Medtronic News

First Results from Medtronic Engager European Pivotal Trial Demonstrate Positive Outcomes

Data Demonstrate High Procedural Success in Late-Breaking Trials Session at the European Association for Cardio-Thoracic Surgery Annual Meeting

MINNEAPOLIS - October 29, 2012 - Medtronic, Inc. (NYSE: MDT) today announced promising data from the EngagerTM European Pivotal Trial for the investigational Medtronic EngagerTM Transcatheter Aortic Valve Implantation (TAVI) System. The first results from the multi-center trial support the safety and clinical performance of the valve, which uses a transapical delivery approach to treat patients with severe aortic stenosis who were at high or extreme risk for surgical aortic valve replacement (SAVR).

The positive clinical outcomes, presented during a late-breaking trials session at the European Association for Cardio-Thoracic Surgery (EACTS) Annual Meeting, revealed that the Engager system was deployed in the anatomically correct position in all 60 patients. The Engager valve demonstrated strong hemodynamic performance with low transvalvular gradients, and no patients experienced greater than trace paravalvular leak at 30 days as measured by an independent echocardiography core lab. There were no procedures requiring a second valve, and no occurrences of valve embolization, coronary obstruction or device malposition. The 30-day all-cause mortality rate was 9.9 percent, the cardiovascular mortality rate was 8.3 percent, and the incidence of stroke was 1.8 percent.

"Results from the European Pivotal Study indicate that the Engager valve's design facilitates precise positioning and reduces paravalvular regurgitation, improving two of the most important clinical challenges faced in transcatheter aortic valve implantation. The Engager valve is a valuable new technology and will allow heart teams to meet the varying needs of patients with severe aortic stenosis," said Hendrik Treede, M.D., Engager Pivotal Trial investigator, University Heart Center Hamburg in Hamburg, Germany.

The Engager transapical valve is designed for minimally-invasive delivery via a catheter inserted in the apex (the lower, pointed end) of the heart. The valve is comprised of bovine tissue leaflets and a self-expanding nitinol frame designed to aid in valve positioning. The valve also is designed to promote annular sealing to minimize paravalvular leak, and to provide anatomical alignment with the coronary arteries.

"We are very pleased with these 30-day results from the Engager system," said John Liddicoat, M.D., senior vice president, Medtronic, and president of the Medtronic Structural Heart Business. "The Engager system is a key component of Medtronic's approach to bring heart teams a portfolio of transcatheter valve solutions that consistently delivers optimum fit, deliverability and performance to meet the diverse needs of their patients."

The Engager valve is not available for use outside this Pivotal Trial and is currently being reviewed for Conformité Européenne (CE) Mark in Europe.

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.

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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