Medtronic News

Medtronic Announces FDA Approval and U.S. Launch of Next-Generation Evolut™ PRO+ TAVR System for Treatment of Symptomatic Severe Aortic Stenosis Patients

Improved Functionality Across Four Valve Sizes and Lowest Delivery Profile on the Market, the Evolut PRO+ TAVR System Launches in U.S. as TAVR Patient Population Grows

DUBLIN, Sept. 23, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), a global leader in heart valve therapies, today announced U.S. Food and Drug Administration (FDA) approval and U.S. launch of the Evolut™ PRO+ TAVR System – a new-generation Medtronic TAVR system that builds off the proven self-expanding, supra-annular Evolut TAVR platform. The Evolut PRO+ TAVR System includes four valve sizes with an external pericardial tissue wrap that provides advanced sealing for the largest indicated patient treatment range and the lowest delivery profile currently on the market. The launch comes on the heels of the FDA's recent indication expansion for the Evolut TAVR platform to treat patients with symptomatic severe aortic stenosis at a low risk of surgical mortality, the final surgical risk category to be approved for TAVR.

"As TAVR becomes a preferred treatment option for more patients with severe aortic stenosis, it's critically important to have valve technology available that keeps pace with the evolution of the therapy," said Mathew R. Williams, M.D., director of the Heart Valve Program at the NYU Langone Health in New York City. "Valve technologies that are designed to help minimize paravalvular leak, simplify the valve delivery during the procedure, and for unobstructed blood flow are factors that have made TAVR an excellent choice for many patients."

The Evolut PRO+ TAVR System can treat the broadest annulus range and offers the lowest delivery profile on the market (the 23, 26- and 29-mm valves can treat vessels down to 5.0 mm). It features four valve sizes – including the 34 mm (treats vessels down to 6.0 mm) – with an external tissue wrap and an integrated, inline sheath, allowing physicians to treat patients with a range of anatomical variations. 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. The valve incorporates an outer porcine pericardial tissue wrap that adds surface area contact and tissue interaction between the valve and the native aortic annulus to help potentially reduce incidences of paravalvular leaks.

"Physicians are treating a broader range of patient anatomies than ever before – from large to small, from simple to complex," said Guilherme Attizzani, M.D., interventional cardiologist and director Valve and Structural Heart Disease Center at University Hospitals in Cleveland. "Adding the external tissue wrap to the large 34mm valve size, which wasn't previously available, is a major technological improvement that will benefit many patients with larger anatomies."

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 anticipate the Evolut PRO+ TAVR System will help heart teams fine-tune their TAVR procedures, further building on the consistent and reliable outcomes that they have come to expect from the Evolut TAVR platform– including positive hemodynamic outcomes in part, due to its supra-annular valve design – which we continue to see with the Evolut platform across large-scale, randomized clinical trials," 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. "In addition to a decrease in profile for the core sizes to help minimize burden on the vessels during the procedure, the Evolut PRO+ TAVR System gives heart teams a familiar technology that's been fine-tuned to help drive excellent patient outcomes."

The Evolut TAVR platform, including the Evolut™ R, Evolut™ PRO and Evolut PRO+ TAVR Systems, is indicated for

symptomatic severe aortic stenosis patients across all risk categories (extreme, high, intermediate and low) 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.

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