Medtronic News

Medtronic Announces CE Mark for Engager(TM) Transcatheter Valve

New Valve Provides Transapical Option for Physicians Treating Patients with Aortic Stenosis

MINNEAPOLIS - February 28, 2013 - Medtronic, Inc. (NYSE: MDT) today announced CE (Conformité Européenne) Mark of the Engager Transcatheter Aortic Valve Implantation (TAVI) System with transapical delivery catheter to treat patients with severe aortic stenosis who are at high or extreme risk for surgical aortic valve replacement (SAVR).

The new valve demonstrated positive clinical outcomes in its European Pivotal Trial. Results from the multi-center trial, which were presented during late-breaking trial sessions at the recent European Association for Cardio-Thoracic Surgery and the Society of Thoracic Surgeons annual meetings, revealed high rates of procedural success, minimal paravalvular leak (PVL) and continuing clinical benefits for patients over time.

In the Trial, the Engager valve was delivered transapically and had 94.3 percent overall device success (according to Valve Academic Research Consortium modified definitions). There were no procedures requiring a second valve and no occurrences of valve embolization, coronary obstruction or device malposition. No patients had moderate or severe PVL at six months, as measured by an independent echocardiography core lab. In addition, while most patients (88 percent) were NYHA Class III or IV at baseline, at six months 82 percent of patients had improved to NYHA Class I or II.

"The Engager valve has demonstrated exceptional clinical results, and by adding it to our transcatheter valve portfolio, we are providing heart teams with more options for achieving the best outcomes for every patient with severe aortic stenosis," said John Liddicoat, M.D., senior vice president of Medtronic and president of the Medtronic Structural Heart Business.

The Medtronic Engager System is not available in the United States.

The Engager valve uses a minimally-invasive delivery system 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 promote annular sealing to minimize paravalvular leak. Control arms simplify implantation, and the supra-annular valve positioning facilitates leaflet coaptation (connections) in non-circular anatomy for optimal hemodynamic performance. A direct aortic delivery system for Engager will be introduced in the future.

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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