Medtronic News

Medtronic Gains First FDA Approval to Conduct Early Feasibility Medical Device Study

Shared Commitment to Innovation Enables Early Study of Novel Native Outflow Tract Transcatheter Pulmonary Valve in Patients with Pulmonary Valve Failure

MINNEAPOLIS - February 26, 2013 - Medtronic, Inc. (NYSE: MDT) today announced that it has received U.S. Food and Drug Administration (FDA) approval to conduct an early feasibility study using the Medtronic Native Outflow Tract Transcatheter Pulmonary Valve (TPV). This approval represents the first-ever FDA approval of an investigational device exemption (IDE) following the new draft FDA guidance for early feasibility studies.

"The approval of this study is an excellent example of how the FDA and manufacturers can work together to advance medical innovation by studying initial device design and functionality, with the long-term goal of delivering novel therapies to patients in need," said John Liddicoat, M.D., senior vice president of Medtronic and president of the Medtronic Structural Heart Business. "In this case, the early feasibility study will help us develop a minimally invasive therapy for patients whose only current treatment option is open-heart surgery."

The Native Outflow Tract TPV is a minimally invasive therapy for patients with congenital heart disease who don't have a right ventricle-to-pulmonary artery conduit, and need a pulmonary valve to maintain adequate blood flow from the right ventricle and the pulmonary artery. Delivered in a minimally invasive procedure using a catheter (small tube) funneled through the veins, the valve is designed to restore pulmonary valve competency without invasive open-heart surgery.

The intent of the FDA's draft guidance, "Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, including First in Human (FIH) Studies," is to foster early-stage development of medical devices within the U.S. It is a new approach to clinical studies conducted in the early stages of development, and is designed to facilitate early clinical experience with investigational medical devices to reach patients sooner and create incentives to innovate in the United States.

This new approach is intended to allow studies to start earlier in the device development process than previously allowed, while still providing appropriate human subject protections. It also permits sponsors (manufacturers) and FDA device reviewers more flexibility to make device modifications once the study begins.

The Medtronic early feasibility study will evaluate the design, procedural success and initial performance of the Native Outflow Tract TPV to enable further development of the device prior to conducting an additional clinical study.

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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