Medtronic believes that transcatheter mitral valve replacement will have a vital role in treating patients with mitral valve disease and this early feasibility study is another step forward in our Intrepid program," said Nina Goodheart, vice president and general manager, Structural Heart business, which is part of the Cardiac and Vascular Group at Medtronic.

The Intrepid TMVR system integrates self-expanding, dual-stent technology with a tissue valve that is delivered through a catheter and placed directly into the native mitral valve to restore normal blood flow through the heart without the need for open-heart surgery.

The Intrepid TMVR system is available for investigational use only and it is not approved anywhere for use outside of clinical studies. As part of its commitment to developing solutions for the treatment of valve disease, Medtronic is sponsoring and currently enrolling participants to the landmark APOLLO Trial. APOLLO is designed to evaluate the safety and efficacy of the Intrepid system in correcting MR.

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.

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