Medtronic News

Medtronic Evolut TAVI System Receives Expanded Indication in Europe to Treat Severe Aortic Stenosis Patients at Low Risk for Surgical Mortality

The Evolut TAVI Platform Receives New Indication for Patients with Bicuspid Aortic Valves at Extreme, High or Intermediate Risk of Surgical Mortality

DUBLIN, June 22, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced CE (*Conformité Européenne*) mark and European launch of the Evolut™ Transcatheter Aortic Valve Implantation (TAVI) system for patients with 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 younger1 and more active than higher-risk patients. The Evolut TAVI platform also received a new indication approval that allows for the treatment of patients with bicuspid aortic valves who are at intermediate, high and extreme risk of surgical mortality.

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

“The low-risk indication marks an important milestone for patients across Europe as TAVI expands into a potentially younger and more active patient population,” said Thomas Modine, M.D., Ph.D, MBA, cardiac surgeon at Hôpital Cardiologique Lille, in Lille, France, and investigator in the Evolut Low Risk Trial. “While surgical valve replacement will still be an option for many patients, we anticipate TAVI to be accepted as an important valve replacement therapy in patients for whom it is an appropriate treatment option. Heart teams will have more freedom to choose the best aortic valve replacement procedure based on each patient’s individual characteristics.”

The Evolut TAVI System, with its excellent hemodynamics, allows for improved heart function that helps many patients resume their pre-aortic stenosis activity. 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 device leads the industry in longer-term clinical data, reporting durability data out to 8 years with the Italian Registry on the original CoreValve TAVI.

Severe aortic stenosis, which occurs when the aortic valve becomes diseased (stenotic), affects approximately more than 500,000 patients in western Europe per year. 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, symptomatic patients with severe aortic stenosis can die from heart failure in as little as two years.

With this approval, the Evolut TAVI platform is now indicated in Europe for severe aortic stenosis patients across all risk categories (extreme, high, intermediate and low), and includes new labeling that allows for the treatment of patients with bicuspid aortic valves for patients at extreme, high and intermediate risk of surgical mortality. The Evolut TAVR platform is indicated in the U.S. for symptomatic severe aortic stenosis patients across all risk categories (extreme, high, intermediate and low). Bicuspid valve patients at intermediate risk or higher may be candidates for TAVR in the U.S.

“It is important that we expand access to a less invasive treatment option to this low-risk patient population. It’s also encouraging that we now have new labeling to address a large portion of bicuspid valve patients, too,” said Didier Tchétché, M.D., interventional cardiologist and director of the Structural Heart Disease Department at Clinique Pasteur in Toulouse, France, and investigator in the Evolut Low Risk Trial. “Based on excellent data from the STS/ACC TVT Registry, bicuspid patients (excluding low risk), will for the first time, be indicated for TAVI, which is another big win for patients and the future of the therapy.”

Bicuspid aortic valves are a congenital heart defect affecting 1-2 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). Further, bicuspid aortic valve stenosis represents almost 40 percent of the intermediate and high risk severe symptomatic aortic stenosis patient population.2

“With these approvals, more patients will now be candidates for the Evolut TAVI system while surgical aortic valve replacement will evolve to serve a more complex patient population,” 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. “Medtronic is well positioned to provide a variety of therapy options to meet the varying needs of patients with heart valve disease.”

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 Earlier CoreValve Evolut TAVR trials enrolled patients at an average age of 80 to 83 while the Evolut Low Risk

trial enrolled patients at an average age of 74).

2 Medtronic data on file.

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