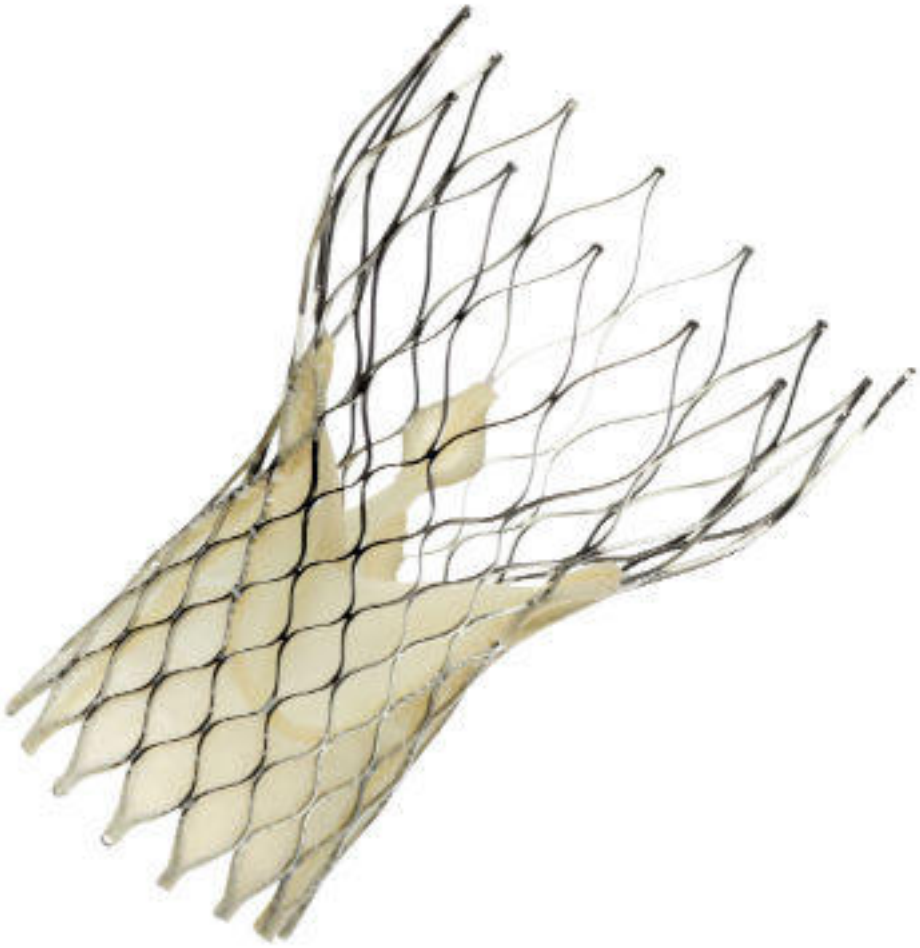
Medtronic CoreValve U.S. Pivotal Trial Results Reveal Positive Outcomes for Patients

Medtronic

- Trial Finds Lifesaving Technology Successfully Meets Primary and Secondary Endpoints
- FDA Determines Expert Panel Not Required for Extreme Risk
- FDA Will Evaluate Extreme Risk Patients Separately from High Risk Patients



Medtronic, Inc. today announced the highly anticipated results from the CoreValve U.S. Pivotal Trial, the first U.S. data presented on the Medtronic CoreValve® System. The study of the novel self-expanding device, presented at a late-breaking clinical trial session of the Transcatheter Cardiovascular Therapeutics (TCT) 2013 Conference, met its primary endpoint in patients who were considered too ill or frail to have their aortic valves replaced through traditional open-heart surgery, with a rate of death or major stroke at one year of 25.5 percent. This result is highly significant ($p<0.0001$) as it was 40.7 percent lower in patients treated with the CoreValve System than

was expected with standard therapy (a pre-specified performance goal of 43.0 percent).

The rate of stroke - one of the complications most concerning to physicians and patients because it increases mortality and affects quality of life - is among the lowest reported. At one month, the major stroke rate was 2.4 percent, and it remained low over time with a one-year rate of 4.1 percent. In addition, in more than 800 extreme risk patients enrolled in the CoreValve Continued Access Study, CoreValve patients experienced an even lower rate of major stroke (1.8 percent at one month).

"The fact that nearly three-quarters of patients were alive and free of strokes at one year is remarkable, given the complex medical conditions and extreme frailty of this population. Not only do the results meet the CoreValve study's safety and efficacy endpoints for patients at extreme risk for surgery, but the positive clinical outcomes and low complication rates set a high standard for what transcatheter valves can achieve," said Jeffrey J. Popma, M.D., director of Interventional Cardiology at the Beth Israel Deaconess Medical Center, Boston, and co-principal investigator of the Trial who presented the results at TCT.

The study also found significant and sustained functional and quality-of-life improvements, with the heart failure symptoms of most patients (90.0 percent) improving at least one class at one year (as measured by NYHA Class), and quality-of-life scores improving 27.4 points at one year (as measured by the KCCQ 100-point scale, in which a 20-point change is considered highly significant).

Overall hemodynamic (blood flow) performance was strong with mean gradients (resistance) of 8.5 mmHg at one month and 8.8 mmHg at one year, similar to the gold standard surgical valves. Paravalvular leak (PVL) rates were low and improved over time with only 11.5 percent of patients having more than mild PVL at one month, which improved to only 4.1 percent at one year. Notably, more than 80 percent of patients with moderate PVL at one month had a reduction in the severity of PVL by one year, an improvement that has not been reported in other major transcatheter aortic valve replacement (TAVR) trials. Furthermore, CoreValve patients with moderate PVL had no greater mortality risk than patients with less PVL.

Major vascular complication rates were low: 8.3 percent at one month and 8.5 percent at one year. Consistent with previous studies on self-expanding technology, the permanent pacemaker rate was 22.2 percent at one month and, importantly, pacemaker implants were not associated with mortality for these patients.

"In the recent past, these patients had no good treatment option and a 50 percent chance of death at one year. Along with the clinical community, we are very encouraged by the results in this rigorously conducted Trial and look forward to continuing our effort to bring this transformational therapy to patients with life-threatening aortic valve disease in the United States," said John Liddicoat, M.D., senior vice president, Medtronic, and president of the Medtronic Structural Heart Business. "In particular we wish to commend the 40 enrolling sites and their heart

teams for their exceptional commitment to patients and for the meticulous conduct of this Trial."

In the study, 471 patients were treated with the CoreValve System, a self-expanding, low 18Fr profile system with three valve sizes (26mm, 29mm, 31mm) delivered via the femoral artery. Patients were monitored by independent core labs and evaluated against a performance goal developed in partnership with the U.S. Food and Drug Administration. In the CoreValve Continued Access Study, 830 extreme risk patients have been treated with CoreValve System.