Medtronic News

Medtronic Receives Breakthrough Device Designation from FDA, Begins Early Feasibility Study for Investigational Intrepid™ Transcatheter Valve System for the Treatment of Tricuspid Valve Regurgitation

DUBLIN, Sept. 9, 2020 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in structural heart therapies, today announced U.S. Food and Drug Administration (FDA) approval of an early feasibility study (EFS) of the Intrepid™ Transcatheter Tricuspid Valve Replacement (TTVR) system in patients with severe, symptomatic tricuspid regurgitation, a disease in which the diseased, damaged or malfunctioning tricuspid valve allows blood to flow back into the heart's upper right chamber causing eventual heart failure or death. The study begins on the heels of a recent Breakthrough Device Designation issued by the FDA for the Intrepid TTVR System. The Intrepid TTVR system is an investigational device worldwide.

"We're beginning a new journey that we believe will open the door for the potential future treatment of patients with tricuspid valve regurgitation, who constitute a significant, patient population suffering from heart valve disease today," said Azeem Latib, M.D., section head of interventional cardiology and medical director of structural heart interventions at Montefiore Medical Center in New York City and co-principal investigator in the study. "There has been much progress regarding transcatheter replacement of diseased aortic valves, but whether we can replace the tricuspid valve without open heart surgery represents a new frontier in cardiology."

Representing a large, unmet clinical need, tricuspid regurgitation affects more than 2 million patients in the United States. It is a highly undertreated disease due to the morbidity and mortality associated with surgical intervention.

Medtronic recently received Breakthrough Device Designation by the FDA for the Intrepid TTVR system. The FDA Breakthrough Device Program is intended to help patients receive more timely access to certain technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions.

"The clinical experience generated during this initial study phase will be critical for the future of the therapy, as many of these patients are not good candidates for traditional surgical tricuspid valve interventions due to their poor right heart functions and are higher risk due to co-morbidities," said Vinayak (Vinnie) Bapat, M.D., chief of cardiothoracic surgery at theMinneapolis Heart Institute and co-principal investigator in the study. "We are optimistic that these early learnings will help fuel additional clinical research and device innovation around this treatable disease."

The Intrepid transcatheter valve is the same valve being evaluated for the treatment of symptomatic mitral valve regurgitation in the transfemoral mitral early feasibility study. The device is implanted using a transfemoral delivery catheter, which assists physicians in delivering and placing the valve through a catheter inserted in the femoral vein.

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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