Medtronic News

Medtronic Builds on TAVR Clinical Evidence Portfolio with Five-Year CoreValve Durability Data and Complete Two-Year Outcomes in Intermediate Risk Aortic Stenosis Patients

(GLOBE NEWSWIRE via COMTEX) --TCT18: New Five-Year Data with CoreValve TAVR System Suggests Durability Over Time, While Complete Results from the SURTAVI Trial Show Benefits of TAVR in Intermediate Risk Patients

DUBLIN and SAN DIEGO - September 24, 2018 - Medtronic plc (NYSE:MDT), a global leader in heart valve therapies, today announced new data presented at the 30th Transcatheter Cardiovascular Therapeutics (TCT) conference, the annual scientific symposium of the Cardiovascular Research Foundation. Over the weekend, investigators presented the longest-term data to-date from the CoreValve U.S. Pivotal Trial, in addition to the complete two-year outcomes from the SURTAVI trial, which confirmed the excellent outcomes previously predicted in aortic stenosis patients at intermediate surgical risk.

CoreValve U.S. Pivotal High-Risk Trial

The longest-term follow-up data ever presented from the randomized CoreValve U.S. Pivotal High-Risk Trial showed that patients implanted with the CoreValve(TM) System experienced excellent valve durability out to five years with low severe hemodynamic structural valve deterioration (0.8 percent) compared to patients who received a surgical aortic valve replacement (1.8 percent). Of the 750 patients (391 TAVR; 359 SAVR) followed out to five years, patients treated with the CoreValve System showed similar outcomes compared to surgery for the primary endpoint of all-cause mortality 55.3 percent versus 55.4 percent; p=0.50). Additionally, rates were similar for major stroke (12.3 percent versus 13.2 percent; p=0.49) at five years.

"These were early CoreValve patients, some of the first patients to receive the therapy, and it's reassuring to see that the CoreValve System has proven to be durable out to five years," said Thomas G. Gleason, M.D., co-director of UPMC's Heart and Vascular Institute and professor and chief of the Division of Cardiac Surgery at the University of Pittsburgh School of Medicine, who presented the data at the meeting. "As the technology and heart team experience continues to improve, this longer-term follow-up data is an encouraging indicator for TAVR patients in the future. Earlier concerns regarding the durability of TAVR are certainly tempered by these mid-term data."

SURTAVI Trial - Complete 2-Year Results

Moving down the risk spectrum to patients at intermediate risk for open-heart surgery, the complete two-year data from the global, prospective, multi-center, randomized SURTAVI trial showed the Medtronic self-expanding TAVR platform was similar to surgery for the primary endpoint of all-cause mortality or disabling stroke at two years, confirming what the Bayesian statistical analysis demonstrated at the American College of Cardiology (ACC) 66th Annual Scientific Session in 2017, which was published simultaneously in The New England Journal of Medicine (NEJM). The study evaluated the Medtronic CoreValve and CoreValve(TM) Evolut(TM) R Systems in intermediate risk aortic stenosis patients versus open-heart surgery at two years.

The full two-year data set confirmed that rates of all-cause mortality or disabling stroke at two years were similar to SAVR (12.7 percent for TAVR versus 12.6 percent for SAVR; p=0.97). The minimally-invasive TAVR procedure also demonstrated significantly better mean aortic valve gradient compared to SAVR (8.2 mm Hg vs. 11.6 mm Hg; p<0.0001) at two years. Patients treated with TAVR experienced statistically lower rates of stroke, lower rates of new onset atrial fibrillation, a quicker hospital discharge, less acute kidney injury and fewer transfusions. SAVR patients experienced fewer permanent pacemaker

implantations and less aortic regurgitation.

"The excellent outcomes from this study tell us two important things: first, we can be confident that TAVR performs well in the intermediate risk patient population, and secondly, the Bayesian statistical analysis that allowed us to evaluate these data more than a year early, is a reliable methodology that we can trust and use in future studies," said Jeffrey J. Popma, M.D., director of Interventional Cardiology at the Beth Israel Deaconess Medical Center in Boston, Mass., principal investigator of the SURTAVI trial.

One-year outcomes from the SURTAVI Continued Access Study also showed low mortality (3.5 percent) and low disabling stroke (0.7 percent) for TAVR patients, the majority (93 percent) of whom were treated with the second-generation Evolut(TM) R TAVR System.

Medtronic is a leading innovator of heart valve therapies, including the first transcatheter pulmonic valve, the first self-expanding and recapturable transcatheter aortic valve, and the first transcatheter mitral valve replacement technology to be studied in a global pivotal trial. The Medtronic CoreValve System received CE (Conformite Europeenne) Mark in 2007. Following the U.S. launch of the self-expanding CoreValve System in 2014, and the Evolut(TM) R system in 2015, the third-generation Evolut(TM) PRO TAVR system was approved in the U.S. and Europe for extreme-, high-, and intermediate-risk patients in 2017.

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 86,000 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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