Medtronic News

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

(Thomson Reuters ONE via COMTEX) --- 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

SAN FRANCISCO and MINNEAPOLIS - Oct. 29, 2013 - Medtronic, Inc. (NYSE: MDT) 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.

Update on FDA Review

The FDA has determined it will conduct separate reviews for the Trial's Extreme Risk and High Risk studies. Upon reviewing the CoreValve Trial's results for extreme risk patients, the FDA has determined it has sufficient information to evaluate the safety and efficacy of the Medtronic CoreValve System for this patient group without the need for an external expert panel.

The Company anticipates receiving FDA approval of Core Valve System for extreme risk patients by the end of its fiscal year 2014.

Approximately 300,000 people worldwide suffer from severe aortic stenosis, including one-third who are ineligible for open-heart surgery because they are deemed at too high risk.[1]Since receiving CE (Conformite Europeenne) Mark in 2007, the CoreValve System has been implanted in more than 45,000 patients in more than 60 countries. The CoreValve System currently is not approved for commercial use in the United States.

The Company will webcast an Investor Briefing later today, where Medtronic management will review these clinical results. The live audio webcast of the presentation can be accessed beginning at 4:00 p.m. PDT by clicking on the Investors link on the Medtronic home page at http://www.medtronic.com. Within 24 hours of the webcast, a replay will be available under the Events and Presentations page in the Investors section of the Medtronic website. This event is not part of the official TCT Annual Scientific Session.

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.

Multimedia Release

A multimedia version of this release, with downloadable graphics, can be found at: http://bit.ly/1dhTr1S

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]Iung B, Cachier A, Baron G, et al. Decision-making in elderly patients with severe aortic stenosis: Why are so many denied surgery? Eur Heart J. 2003;26:2714-2720.

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