Medtronic News

Medtronic Revises Design ofCoreValve(R) U.S. Pivotal Trial

Inoperable Patients Will Be Evaluated in Single Arm Study, Not Randomized to Medical Management

MINNEAPOLIS, Jan 18, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced it has received conditional approval from the U.S. Food and Drug Administration (FDA) to modify its CoreValve U.S. Pivotal Clinical Trial. In the revised design, the trial will assess the CoreValve System in extreme risk (i.e. inoperable) patients in a single arm study with a primary endpoint of all-cause death or major stroke within 12 months. Furthermore, the revision includes the evaluation of alternate implantation routes for delivering the transcatheter valve, such as the subclavian approach.

The Medtronic CoreValve U.S. Trial includes two studies in different patient populations: one study of patients diagnosed as high risk for aortic valve surgery, and a second study of patients diagnosed as extreme risk. In the revised trial design, patients deemed at extreme risk will not be randomized to optimal medical management, where outcomes for these patients have been shown to be significantly worse than those treated with transcatheter valves. Rather, this patient group will be evaluated against a performance goal derived from contemporary studies. As previously planned, patients in the high risk group will be randomized one-to-one to either transcatheter aortic valve implantation (TAVI) with CoreValve or to surgical aortic valve replacement (SAVR).

Importantly, the modified trial will now include the assessment of alternative implantation routes, including the subclavian approach, in both patient populations. Transcatheter aortic valves traditionally are delivered through the femoral artery in the groin. These alternative routes will allow patients with poor peripheral vasculature (blood vessels) to be considered for treatment, thereby expanding the potential patient population.

"For some patients, transfemoral access simply is not feasible due to vessel size or impairment. Studying these patients will provide meaningful experience and data on the use of CoreValve via alternate access routes," said David H. Adams, M.D., chair of the Department of Cardiothoracic Surgery at The Mount Sinai Medical Center and national co-principal investigator of the CoreValve U.S. clinical trial.

The first implants in the Medtronic CoreValve U.S. Pivotal Clinical Trial occurred last month. Overall, the trial will enroll more than 1,300 patients at 40 U.S. clinical sites which are identified on www.clinicaltrials.gov. Additional information for patients and referring physicians can be found at www.aorticstenosistrial.com.

"We have taken extensive input from the medical community, our investigators and the FDA, and we are very pleased to proceed with modifications to the trial design based on these discussions," said John Liddicoat, M.D., vice president and general manager of the Structural Heart division at Medtronic.

The CoreValve System is designed to provide a minimally invasive, non-surgical treatment option for patients with symptomatic, severe aortic stenosis who are at high risk, or are ineligible, for open-heart surgery. Worldwide, approximately 300,000 people have been diagnosed with this condition, and approximately one-third of these patients are deemed at too high a risk for open-heart surgery,1 the only therapy with significant clinical effect that is currently available in the U.S. The Medtronic CoreValve System is not yet commercially available in the U.S.

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.

1*Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery?* Bernard Iung et al. Eur Heart J (December 2005) 26(24): 2714-2720.

SOURCE: Medtronic, Inc.

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