

Medtronic Evolut TAVR System Receives Updated U.S. Labeling Revising Precaution for Treatment of Low-Risk Patients with Bicuspid Aortic Stenosis

Revised Commercial Labeling Broadens Patient Population Who May be Candidates for Transcatheter Aortic Valve Replacement (TAVR)

DUBLIN, Aug. 21, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced the U.S. Food and Drug Administration (FDA) has approved revised commercial labeling for the Evolut™ TAVR platform that modified a precaution for the treatment of bicuspid severe aortic stenosis (AS) patients at a low risk of mortality during surgical aortic valve replacement. The revised commercial labeling includes recommendations heart teams should consider when assessing TAVR as a potential treatment option for bicuspid patients, including patients' anatomical characteristics, age, long term durability, and the existing clinical data.

Bicuspid aortic valve disease is a congenital heart defect that is prevalent in 1-2% of the population and accounts for nearly half of all severe symptomatic aortic stenosis patients in the U.S. The condition is an abnormality of the aortic valve resulting in the patient having two functional valve leaflets instead of the more common three leaflets (tricuspid).

"Clinical outcomes generated to date through the TAVT Registry and the Low Risk Bicuspid Trial have shown that the Evolut TAVR system achieves favorable early results for patients with bicuspid aortic valve disease," said John Forrest, M.D., associate professor of medicine at The Yale University School of Medicine in New Haven, Conn. "The updated labeling is indicative of the progress that has been made to find minimally invasive treatment options for this particular group of patients with severe AS and should be part of the decision process made by heart teams evaluating patients with bicuspid aortic stenosis."

The revised labeling is supported by recent data from the Low Risk Bicuspid Study, which showed bicuspid patients implanted with Evolut TAVR had low rates of all-cause mortality or disabling stroke at 30 days (1.3%), a low rate of serious procedural complications, no annular ruptures or aortic dissections and no moderate/severe paravalvular leak. The study also maintained the Evolut TAVR platform's industry-leading hemodynamics (blood flow) with patients experiencing low mean AV gradients (7.6 ± 3.7 mm Hg), and large effective orifice area (2.3 ± 0.7 cm²). The pacemaker rate was 15.1%.

"The increased adoption of the Evolut platform globally is partially attributed to the fact that it meets the needs of a broad variety of patients including those who have unique anatomical variations," said Jeffrey Popma, M.D., chief medical officer and vice president, medical affairs for the Structural Heart business, which is part of the Cardiac and Vascular Group at Medtronic.

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 investigational 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. In addition, bicuspid aortic valve patients across all risk categories 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.

-end-

Joey Lomicky
Public Relations
+1-763-526-2494

Ryan Weispfenning
Investor Relations
+1-763-505-4626

<https://news.medtronic.com/2020-08-21-Medtronic-Evolut-TAVR-System-Receives-Updated-U-S-Labeling-Revising-Precaution-for-Treatment-of-Low-Risk-Patients-with-Bicuspid-Aortic-Stenosis>