Medtronic News

Medtronic announces early data for the Intrepid™ transcatheter mitral valve replacement (TMVR) system using new transfemoral delivery system

Transfemoral access added into landmark APOLLO Pivotal Trial following IDE approval from FDA

DUBLIN and ORLANDO, Fla., Nov. 6, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today presented early data for its self-expanding Intrepid™ transcatheter mitral valve replacement (TMVR) system in patients with severe, symptomatic mitral valve regurgitation (MR) utilizing the transfemoral access route. Presented as Late-Breaking Clinical Science at the 33rd Transcatheter Cardiovascular Therapeutics (TCT) conference, the annual scientific symposium of the Cardiovascular Research Foundation, data from the first 15 patients enrolled in an Early Feasibility Study of the Intrepid Transfemoral System showed 100% survival and no stroke, a median procedure time of 46 minutes, and none/trace MR in all implanted patients at 30 days. The data were published simultaneously in the *Journal of the American College of Cardiology (JACC): Cardiovascular Intervention*.

"These data indicate that the new Intrepid Transfemoral Delivery System is a promising option for the delivery of the Intrepid valve with all patients in the study showing almost complete elimination of MR at 30 days," said Firas Zahr, M.D., interventional cardiologist and co-director of the Complex Heart Valve Program at Oregon Health and Science University and investigator in the study. "The addition of transfemoral access into the Apollo Trial will provide study investigators with an access route that could present less risk to patients during the procedure."

Mitral regurgitation (MR) occurs when blood flows backward through the mitral valve and into the atrium each time the left ventricle contracts. If left untreated, MR 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 valve has been used to treat more than 350 patients as part of global clinical trials. Currently, the Medtronic APOLLO Trial is evaluating the Intrepid TMVR system in patients with severe MR with one cohort evaluating patients with primary or secondary MR who are unsuitable for conventional mitral valve surgery or transcatheter edge-to-edge repair (TEER). A second cohort is evaluating patients with severe symptomatic MR who are deemed ineligible for conventional mitral valve surgery with mitral annular calcification (MAC). To date, patients enrolled in the study have received the Intrepid TMVR system using the transapical access route where the valve is compressed inside a hollow catheter and inserted between the ribs into the heart. With IDE approval, APOLLO study investigators will now have the additional option to insert the valve via an incision in the groin into the femoral vein, which has historically been the preferred approach for most transcatheter procedures.

The Intrepid TMVR system, which received Breakthrough Device Designation from FDA (for patients unsuitable for transcatheter edge-to-edge repair or mitral valve surgery), integrates self-expanding, dual-stent technology with a replacement tissue heart valve to facilitate a catheter-based implantation. Using a delivery catheter to insert the valve into 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 development of the Intrepid Transfemoral Delivery System is an important milestone for the Intrepid TMVR program and we are excited to introduce it into the Apollo Trial," said Nina Goodheart, senior vice president and president of the Structural Heart & Aortic business, which is part of the Cardiovascular Portfolio at Medtronic. "We believe this advancement will expand our clinical trial offerings to more patients."

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

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 90,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for all. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

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.

Contacts:	
Joey Lomicky	Ryan Weispfenning
Public Relations	Investor Relations
+1-763-526-2494	+1-763-505-4626

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