Medtronic News

Medtronic Evolut™ TAVR System Shows Strong Performance at Two Years in Low Risk Trial

EuroPCR: Low Risk Study Demonstrates Hemodynamic Advantages of Evolut™ Transcatheter Aortic Valve Replacement (TAVR) System Over Open Heart Surgery Out to Two Years

DUBLIN, May 18, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced the complete two-year outcomes from the landmark Evolut Low Risk Trial comparing the minimally invasive Evolut™ transcatheter aortic valve replacement (TAVR) system to the gold standard of open-heart surgery in characteristically younger, healthier aortic stenosis patients. Presented virtually today as a late-breaking clinical trial at the EuroPCR 2021 e-Course, results showed the Evolut TAVR platform was non inferior to surgery for the primary endpoint of all-cause mortality or disabling stroke at two years (4.3% for TAVR versus 6.3% for surgery; $p< 0.0001$ for non-inferiority), and trended the same or lower on all critical events, confirming the earlier Bayesian statistical analysis presented at the American College of Cardiology (ACC) 68th Annual Scientific Session in 2019.

"We know that TAVR has an advantage over surgery in certain near-term outcomes; however, in these low-risk studies, longer term outcomes are more important than ever. The full two-year data from the randomized Evolut Low Risk Trial demonstrate that between years one and two, patients who have undergone TAVR continue to do exceptionally well with no convergence of the primary outcome curves," said John Forrest, M.D., director of interventional cardiology at theYale School of Medicine in New Haven, Conn., and principal investigator in the Evolut Low Risk Trial. "Heart teams can be confident that low-risk patients who undergo TAVR are doing exceptionally well at two years. There are some clear differences in secondary outcomes, and the long-term impact in areas such as hemodynamics, pacemakers, and prosthesis-patient mismatch will be important to follow."

At two years, results from the study showed there was no convergence of the divergent Kaplan-Meier curves for death or disabling stroke between TAVR and surgery, demonstrating that improved safety shown early on for TAVR was sustained over time. In addition, results from the study showed:

- Excellent hemodynamic (blood flow) performance for TAVR with statistically significantly lower mean aortic valve gradient (9.0 mm Hg versus 11.7 mm Hg) and larger effective orifice area than surgery (2.2 cm^2 versus 2.0 cm^2) at two years, ($p < 0.001$ for both comparisons).
- Numerically lower rates of death in the TAVR arm (3.5% versus 4.4%), heart failure hospitalizations (5.3% versus 7.1%) and disabling stroke (1.5% versus 2.7%) compared to surgery at two years.
- Prosthesis-patient mismatch was lower for TAVR compared to surgery at two years with a difference of 2.1% versus 4.9% in the severe category ($p<0.001$).
- Valve thrombosis rates showed no signs of increase and remained low at two years (0.3% for TAVR versus 0.2% for SAVR).

The global randomized Evolut Low Risk Trial evaluated three valve generations (CoreValve™, Evolut™ R and Evolut™ PRO valves) across a variety of valve sizes in more than 700 patients with severe aortic stenosis deemed to have a low mortality risk with surgery with a predicted risk of mortality of less than 3%.

"Results from this landmark study reassure us that the positive outcomes presented using the Bayesian statistical analysis at ACC.19, before the full two-year outcomes were available, matched the actual two-year outcomes and thus was an extremely accurate and scientifically rigorous methodology that researchers can feel confident about moving forward," said Jeffrey J. Popma, M.D., vice president and chief medical officer for the Coronary & Renal Denervation business and the Structural Heart & Aortic business, which are part of the Cardiovascular Portfolio at Medtronic. "Furthermore, the Evolut TAVR platform continues to show it is a treatment option well-suited for lower-risk patients who are living longer and may be more active."

The Evolut TAVR platform, including the Evolut™ R, Evolut™ PRO and Evolut PRO+ TAVR Systems, is indicated for

symptomatic patients with severe aortic stenosis across all surgical risk categories (extreme, high, intermediate and low) in the U.S. and countries that recognize CE Mark. It is estimated that 165,000 low-risk patients suffer from severe aortic stenosis per year in the U.S., Western Europe, and Japan. If left untreated, it can cause heart failure in as little as two years.

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.

Contacts:

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

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