Medtronic News

Medtronic Receives FDA Approval for Expanded Indication Trial in Low-Risk Aortic Stenosis Patients

DUBLIN - February 22, 2016 - Medtronic plc (NYSE: MDT) today announced that the U.S. Food and Drug Administration (FDA) approved an expanded indication trial for the CoreValve® Evolut® R System, the first and only next-generation recapturable, self-expanding transcatheter aortic valve replacement (TAVR) system commercially available in the United States. Patients with aortic stenosis, who are at a low surgical mortality risk as determined by a heart team, will be enrolled in the trial.

Enrollment for the investigational device exemption (IDE) trial is expected to begin during the spring of 2016 and will include 1,200 patients with severe aortic stenosis who have a less than 3 percent risk of mortality, as determined by a heart team. The trial will enroll low-risk patients from up to 80 clinical sites with 1:1 randomization to receive the Evolut R System or undergo open-heart surgery (surgical aortic valve replacement or SAVR). The IDE is designed as an adaptive trial with a primary endpoint of all-cause mortality or disabling stroke. The trial has a 2-year endpoint and allows for a one-year analysis for early FDA submission. Additionally, the trial will include a sub-study of leaflet mobility in 400 patients.

"This trial comes on the heels of data showing patients who underwent TAVR with this self-expanding platform demonstrated superior survival benefit -with low and stable stroke rates- compared to SAVR patients," said Michael Reardon, M.D., professor of cardiothoracic surgery at Houston Methodist DeBakey Heart & Vascular Center and principal investigator of the IDE study. "This study is an important next step in developing robust clinical evidence to help heart teams understand the potential benefits of TAVR in a broader patient population."

The Evolut R system is optimized to increase conformability and sealing at the annulus, while maintaining supra-annular valve positioning for improved blood flow and hemodynamic performance. The valve is delivered through the EnVeo(TM) R Delivery Catheter System, which features an InLine Sheath that provides the lowest profile on the market (14 Fr equivalent, less than 1/5 inch). The low profile enables treatment of patients with vessels down to 5mm through the preferred transfemoral access route, and may minimize the risk of major vascular complications in some patients.

"Medtronic is committed to expanding access to TAVR for patients who may benefit based on a robust clinical evidence portfolio," said Rhonda Robb, vice president and general manager of the heart valve therapies business, which is part of the Cardiac and Vascular Group at Medtronic. "We are excited to partner with such proven heart teams to study the CoreValve Evolut R self-expanding platform in this low risk patient population."

The CoreValve Evolut R transcatheter valve and the CoreValve EnVeo R Delivery Catheter System were FDA-approved for commercial use in the United States in June 2015. It is also available in Europe and other countries that recognize the 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 85,000 people worldwide, serving physicians, hospitals and patients in approximately 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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