Medtronic News

Medtronic Completes Enrollment of Extreme Risk Patient Group in CoreValve(R) U.S. Pivotal Trial

CoreValve U.S. Trial to Continue Enrolling Patients in High Risk Study, and Will Maintain Therapy Access to Extreme Risk Patients via Continued Access Phase of Trial

MINNEAPOLIS, Jan 24, 2012 (BUSINESS WIRE) --Medtronic, Inc. (NYSE: MDT) today announced it has completed patient enrollment in the extreme risk study in its CoreValve U.S. Pivotal Trial. The company also received approval from the U.S. Food and Drug Administration (FDA) for an extended investigation (under the FDA's Continued Access Policy) to continue enrolling extreme risk patients under a Continued Access Study protocol. In the Trial's second study evaluating high risk patients for aortic valve surgery, enrollment completion is anticipated later this year.

The CoreValve U.S. Trial is evaluating the self-expanding CoreValve System in three sizes (26mm, 29mm and 31mm) and using three delivery access routes: through the transfemoral artery in the upper leg, through the subclavian artery beneath the collar bone, and directly through the aorta via a commonly-used, minimally invasive surgical incision that does not penetrate the heart's ventricular wall.

"The CoreValve Trial investigators are very encouraged by our experience using the investigative CoreValve system to treat patients with severe aortic stenosis, and we are eager to fulfill the requirements of the Trial in hopes of offering the valve to more patients in the future," 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. "With its varying sizes and vascular access routes, the CoreValve System provides flexibility that we hope will accommodate most patients' anatomical circumstances."

Overall, the trial is enrolling more than 1,500 patients in 45 U.S. clinical sites, with approximately two-thirds of patients in the high risk study. Patients in the extreme risk study are being evaluated against a performance goal derived from contemporary studies. Patients in the high risk group are being randomized one-to-one to either transcatheter aortic valve implantation with the CoreValve System, or to surgical aortic valve replacement.

"Medtronic is very pleased with our investigators' enrollment progress and with the clinical community's enthusiasm for the CoreValve U.S. Trial," said John Liddicoat, M.D., senior vice president, Medtronic, and president of the Medtronic Structural Heart Business.

The CoreValve System is designed to replace diseased aortic valves without 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 surgery1. Since 2007, the Medtronic CoreValve System has been implanted in more than 25,000 people in more than 50 countries outside the U.S.

Additional information about the U.S. trial is available onwww.clinicaltrials.gov and www.aorticstenosistrial.com.

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.

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Medtronic, Inc.
Kathleen Janasz, 763-526-3676
Public Relations
or
Jeff Warren, 763-505-2696
Investor Relations

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