Medtronic News

Medtronic CoreValve® System Demonstrates Superior Survival to Surgery in Aortic Stenosis Patients with Lower STS Scores

New Sub-study at ACC.16 from the CoreValve U.S. High Risk Trial Shows Exceptional Valve Performance for the Self-Expanding Transcatheter Heart Valve at Two Years

DUBLIN and CHICAGO - April 2, 2016 - Medtronic plc (NYSE: MDT) today unveiled new clinical data on the self-expanding CoreValve® System from the High Risk Study of the CoreValve U.S. Pivotal Trial, showing superior outcomes in survival for transcatheter aortic valve replacement (TAVR) compared to surgery at two years for the subgroup of patients with an STS Predicted Risk of Mortality estimate ≤7 percent. An STS score is used to help physicians determine whether patients with severe aortic stenosis should undergo surgical or transcatheter aortic valve replacements.

Unveiled at the 65th Annual Scientific Session of the American College of Cardiology (ACC.16), the analysis of the sub-cohort compared 202 patients treated with the CoreValve System against 181 patients who received surgical aortic valve replacement (SAVR). The CoreValve TAVR patients demonstrated superior outcomes in all-cause mortality at two years compared to patients treated with surgical aortic valve replacement (15.0 percent vs. 26.3 percent; p=0.01). In addition, rates of combined all-cause mortality or major stroke were superior for TAVR with the CoreValve System (17.1 percent vs. 31.9 percent; p=0.0018).

"It was encouraging to see that CoreValve patients with lower STS mortality risk scores within the High Risk Study achieved a superior survival benefit relative to surgery as did all patients in the study at two years. The survival advantage compared to surgery appeared to widen between year one and year two, reinforcing the notion that the CoreValve System is a viable treatment solution for patients with severe aortic stenosis at high risk," said Michael Reardon, M.D., professor of cardiothoracic surgery and Allison Family Distinguished Chair of Cardiovascular Research at Houston Methodist DeBakey Heart & Vascular Center, and chairman of the patient screening committee of the CoreValve U.S. Pivotal Trial.

In the CoreValve treatment arm of the analysis, patients also experienced significantly better valve hemodynamics (blood flow through the valve) than patients treated with surgery, as both gradients and the rates of severe patient prosthesis mismatch were statistically lower at each time point in the follow-up (p< 0.0001). Rates of life-threatening or disabling bleeding were also statistically lower in the CoreValve group. (20.2 percent vs. 34.9 percent; p=0.001). The pacemaker rate for the CoreValve group was 27.7 percent at two years, which is in line with CoreValve patients in the broader High Risk Study.

These patients also demonstrated notable improvements in their quality of life (QoL). QoL scores for the CoreValve-treated patients showed strong medical benefit defined as KCCQ summary score of >=60 and with <10-point decrease from baseline.

The CoreValve System was approved by the U.S. Food and Drug Administration in 2014 for patients at extreme risk and high risk for surgery, and was the first TAVR device approved in the United States for valve-in-valve procedures in both high- and extreme-risk patients with failed surgical valves. Since receiving CE (Conformité Européenne) Mark in 2007, the CoreValve System has been implanted in more than 100,000 patients from more than 60 countries.

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 more than 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.

-end-

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

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

---

https://news.medtronic.com/2016-04-02-Medtronic-CoreValve-R-System-Demonstrates-Superior-Survival-to-Surgery-in-Aortic-Stenosis-Patients-with-Lower-STS-Scores