Medtronic News

# Medtronic Begins Global Clinical Study of Investigational Pericardial Surgical Aortic Heart Valve

MINNEAPOLIS - October 28, 2014 - Medtronic, Inc. (NYSE: MDT) today announced it has initiated the PERIGON (PERIcardial SurGical AOrtic Valve ReplacemeNt) Pivotal Trial, a global, prospective clinical trial evaluating an investigational surgical aortic heart valve made from bovine pericardial (cow heart) tissue that is intended to replace a diseased, damaged or malfunctioning native or prosthetic aortic valve. The valve was recently implanted in the first U.S. patient at the ProMedica Toledo Hospital in Toledo, Ohio. The investigational surgical aortic heart valve currently is only available for investigational use in the United States.

Designed with a low profile and interior-mounted leaflets (which allow the passage of blood through the heart) to help lessen the risk of coronary obstruction, the new aortic valve will be evaluated in the trial for its ease of implantation, durability and hemodynamic performance (blood flow). In addition to replacing a diseased native aortic valve, the next-generation valve also is designed to allow for future transcatheter aortic valve-in-valve interventions.

"I am thrilled to be the first physician in the U.S. to implant this innovative pericardial heart valve for patients with aortic stenosis. Based on my involvement in the trial, the valve's new design makes it easy to implant, which may offer important advantages critical to long-term patient outcomes," said Michael Moront, M.D., FACS, cardiovascular surgeon at the ProMedica Toledo Hospital in Toledo, Ohio. "We look forward to confirming this through the results from this trial."

Worldwide, approximately 300,000 people have been diagnosed with severe aortic stenosis or narrowing of the valve,1 which restricts blood flow to the body. The newly designed heart valve is the latest advancement in Medtronic's portfolio of surgical aortic valves and represents the company's continued commitment over more than 20 years to deliver aortic valve technologies to meet the varied needs of patients.

"As a global leader in surgical and transcatheter aortic valve technologies, Medtronic looks forward to gathering clinical insights about our newest heart valve," said Rhonda Robb, vice president and general manager of Heart Valve Therapies at Medtronic. "We are pleased with the progress of the trial thus far and the overall reception to this next-generation aortic valve."

The PERIGON Trial will study up to 650 patients at up to 40 sites in Europe, the U.S. and Canada.

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. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

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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1 Iung B, Cachier A, Baron G, et al. Decision-making in elderly patients with severe aortic stenosis: why are so many denied

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