Medtronic News

Medtronic Evolut TAVR System Demonstrates Excellent Outcomes in Study of Low-Risk Patients with Bicuspid Aortic Stenosis

ACC.20/WCC: Low Rates of Paravalvular Leak and High Survival Observed in Late-breaking Clinical Trial of Low-Risk Bicuspid Aortic Stenosis Patients

DUBLIN, March 29, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced late-breaking clinical data from the Low Risk Bicuspid Study assessing the use of the Evolut™ transcatheter aortic valve replacement (TAVR) system in patients with bicuspid aortic valve stenosis at low surgical risk. The study showed low rates of all-cause mortality or stroke at 30 days (1.3%) with a low rate of serious procedural complications, and no annular rupture or aortic dissection. The study was presented as part of the American College of Cardiology together with World Congress of Cardiology Scientific Sessions (ACC.20/WCC) meeting.

Results from the 150-patient, single-arm study showed excellent outcomes at 30 days, with a 95.3% device success rate and a low rate of serious procedural complications including no annular ruptures or aortic dissection. In addition, results from the study showed:

- Low rate of all-cause mortality (0.7%)
- Low rate of disabling stroke (0.7%)
- Exceptional hemodynamics with low mean AV gradients (7.6 ± 3.7 mm Hg), and large effective orifice area (2.3 ± 0.7 cm2)
- No incidence of moderate or severe paravalvular leak (PVL)
- Low rate of major vascular complications (1.3%)
- High utilization of the Evolut 34 mm (41.6% of patients in the study were implanted with this larger valve size)
- New pacemaker rate (15.1%) was lower than in the Evolut Low Risk Trial

“These findings point to a potentially less invasive treatment for patients who otherwise would undergo open heart surgery due to their anatomical valve structure,” said Basel Ramlawi, M.D., chair of The Heart & Vascular Center at FACC Valley Health System in Winchester, Va., and co-primary investigator of the study who presented the data at the meeting. “We feel confident that these primary early outcomes provide additional evidence that the Evolut TAVR platform is a suitable treatment option for patients with bicuspid valves who have previously been left out of TAVR trials.”

Aortic stenosis (AS) is one of the most common valvular heart diseases in the world1, affecting 1.5 million individuals2. Bicuspid aortic valve disease (BAVD) is a congenital heart defect affecting approximately two percent of the general population and is an abnormality of the aortic valve resulting in the patient having two functional valve leaflets instead of the more common three leaflets (tricuspid). Often younger than tricuspid AS patients (median age of 70 in the study), patients with BAVD were generally excluded from prior TAVR trials due to concerns of asymmetric calcification, elliptical shape, potential incomplete valve expansion, procedural technical concerns and other risk factors. In 2018, Medtronic received U.S. Food and Drug Administration (FDA) approval for revised commercial labeling for the Evolut TAVR system that removed a precaution for the treatment of bicuspid severe AS patients deemed at intermediate or greater risk for surgical aortic valve replacement. It is estimated that approximately 60% of the low risk TAVR patient population have BAVD. The Evolut TAVR system is not currently approved in any geography for use in patients with bicuspid aortic valve stenosis at low surgical risk.

“Evidence continues to support the use of TAVR with the Evolut platform in groups of patients previously thought to be more challenging, or non-candidates for the procedures. In addition to reaffirming the Evolut valve’s exceptionally strong hemodynamic, today’s data indicate that low-risk bicuspid aortic stenosis patients implanted with TAVR do very well,” said Pieter Kappetein, M.D., vice president, medical affairs for the Structural Heart business, which is part of the Cardiac and Vascular Group at Medtronic. “We’ve observed the Evolut TAVR valve to be a suitable treatment option for many patients with bicuspid aortic valve disease at intermediate risk or higher, and these data are encouraging that we may see a similar outcome

in low-risk patients."

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 Evolut TAVR platform – including the Evolut™ R, Evolut™ PRO and Evolut PRO+ TAVR Systems – is indicated for symptomatic severe AS patients across all risk categories (extreme, high, intermediate and low) in the U.S. Bicuspid valve patients at intermediate risk or higher may be candidates for TAVR in the U.S.

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.

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1 Aortic Stenosis: An Update Sangeetha Nathaniel-Shreyas Saligram-Anthony Innasimulthu-
https://www.ncbi.nlm.nih.gov/pmc/articles/pmc2999052/

2 Bach D, Radeva J, Birnbaum H, et al. Prevalence, Referral Patterns, Testing, and Surgery in Aortic Valve Disease: Leaving Women and Elderly Patients Behind. J Heart Valve Disease. 2007:362-9.

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