Medtronic News

Medtronic Unveils Baseline Data Of Extreme Risk Patients Enrolled In CoreValve® U.S. Pivotal Trial

(Thomson Reuters ONE via COMTEX) --Study Presents Comprehensive Dataset of Patient Characteristics

Collected on Extreme Risk TAVR Patients

VANCOUVER - June 14, 2013 - Medtronic, Inc. (NYSE: MDT) today presented baseline characteristics of patients enrolled in the Extreme Risk Study of the Medtronic CoreValve U.S. Pivotal Trial at the Transcatheter Valve Therapies (TVT) conference. The study was designed to evaluate the outcomes of patients unsuitable for conventional aortic valve surgery who underwent treatment with the CoreValve® transcatheter aortic valve replacement (TAVR).

The Extreme Risk Study enrolled 487 elderly patients who underwent extensive demographic evaluation including assessment of co-morbidities, frailty and disability, and identified a very ill group of patients who were unsuitable for conventional surgery. To be included in the study, patients were required to have a diagnosis of severe symptomatic aortic stenosis measured by hemodynamic (blood flow) assessments and New York Heart Association Class assignment, and a predicted mortality or irreversible morbidity >= 50 percent at 30 days.

Surgical risk was assessed by the clinical site Heart Teams composed of interventional cardiologists and cardiac surgeons at 40 clinical sites, and confirmed by a national committee of cardiac surgeons and interventional cardiologists. The study reported that patients treated with TAVR using an iliofemoral approach had a high frequency of medical co-morbidities including coronary artery disease (82.1 percent), peripheral vascular disease (35.7 percent), previous myocardial infarction (31.2 percent) and severe STS Chronic Lung Disease (24.6 percent). In addition, the patients in the Extreme Risk Study were extremely frail, as assessed by severe (Score 5) Charlson Score Co-Morbidity (a frailty index) (58.3 percent), and had a low body mass index (7.4 percent less than 21 kg/m2), poor grip strength (67.4 percent) and dependence on home oxygen (30.8 percent).

Patients in the Extreme Risk Study will be evaluated against a performance goal derived from contemporary studies. The primary endpoint data from the Extreme Risk Study will be presented later this year at the Transcatheter Cardiovascular Therapeutics (TCT) 2013 Meeting.

Since receiving CE (Conformite Europeenne) Mark in 2007, the CoreValve System has been implanted in more than 40,000 patients in more than 60 countries. The CoreValve System currently is not approved for commercial use in the United States.

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, 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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Contacts:

Kathleen Janasz

Public Relations

+1-763-526-3676

Jeff Warren

Investor Relations

+1-763-505-2696

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