Medtronic News

Medtronic Announces CE Mark of Evolut™ PRO+ TAVI System for Treatment of Symptomatic Severe Aortic Stenosis Patients in Europe

As TAVI Patient Population Grows, PRO+ TAVI System Launches with Four Valve Sizes and Lowest Delivery Profile

DUBLIN, May 3, 2021 /PRNewswire/ -- Medtronic plc (NYSE: MDT), the global leader in medical technology, today announced CE (Conformité Européenne) Mark of the Evolut™ PRO+ TAVI System – the newest-generation Medtronic TAVI system that builds off the proven self-expanding, supra-annular Evolut TAVI platform. The Evolut PRO+ TAVI System includes four valve sizes with an external pericardial tissue wrap that provides advanced sealing for the largest annular range (for self-expanding TAVI technology) on the market. The approval follows a recent indication expansion for the Evolut platform in Europe for patients with severe aortic stenosis who are at a low risk of surgical mortality and patients with bicuspid aortic valves who are at intermediate, high and extreme risk of surgical mortality.

"As TAVI expands to a broader patient population, including patients at a low risk of surgical mortality and those with bicuspid valves, having the right valve technology becomes a critically important factor in making treatment decisions," said Haim Danenberg, M.D., Ph.D., professor of medicine and head of Interventional Cardiology at Wolfson Medical Center in Israel. "Heart teams pursue a valve solution that is safe, effective and durable. We need a system that can be delivered through the femoral arteries without losing any feature of efficacy such as reducing paravalvular leak and achieving excellent hemodynamics. Because of its design and long track record of exceptional clinical outcomes, the Evolut TAVI platform is well-suited to meet these needs."

The Evolut PRO+ TAVI System is approved in four valve sizes (the 23, 26 and 29mm systems can access vessels down to 5.0 mm) with the 34 mm system able to access vessels down to 6.0 mm. The system is designed with an outer porcine pericardial tissue wrap that adds surface area contact and tissue interaction between the valve and the native aortic annulus, and includes an integrated, inline sheath, allowing physicians to treat patients with a range of anatomical variations with a low delivery profile. Consistent with the Evolut platform design, the PRO+ valve is designed with a self-expanding nitinol frame that conforms to the native annulus with consistent radial force and advanced sealing.

"Anatomical variations can present unique challenges and demand tailored transcatheter valve selection," said Nicolas Van Mieghem , M.D., Ph.D., professor of interventional cardiology, department of cardiology, Thoraxcenter, Erasmus University Medical Center. "This is the first time European physicians will have access to the large 34mm Evolut PRO+ valve size that contains an external tissue wrap for patients with large aortic root dimensions."

Severe aortic stenosis occurs when the aortic 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 symptomatic severe aortic stenosis can die from heart failure in as little as two years.

"We believe that continued iteration of the CoreValve/Evolut family of supra-annular transcatheter aortic valves will result in progressive improvements in patient outcomes," said Jeffrey J. Popma, M.D., vice president and chief medical officer for the Coronary & Renal Denervation business and the Structural Heart and Aortic

business, which are part of the Cardiovascular Portfolio at Medtronic. "The Evolut PRO+ TAVI system will provide heart teams a valve with strong hemodynamic performance, with a lower vascular access profile, thereby allowing more patients to be treated by a transfemoral approach rather than alternative access methods. The additional pericardial wrap in the 34 mm Evolut PRO+ may also reduce the degree of residual perivalvular regurgitation."

The Evolut TAVR platform, including the Evolut™ R, Evolut™ PRO and Evolut PRO+ TAVI Systems, is indicated for symptomatic severe native aortic stenosis patients across all surgical risk categories (extreme, high, intermediate and low) in the U.S. and countries that recognize CE Mark.

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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