Medtronic News

Medtronic Announces Start of Pivotal Trial for EngagerTM Transcatheter Aortic Valve Implantation System

Study will evaluate new therapy option for patients suffering from valvular heart disease

MINNEAPOLIS, Sep 27, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced the start of the Engager(TM) European Pivotal Trial to pursue CE (Conformité Européenne) Mark for the Engager Transcatheter Aortic Valve Implantation System in patients suffering from severe aortic stenosis. The 150-person trial will be conducted at 11 centers in Germany, Israel, France, Belgium and Switzerland, and will evaluate the safety and clinical performance of the new valve and delivery system.

The Engager therapy is designed for minimally-invasive delivery via a catheter inserted in the apex (the lower, pointed end) of the heart. Engager is intended to give physicians a "transapical valve" therapy option to meet the varying needs of patients with severe aortic stenosis.

"There is a distinct need for more minimally-invasive therapies that provide direct access to the diseased aortic valve," said John Liddicoat, M.D., senior vice president, Medtronic, and president of the Medtronic Structural Heart Business. "Transapical valve delivery can be a valuable alternative for cardiac surgeons, who will want to consider various approaches for patients who are at high risk for open-heart surgery or patients suffering from conditions - such as peripheral artery disease - that can make other transcatheter procedures less suitable."

First implants in the pivotal trial were performed by Hendrik Treede, M.D., Lenard Conradi, M.D., and Prof. Stephan Baldus, M.D., of University Medical Center Hamburg-Eppendorf in Hamburg, Germany, and by Prof. Rüdiger Lange, M.D., Ph.D., and Sabine Bleiziffer, M.D., of The German Heart Centre in Munich, Germany.

The Engager transapical valve is comprised of bovine tissue leaflets and a self-expanding nitinol frame designed to facilitate accurate positioning and stability when implanted. Once approved, the valve will become a key component of Medtronic's portfolio of transcatheter valve solutions to meet diverse patient medical needs. The Engager System was evaluated successfully in Europe in a feasibility trial earlier this year. Medtronic obtained the Engager valve through its acquisition of Ventor Technologies Ltd. in February 2009. The Engager valve is not available for use outside this Pivotal Trial.

Worldwide, approximately 300,000 people have been diagnosed with symptomatic, severe aortic stenosis, and approximately one-third of these patients are deemed at too high a risk for open-heart surgery.1 Aortic stenosis prevents the valve from opening completely, thereby preventing healthy blood flow from the aorta to the rest of the body; untreated, aortic stenosis can lead to serious heart problems including heart failure and even death.

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.

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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