Medtronic News

Medtronic Expands TAVR Access to More Patients With Symptomatic, Severe Aortic Stenosis Upon Intermediate Risk FDA Approval

Self-Expanding CoreValve(TM) Evolut(TM)TAVR Platform with Excellent Procedural Safety and Proven Valve Performance Helps Address Needs of Intermediate-Risk Patients

DUBLIN - July 10, 2017 - Medtronic plc (NYSE: MDT) today announced the expanded U.S. Food and Drug Administration (FDA) approval of the self-expanding CoreValve(TM) Evolut(TM) transcatheter aortic valve replacement (TAVR) platform to include patients with symptomatic severe aortic stenosis who are at an intermediate risk for open-heart surgery. With hemodynamic performance (a measure of blood flow efficiency) shown to be superior to surgical aortic valve replacement (SAVR), the CoreValve Evolut platform is designed to deliver excellent valve performance for these patients who are often considered to be more active than high- or extreme-risk patients previously indicated for the procedure.

Patients who are at intermediate risk for open-heart surgery have a risk of mortality of >= 3 percent at 30 days following the procedure. The risk assessment is determined by a heart team (including an interventional cardiologist and cardiac surgeon), in combination with the Society of Thoracic Surgeons (STS) score and other factors, such as co-morbidities, frailty, prior surgical intervention and disabilities.

"As evidenced by the landmark SURTAVI trial, the CoreValve Evolut platform is well-suited for the intermediate-risk patient population due to its supra-annular design for unsurpassed hemodynamics, low rates of mortality and disabling stroke, earlier improvement in quality of life, fast functional recovery times and short hospital stays," said Michael Reardon, M.D., professor of cardiothoracic surgery and Allison Family Distinguished Chair of Cardiovascular Research at Houston Methodist DeBakey Heart & Vascular Center. "It's important to consider that in the first 30 days, patients treated with TAVR showed functional improvements and lower rates of stroke than the surgical patients in the study."

Recently unveiled at the 2017 American College of Cardiology meeting, the global SURTAVI trial evaluated intermediate-risk patients and compared 863 TAVR patients treated with the CoreValve and Evolut R Systems (STS: 4.4 percent) to 794 surgical patients (STS: 4.5 percent). Against the strongest surgical performance (compared to predicted surgical risk of mortality) seen to date in a randomized trial, the CoreValve Evolut platform met its primary endpoint of non-inferiority compared to surgery in all-cause mortality or disabling stroke (12.6 percent for TAVR versus 14.0 percent for SAVR; posterior probability of non-inferiority >0.999). The CoreValve Evolut platform also demonstrated significantly better mean aortic valve gradients (7.8 mm Hg vs. 11.8 mm Hg; $p<0.001$) at two years. SAVR was associated with less aortic regurgitation, major vascular complications and need for permanent pacemaker implantation.

"Patients at intermediate risk for open-heart surgery account for a large portion of the severe aortic stenosis population," said Rhonda Robb, vice president and general manager of the Heart Valve Therapies business, a part of Medtronic's Cardiac and Vascular Group. "We are delighted to take the self-expanding CoreValve Evolut platform to more patients with aortic stenosis who can benefit from this therapy."

The CoreValve Evolut platform consists of the CoreValve, CoreValve Evolut R and the recently FDA-approved CoreValve Evolut PRO systems, which are available for use in the United States with severe aortic stenosis patients at an intermediate surgical risk or greater. The CoreValve Evolut PRO System is currently not approved for commercial use outside of the United States.

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 91,000 people worldwide, serving physicians, hospitals and patients in more than 160 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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