Medtronic News

Landmark Medtronic CoreValve(R) U.S. Clinical Trial Begins

Investigational Therapy Offers Treatment Alternative to Open Heart-Surgery for Patients with Severe Aortic Stenosis

MINNEAPOLIS, Dec 21, 2010 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced the beginning of its Medtronic CoreValve(R) U.S. Pivotal clinical trial in the United States. The first CoreValve transcatheter aortic valve implantation (TAVI) procedure was performed by David H. Adams, M.D., and Samin K. Sharma, M.D., at The Mount Sinai Medical Center in New York City. The Medtronic CoreValve(R) System, a revolutionary treatment alternative to open-heart surgery for patients with severe aortic stenosis, will be investigated in more than 1,200 patients at up to 40 U.S. clinical trial sites. A second CoreValve case took place this week at El Camino Hospital in Mountain View, Calif.; St. Francis Hospital, The Heart Center in Roslyn, N.Y, also has been activated in the trial and is screening patients.

"Through this trial, we are investigating a minimally invasive, non-surgical alternative to open-heart surgery for valve replacement in patients with severe aortic stenosis," said Dr. Adams, who is chair of the Department of Cardiothoracic Surgery at Mount Sinai and is a national co-principal investigator of the CoreValve U.S. clinical trial. "This study will evaluate the safety and efficacy of the CoreValve system for use in the United States, where many thousands of patients are diagnosed with severe aortic stenosis every year."

The CoreValve System is designed with self-expandable technology to replace a diseased aortic valve percutaneously (through the skin), usually through the femoral artery, without open-heart surgery or surgical removal of the native valve. The CoreValve device is delivered through a controlled deployment delivery system.

"We are very excited with this first step in bringing this important transformational therapy to patients in the United States with life-threatening aortic valve disease, particularly those patients who have limited surgical options," said Jeffrey Popma, M.D., national co-principal investigator of the Medtronic CoreValve U.S. Pivotal Trial and director, Interventional Cardiology at the Beth Israel Deaconess Medical Center in Boston.

About Symptomatic Severe Aortic Valve Stenosis

Aortic stenosis is a condition where the aortic valve narrows, thereby limiting blood flow from the aorta to the rest of the body. Untreated, aortic valve stenosis can lead to serious heart problems including heart failure and even death.

Worldwide, approximately 300,000 people have been diagnosed with severe aortic stenosis (100,000 in the U.S.), 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 currently available in the United States.

About the Medtronic CoreValve U.S. Pivotal Clinical Trial

The Medtronic CoreValve System with the AccuTrak(TM) stability layer will be investigated in two independent studies, evaluating patients who have been deemed at high risk for aortic valve surgery, and those who have been deemed at extreme risk for aortic valve surgery (i.e. inoperable). Clinical sites across the U.S. will be identified on www.clinicaltrials.gov. For more information about the Medtronic CoreValve U.S. Clinical Trial, see 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 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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