Medtronic News

Medtronic CoreValve(R) System Gains CE Mark for New Direct Aortic Approach to Transcatheter Aortic Valve Implantation

New Access Will Expand Treatment Options for Patients with Severe Aortic Stenosis

MINNEAPOLIS, Nov 07, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced it has received CE (*Conformité Européenne*) Mark for the Medtronic CoreValve(R) System to be delivered using direct aortic access. The Medtronic CoreValve System is now the only transcatheter aortic valve implantation (TAVI) system approved for direct aortic and subclavian implantation. The Medtronic CoreValve System is currently limited to investigational use in the United States.

"For patients at high risk for surgery, transcatheter aortic valve implantation has become an established alternative for aortic valve replacement, yet we have found that some patients are considered unsuitable because of small vessel size," said Giuseppe Bruschi, M.D., cardiac surgeon at A De Gasperis Cardiology & Cardiac Surgery Department, Niguarda Ca' Granda Hospital, Milan, Italy. "For these patients, the direct aortic approach provides a minimally-invasive surgical option."

This new approach will provide severe aortic stenosis patients with a viable treatment alternative to the transfemoral (in the upper leg), transapical (through the wall of the heart), and subclavian artery (beneath the collar bone) approaches used by TAVI practitioners. In the procedure, physicians replace the diseased valve through a minimally invasive incision without stopping the heart or penetrating the heart's ventricular wall. Early evaluations have shown the direct aortic approach demonstrates high procedural success rates and high overall survival rates that are similar to those from transfemoral and subclavian approaches. The new approach also may allow for easier manipulation and positioning of the valve due to the short distance from access site to implantation site.

"The direct aortic approach gives heart teams a new, minimally-invasive option as they seek to customize care for their patients," said John Liddicoat, senior vice president of Medtronic and president of the Medtronic Structural Heart Business. "The CoreValve System is now available in three sizes (26mm, 29mm and 31mm) via three access routes, all based on the System's original self-expanding platform that received CE Mark in 2007."

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 20,000 people in more than 50 countries.

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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