Medtronic News

Medtronic CoreValve® System Gains First Approval for Transcatheter Valve-In-Valve Procedures

Replacing Degenerated Surgical Valves with CoreValve Results in Significant Hemodynamic Improvements for Patients

MINNEAPOLIS - May 23, 2013 - Medtronic, Inc. (NYSE: MDT) today announced it has received Conformité Européenne (CE) Mark for valve-in-valve (VIV) procedures using the CoreValve® and CoreValve® Evolut(TM) transcatheter aortic valve implantation (TAVI) systems in degenerated bioprosthetic surgical aortic valves. This is the first ever regulatory approval for VIV procedures, which provide a minimally invasive treatment option for patients whose surgical aortic valves have degenerated, and who are at extreme or high risk for surgery and would otherwise go untreated. The CoreValve VIV procedures are not approved in the United States.

Results from the largest global VIV registry, published in *Circulation* in November (Transcatheter Aortic Valve Replacement for Degenerative Bioprosthetic Surgical Valves: Results from the Global Valve-in-Valve Registry), showed the VIV approach resulted in considerable hemodynamic (blood flow) improvements, including a decrease in valve gradients (blood flow resistance). Positive procedural outcomes were maintained at 1-year follow-up (with 89 percent survival at one year), which was comparable with other non-VIV TAVI studies.1

"While surgical valves provide effective therapy for many patients, the replacement valves eventually degenerate over time, so valve-in-valve has become a topic of great clinical interest due to the needs of these patients," said Ran Kornowski, M.D., chair of cardiology at Rabin Medical Center and Tel-Aviv University in Tel-Aviv, Israel, and previously at Washington Hospital Center in Washington, D.C., and senior author of the Global Valve-in-Valve Registry. "European approval of the CoreValve procedure is a very important advance in the treatment of severe aortic stenosis and enables an entirely new group of patients to benefit from this transcatheter valve."

The Global VIV registry evaluated the safety and efficacy of the VIV approach in 202 patients at 38 sites in Europe, North America, Australia, New Zealand and the Middle East,1 with 124 patients receiving the CoreValve System. In the study, the CoreValve System demonstrated superior hemodynamic outcomes and high procedural success rates (96.8 percent).1

The valve-in-valve procedure, in which the CoreValve System is placed inside the degenerated surgical aortic valve through a low-profile, 18Fr delivery catheter, is approved for use with all four CoreValve sizes (23mm, 26mm, 29mm and 31mm), as well as three delivery approaches (transfemoral, subclavian and direct aortic access).

"We are pleased to now extend this safe and less-invasive, valve-in-valve procedure. This approach allows patients to avoid a second open-heart surgery to replace a failing surgical valve, which was originally performed to replace their own diseased valve." said John Liddicoat, M.D., senior vice president, Medtronic, and president of the Medtronic Structural Heart Business. "Furthermore, the impressive improvements in hemodynamic performance, due to CoreValve's supra-annular design, are showcased in the results of these valve-in-valve procedures."

Each year, approximately 200,000 people worldwide receive surgical aortic valves,2 which typically last 15 years or more. When the surgical valves degenerate due to the aging process, patients require another valve replacement. However, some patients are not eligible for a second open-heart surgery, and the transcatheter VIV procedure now may provide them with a new treatment option.

The Medtronic CoreValve System is available in the United States for investigational use only. In the Medtronic CoreValve U.S. Expanded Use Study, the U.S. Food and Drug Administration has approved investigational VIV procedures in extreme-risk patients (part of the pivotal trial evaluating the CoreValve System in the U.S.).

In collaboration with leading clinicians, researchers and scientists, 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 worldwide.

To view the hi-res image of the Medtronic CoreValve® Evolut(TM) in a surgical bioprosthetic valve ("valve-in-valve"), click here

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

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 Dvir, D. et al. "Transcatheter Aortic Valve Replacement for Degenerative Bioprosthetic Surgical Valves: Results From the Global Valve-in-Valve Registry." *Circulation.* October 2012

2 Brown JM et al; The Journal of Thoracic and Cardiovascular Surger; V.137; No.1; 1/09; p82

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