Medtronic News

Medtronic self-expanding TAVR platform shows excellent longer-term performance at five years in SURTAVI Trial

TCT 2021: Intermediate risk TAVR patients demonstrate strong hemodynamics and stable valve performance at five years

DUBLIN and ORLANDO, Fla., Nov. 5, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today unveiled five-year clinical data from the Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) Trial, which was presented as a Late Breaking Clinical Trial at the 33rd Transcatheter Cardiovascular Therapeutics (TCT) conference, the annual scientific symposium of the Cardiovascular Research Foundation. Data from the trial showed that the hemodynamic (blood flow) benefits of the Medtronic CoreValve™ and Evolut™ platforms were maintained at five years with an excellent safety profile and stable valve performance in patients with symptomatic, severe aortic stenosis who are at an intermediate risk for open-heart surgery.

At five years, rates of all-cause mortality were similar between TAVR with the CoreValve/Evolut platform and surgical aortic valve replacement (SAVR) (30.0% for TAVR versus 28.7% for SAVR; p=0.55), while rates of disabling stroke were also similar (4.1% for TAVR versus 5.8% for SAVR, p = 0.12). The TAVR arm continued to demonstrate durable valve longevity, as evidenced by better mean aortic valve gradients (8.6 mm Hg vs. 11.2 mm Hg; p<0.001) at five years. Additionally, valve thrombosis remained low out to five years for both TAVR and SAVR.

In the study, patients considered to be at intermediate risk for open-heart surgery had a risk of mortality of ≥ 3 and < 15% at 30 days following the procedure in combination with other factors.

"TAVR has revolutionized the treatment of aortic stenosis with more TAVR cases now performed than surgical aortic valve replacement for this disease. With this shift in treatment, longer-term, randomized data is increasingly important as we strive to better understand the lifetime management of these patients," said Michael Reardon, M.D., professor of cardiothoracic surgery and Allison Family Distinguished Chair of Cardiovascular Research at Houston Methodist DeBakey Heart & Vascular Center, principal investigator in the SURTAVI trial.

The global, prospective, multi-center, randomized SURTAVI Trial evaluated two early valve generations (CoreValve™, Evolut™ R) across a variety of valve sizes in 864 intermediate-risk symptomatic severe aortic stenosis patients. Patients in the TAVR arm were compared to 796 intermediate-risk patients who were randomized to open-heart surgery.

"These longer-term outcomes are remarkably similar after TAVR and surgery in patients with severe aortic stenosis at intermediate operative risk," said Nicolas Van Mieghem, M.D., Ph.D., professor of interventional cardiology, department of cardiology, Thoraxcenter, Erasmus University Medical Center in Rotterdam, The Netherlands, who presented the data at the meeting. "Additionally, results from this study are particularly impressive given the TAVR devices evaluated were first- and second-generation systems."

The Evolut TAVR platform, which includes the Evolut™ R, Evolut™ PRO, Evolut™ PRO+, and newest-generation Evolut™ FX valves, is indicated for symptomatic severe aortic stenosis patients across all risk categories (extreme, high, intermediate and low) in the U.S.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered inDublin, 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, cranial and

spinal 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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