Medtronic News

Medtronic Evolut TAVR System Receives Expanded Indication to Treat Symptomatic Severe Aortic Stenosis Patients at Low Risk for Surgical Mortality

Expanded TAVR Indication to Younger, More Active Patients Signals Groundbreaking Shift in the Future Treatment of Heart Valve Disease

DUBLIN, Aug. 16, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced U.S. Food and Drug Administration (FDA) approval of the Evolut™ Transcatheter Aortic Valve Replacement (TAVR) system for patients with symptomatic severe native aortic stenosis who are at a low risk of surgical mortality. The low-risk patient population is the final surgical risk category to be approved for this minimally invasive alternative to open-heart surgical valve replacement (SAVR) and includes patients who may be younger and more active than higher-risk patients.

The expanded indication approval is based on randomized clinical data from the global, prospective, multi-center Evolut Low Risk Trial, which evaluated three valve generations (CoreValve™, Evolut™ R, and Evolut™ PRO valves) in more than 1,400 patients. The data showed TAVR to have an excellent safety profile and be an effective treatment option in low-risk patients with shorter hospitals stays and improved quality-of-life scores compared to SAVR. In addition to a significantly lower rate of the composite of all-cause death or disabling stroke with TAVR at 30 days, the Evolut TAVR system demonstrated superior hemodynamic (blood flow) performance with significantly lower mean aortic valve gradients and larger EOAs (effective orifice area) compared to surgery – important factors for more active patients. The rate of new pacemaker implantation and residual aortic regurgitation was higher in the TAVR group.

“The majority of my patients want a replacement valve that’s going to minimize the risk of death, stroke, and other cardiovascular events during the procedure and allow them to leave the hospital faster and recover sooner. In patients appropriate for a biologic valve, that option is going to be TAVR,” said Michael Reardon, M.D., cardiothoracic surgeon at Houston Methodist DeBakey Heart & Vascular Center, principal investigator and senior author of the Evolut Low Risk Trial. “With the low risk approval, risk stratification for TAVR treatment is becoming obsolete and heart teams will likely need to assess treatment options based on anatomical characteristics, concomitant risk factors, and also patient preference.”

The Evolut TAVR System, with its industry-leading hemodynamics, allows for improved heart function that helps many patients resume their pre-aortic stenosis activity levels. The valve is engineered with a self-expanding nitinol frame that conforms the replacement valve to the native annulus with consistent radial force and includes an external tissue wrap that increases surface area contact with native anatomy for enhanced valve sealing. The CoreValve Evolut TAVR platform leads the industry in longer-term data, reporting durability data out to 8 years with the Italian Registry.

“Low risk patients were younger and healthier than those patients enrolled in our prior studies, and were better able to weigh the risks and benefits of surgery or TAVR based on their value preferences,” said Jeffrey J. Popma, M.D., director of Interventional Cardiology at Beth Israel Deaconess Medical Center in Boston, and co-principal investigator in the Evolut Low Risk Trial. “It is our impression that patients will now be able to make a choice on the method of aortic valve replacement based on an informed risk-benefit discussion with their heart team.”

Severe aortic stenosis affects approximately 165,000 low risk patients per year in the U.S.,Western Europe and Japan, occurring when the aortic valve becomes diseased (stenotic). The valve leaflets become stiff and thickened and have difficulty opening and closing, making the heart work harder to pump blood to the rest of the body and, therefore, impacting an individual’s daily activities. If left untreated, patients with severe aortic stenosis can die from heart failure in as little as two years.

“This expanded indication means that physicians and patients will have more freedom to choose the right aortic valve

replacement procedure based on each patient's health and quality-of-life goals, which may vary based on their age, frailty and anticipated daily activity," said Pieter Kappetein, M.D., Ph.D., vice president and chief medical officer for the Structural Heart and Cardiac Surgery businesses, which are part of the Cardiac and Vascular Group at Medtronic. "This is an exciting time for patients and the clinical community alike as we now have an aortic valve replacement technology clinically demonstrated to be well-suited for the thousands of new patients who seek a less invasive treatment option that helps them get back to active living."

With the approval, the Evolut TAVR platform is now indicated in the U.S. for symptomatic severe aortic stenosis patients across all risk categories (extreme, high, intermediate and low).

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 inMedtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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