Medtronic News

Medtronic CoreValve(TM) Evolut(TM) R System First TAVI to Receive CE Mark for Intermediate Risk Aortic Stenosis Patients

Next-Generation Recapturable Device is the First-of-its-Kind Approved in Europe to Treat Intermediate Risk Patients as an Alternative to Open-Heart Surgery

DUBLIN - August 1, 2016 - Medtronic plc (NYSE: MDT) today announced CE*(Conformité Européenne)* mark for the self-expanding, recapturable and repositionable CoreValve(TM) Evolut(TM) R System to treat aortic stenosis patients who are at intermediate risk for open-heart surgery as determined by a heart team. The Evolut R System is the first transcatheter aortic valve implantation (TAVI) therapy to obtain an expanded indication in Europe for this patient population.

"The unique design of the self-expanding, supra-annular Evolut R System, coupled with its ability to be recaptured and repositioned for accurate valve placement, enables this device to be a viable treatment alternative for patients at intermediate surgical risk," said Prof. Eberhard Grube, M.D., director of the Structural Heart Program at University Hospital in Bonn, Germany. "The highly-anticipated intermediate risk indication marks an important milestone for the industry as we look to safely expand TAVI access to younger and less sick patient populations."

The new intermediate risk indication approval for the CoreValve Evolut R System was based on positive clinical data from the Nordic Aortic Valve Intervention (NOTION) Trial and from a subset analysis from the CoreValve U.S. High Risk Pivotal Trial. Data from the NOTION trial showed that comparable clinical outcomes to surgery can be achieved by using CoreValve in patients who are good surgical candidates. Both datasets demonstrated excellent clinical performance for the CoreValve System with lower rates of all-cause mortality and major stroke compared to surgery. Additionally, data showed low incidences of procedural complications and superior hemodynamic performance (blood flow) compared to surgery.

"This first-of-its-kind TAVI indication in Europe further demonstrates Medtronic's global leadership in the transcathether valve space and commitment to extending these benefits to new patient populations through rigorous clinical research and exceptional physician training and education," 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 continuing to support global heart teams with training and education on the Evolut R System to expand patient access to this minimally-invasive treatment option."

The Evolut R valve is delivered through the EnVeo(TM) R Delivery Catheter System, which features an InLine(TM) Sheath that significantly reduces the profile to the lowest currently on the market (14 Fr equivalent, less than 1/5 inch). A smaller profile size provides a greater opportunity to treat patients with smaller vessels through the preferred transfemoral access route, and may minimize the risk of major vascular complications in some patients.

The CoreValve Evolut R System and the EnVeo R Delivery Catheter System are now approved for use in patients at extreme, high and intermediate surgical risk in Europe and other countries that recognize the CE mark. The CoreValve Evolut R System was FDA-approved for commercial use in the United States in June 2015 for severe aortic stenosis patients who are at high or extreme risk for surgery.

The CoreValve Evolut R System is not approved to treat intermediate risk aortic stenosis patients 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 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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Contacts:

Joey Lomicky
Public Relations
+1-763-526-2494

Ryan Weispfenning
Investor Relations
+1-763-505-4626

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