Medtronic News

Study Provides Insight on Medtronic CoreValve(R) System Implants Through Subclavian Approach

New Access for Aortic Valve Replacement Achieves High Procedural Success in Italian Study of High Risk Patients

PARIS, May 19, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today issued a statement on results of clinical data presented at EuroPCR 2011 that show the Medtronic CoreValve(R) System, delivered through a new approach beneath the collarbone, achieved excellent procedural success rates and low in-hospital complication rates. The new approach, via subclavian access, received CE (Conformité Européenne) Mark in December and has been used primarily for people whose femoral arteries are too narrow or are compromised due to disease.

The multi-center study evaluated 132 consecutive subclavian patients in Italy and found positive patient outcomes, despite patients in the subclavian group being sicker than patients in the femoral access group (based on EuroSCORE and rates of peripheral artery disease, coronary artery disease, prior stroke and prior heart attacks). Procedural success was obtained in 97.7 percent of the subclavian group versus 96.3 percent of the transfemoral group, with intraprocedural mortality of 1.5 percent versus 1.8 percent, respectively. No serious complications were reported as a result of accessing the aortic valve through the subclavian artery. Freedom from cardiac death rates were almost identical (90.6 percent versus 90.4 percent, respectively), and freedom from major adverse cardiac event rates were 87.6 percent for the subclavian group versus 86.3 percent for the femoral group.

"The subclavian approach is a feasible and safe option for TAVI, providing excellent procedural success and low in-hospital complication rates," said Sonia Petronio, M.D., associate professor of Cardiology and Head of the Catheterization Lab of the Azienda Ospedaliero-Universitaria Pisana, Pisa, Italy. "In our opinion, this approach should be considered a valid alternative not only in patients with the impossibility of a femoral approach, but also in patients with a difficult femoral approach with high risk of vascular complications."

CoreValve is the only TAVI therapy available for subclavian access. It is designed to provide a non-surgical valve replacement option for patients with severe aortic stenosis who are at high or prohibitive risk for open-heart surgery. While transcatheter valves typically are implanted through the femoral artery in the leg, there are thousands of people whose femoral arteries are too narrow or are compromised due to disease, and the subclavian approach originally was designed to give this underserved subset of patients access to care. The data presented today demonstrate that physicians may consider TAVI therapy for a broader group of patients.

Worldwide, approximately 300,000 people have been diagnosed with severe aortic stenosis, 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 40 countries outside the U.S. The Medtronic CoreValve System is currently limited to investigational use in the United States, and the subclavian approach is being evaluated in the Medtronic CoreValve U.S. Pivotal Trial.

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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