Medtronic CoreValve® System Receives FDA Approval for Transcatheter Valve-In-Valve Procedures

March 31, 2015 7:30 AM CT

First TAVR Device Indicated for Replacement of Failed Surgical Heart Valves Expands Patient Population That Can Benefit from Minimally Invasive Procedure

DUBLIN - March 31, 2015 - Medtronic plc (NYSE: MDT) today announced the U.S. Food and Drug Administration (FDA) approval of the CoreValve® System for valve-in-valve (VIV) procedures in patients whose surgical aortic heart valves have failed. The CoreValve System is the first transcatheter heart valve approved in the U.S. for VIV procedures in both high and extreme risk patients who have limited options or may otherwise go untreated.

Each year, approximately 200,000 people worldwide receive surgical aortic valves[i], which typically last 15 years or more. When a surgical valve degenerates over time, patients may require another valve replacement. However, some patients are too sick or frail for a second open-heart surgery, and the transcatheter VIV procedure may now provide them with a new treatment option.

During the VIV procedure, the CoreValve System is placed inside a failing surgical heart valve with an inner diameter from 17-29 mm through a low-profile, 18Fr delivery catheter, which 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).

The CoreValve system is engineered with a supra-annular valve design, which helps maximize blood flow for patients whose artificial heart valves have shown either stenosis, regurgitation, or both. Outcomes from an Expanded Use Study, an observational arm of the CoreValve U.S. Pivotal Trial, demonstrated low rates of mortality and stroke (for a combined rate of 4.2 percent at 30 days and 10.7 percent at 6 months) and significant improvements in hemodynamics and quality of life in patients with failed surgical heart valves. Results from the largest global VIV registry also showed the VIV approach resulted in considerable hemodynamic (blood flow) improvements, including a decrease in blood flow resistance. In this registry, positive procedural outcomes were maintained at one year follow-up with 89 percent survival, which was comparable with other non-VIV TAVR studies[ii].

"This first-of-its-kind FDA approval showcases Medtronic's commitment to advancing the TAVR field so that more patients can receive access to this life-saving, minimally invasive therapy," 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. "The CoreValve design is uniquely suited for valve-in-valve implantation due to its supra-annular design. We are pleased to be able to provide physicians and patients with another treatment option to replace surgical heart valves when needed."

The CoreValve System was approved by the FDA in 2014 for patients at extreme risk and high risk for surgery, and received CE (Conformité Européenne) Mark for VIV procedures in May 2013. The CoreValve System has been implanted in more than 75,000 patients in more than 65 countries since receiving CE Mark in 2007. In addition, the CoreValve System offers the broadest range of sizes available to accommodate more patients.

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 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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[i] Brown JM et al; The Journal of Thoracic and Cardiovascular Surgery; V.137; No.1; 1/09; p82

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

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