

Medtronic CoreValve® System Maintains Survival Advantages Over Surgery in High Risk Aortic Stenosis Patients at Three Years

New Data at ACC.16 First to Show Superior, Longer-Term Outcomes for Self-Expanding TAVR vs. SAVR at Three Years Results Published Simultaneously in the Journal of American College of Cardiology (JACC)

DUBLIN and CHICAGO - April 3, 2016 - Medtronic plc (NYSE: MDT) today announced new data from the High Risk Study of the CoreValve U.S. Pivotal Trial that show superior clinical outcomes for transcatheter aortic valve replacement (TAVR) with the CoreValve® System compared to surgical aortic valve replacement (SAVR) out to three years. The positive data were published in the *Journal of American College of Cardiology* and simultaneously presented during a Featured Clinical Research session at 65th Annual Scientific Session & Expo of the American College of Cardiology (ACC.16).

Of the 407 patients (228 TAVR; 179 SAVR) followed out to three years in the randomized High Risk Study, patients treated with the CoreValve System showed superior outcomes compared to surgery for the combined endpoint of all-cause mortality or stroke (37.3 percent vs. 46.7 percent; $p=0.006$) and for all stroke (12.6 percent vs. 19.0 percent; $p=0.03$). All-cause mortality continued to be numerically lower for TAVR compared to SAVR-treated patients (32.9 percent vs. 39.1 percent; $p=0.07$).

"It's reassuring to see that the CoreValve High Risk Study continues to show that TAVR is superior to surgery at three years for the combined endpoint of mortality and stroke, which has the most important impact on patients," said G. Michael Deeb, M.D., Herbert Sloan Collegiate Professor of Cardiac Surgery, University of Michigan Frankel Cardiovascular Center, who presented the data today at ACC.16. "Most importantly, the new data supports the viability of TAVR out to three years with no signal of a significant increase in mean gradient or aortic regurgitation."

Courtesy of the supra-annular design of the CoreValve System, the TAVR group showed exceptional valve performance with sustained single-digit gradients (measurement of blood flow through the valve) that were lower than surgery patients at all follow-up visits through three years ($p<0.001$). The CoreValve System also maintained a favorable safety profile to surgery in these patients with rates of major adverse cardiovascular and cerebrovascular events (MACCE) that were lower in the CoreValve group (40.2 percent vs. 47.9 percent; $p=0.03$).

In an update to a sub-study analysis of the High Risk Study in patients with an STS Predicted Risk of Mortality estimate ≤ 7 percent also presented yesterday at ACC.16, patients treated with the CoreValve System continued to demonstrate significantly lower all-cause mortality compared to surgery at three years follow-up (27.1 percent vs. 38.5 percent, respectively; $p=0.02$).

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 being the first TAVR device to receive CE (Conformite Europeenne) Mark in 2007, the CoreValve System has been implanted in more than 100,000 patients in 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.

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