Medtronic News

Medtronic Receives FDA Approval for Less-Invasive Heart Pump Implant Procedure

(GLOBE NEWSWIRE via COMTEX) --HeartWare(TM) HVAD(TM) System Only LVAD Approved for Implant via Thoracotomy or Median Sternotomy

DUBLIN - July 11, 2018 - Medtronic plc (NYSE: MDT) has received United States Food and Drug Administration (FDA) approval for a less-invasive implant approach of its HVAD(TM) System, a left ventricular assist device (LVAD) for patients with advanced heart failure. The HVAD System is the smallest commercially available LVAD, and the only LVAD approved in the U.S. for implant via thoracotomy, a small lateral, surgical incision between the patient's ribs on the left side of the chest.

LVADs help the heart pump and increase the amount of blood that flows through the body. They are typically implanted via median sternotomy, a surgical procedure in which a vertical incision is made down the middle of the chest, after which the sternum (or breastbone) is divided.

FDA approval for HVAD implantation via thoracotomy is based on data from the LATERAL prospective clinical trial, in which 144 patients, with end-stage heart failure who were eligible for heart transplant, were enrolled at 26 centers in the U.S. and Canada. The primary endpoint of the trial demonstrated non-inferiority of the HVAD implanted in patients via thoracotomy, where survival at six months free from disabling stroke or device explant or exchange due to malfunction was achieved in 88.1 percent of patients. Since the success outcome exceeded the pre-specified performance goal of 77.5 percent, the trial achieved its primary endpoint ($p=0.0012$). The key secondary endpoint revealed a significant reduction in total length of hospital stay, from an average of 26.1 days down to 18 days ($p<0.001$). Overall survival among patients receiving an HVAD via the thoracotomy procedure was 88.8 percent at one year. Detailed outcomes of the LATERAL trial and its secondary endpoints were presented at The International Society for Heart and Lung Transplantation (ISHLT) 2018 Scientific Sessions.

"We have demonstrated that a thoracotomy is a safe and effective implant technique for the HVAD System, which gives physicians added flexibility in treating a broad range of patients," said Edwin McGee, Jr., M.D., professor and director, Heart Transplant & Ventricular Assist Device Program, Loyola University Medical Center, Maywood, Ill., and principal investigator of the LATERAL trial. "Implanting the HVAD via thoracotomy preserves the chest for a subsequent procedure that patients may need, such as a heart transplant. It also has been shown to result in shorter hospital stays."

The HVAD System is the only LVAD approved in the U.S. and Europe for implant via a thoracotomy as well as a median sternotomy. It is approved to treat patients with advanced, refractory heart failure as a bridge to cardiac transplantation and as destination therapy in patients for whom subsequent transplantation is not planned.

In addition to this approval, new surgical implant tools tailored to assist physicians with the thoracotomy approach for the HVAD System are now available in the U.S. and in CE Marked countries.

"The thoracotomy approach showed significant improvements in patients' quality of life and functional capacity, supported by strong safety and effectiveness data from the study," said David Steinhaus, M.D., vice president and general manager of the Heart Failure business, which is part of the Cardiac and Vascular Group at Medtronic. "Further, the added flexibility for implant approach offers a unique advantage of the HVAD System."

The Medtronic portfolio of therapies, diagnostic tools and services for patients suffering from heart failure includes CRT devices, including MR-conditional CRT-Ds and CRT-Ps; mechanical circulatory support therapy for advanced heart failure patients; heart failure diagnostics; and meaningful expert analysis through Medtronic Care Management Services.

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 of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

_ Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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