Medtronic News

Medtronic First to Receive European Approval for Less-Invasive HVAD® Implant Procedure

New Implant Option Gives Physicians Surgical Alternative for Patients with Advanced Heart Failure

DUBLIN - Nov. 29, 2016 - Medtronic plc (NYSE: MDT) today announced that its HVAD® System left ventricular assist device (LVAD) received CE (Conformité Européenne) Mark for a less-invasive implant procedure in patients with advanced heart failure. The HVAD System is the only centrifugal LVAD approved in the European Union for implantation via this new thoracotomy procedure.

Compared to the standard LVAD surgical implant technique, the new approach uses a smaller incision1,2, potentially lessens surgical bleeding1,3 and related blood transfusions1, potentially reduces the development of right heart failure1,4 and may result in shorter hospital stays5. The thoracotomy implantation technique may allow the area around the heart to remain largely intact, potentially preserving the sternum for future procedures or a heart transplant.1

"The HVAD System's small size makes it well-suited for routine thoracotomy implantation," said Jan Schmitto, M.D., Ph.D., director of the Mechanical Circulatory Support Program and cardiothoracic surgeon at Hannover Medical School, Hannover, Germany, which helped pioneer the new procedure. "This less-invasive implant procedure potentially enables faster patient recovery compared to the traditional approach, which may help improve patient outcomes."

The HVAD System features the HVAD® Pump, which is smaller than other commercially available devices, and which more easily enables implantation through a small, lateral thoracotomy incision between a patient's ribs on the left side of the chest.

"The HVAD System is the only full-support, centrifugal LVAD approved in Europe for thoracotomy implantation, providing clinicians with greater freedom to choose the best surgical technique for each patient," said David Steinhaus, M.D., vice president and general manager of the Heart Failure business, and medical director of the Cardiac Rhythm and Heart Failure division at Medtronic. "CE Mark for the thoracotomy procedure is a testament to the HVAD System's flexibility and versatility, and may enable more patients to receive the life-sustaining benefit of the device for the treatment of advanced heart failure."

A study of the thoracotomy HVAD procedure is underway in Canada and the U.S., where the implant procedure currently is not approved. The LATERAL(TM) Study is the largest prospective clinical trial of a full-support ventricular assist device (VAD) to evaluate this implant technique. The study includes patients with end-stage heart failure who have not responded to standard medical management and who are eligible for heart transplantation.

The HVAD System features the world's smallest, full-support centrifugal circulatory assist device, the HVAD Pump, which is designed to be implanted next to the heart in the pericardial space. The HVAD System received CE Mark in the European Union in 2009, and was approved by the U.S. Food and Drug Administration in 2012 as a bridge to cardiac transplantation for patients who are at risk of death from refractory end-stage left ventricular heart failure. Today, more than 11,000 patients with advanced heart failure have received the HVAD System.

The Medtronic heart failure portfolio includes leading cardiac resynchronization therapies, including the first MR-conditional CRT-defibrillators in the U.S., mechanical circulatory support therapy and impactful heart failure

diagnostics and expert analysis through Medtronic Care Management Services.

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 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 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.

-end-

---

1 Schmitto, J. Implantation of a centrifugal pump as a left ventricular assist device through a novel, minimized approach: Upper hemisternotomy combined with anterolateral thoracotomy. *J Thorac Cardiovasc Surg* 2012;143:511-513

2 Deuse, T. and Reichenspurner, H. Do Not Touch the Sternum-Thoracotomy Incisions for HVAD Implantation. *ASAIO Journal* 2014;60:234-236

3 Popov, AR. HeartWare left ventricular assist device implantation through bilateral anterior thoracotomy. *Ann Thorac Surg* 2012;93:674-6

4 Meyer, AL.Minimal-invasive LVAD implantation, is it safe or even better? *J Heart Lung Transplant* 2013;32

5 Rojas, S. Chronic ventricular assist device support: surgical innovation. *Curr Opin Cardiol* 2016;31:308-213

Contacts:
Hailee Tellier
Public Relations
+1-508-361-6722

Ryan Weispfenning
Investor Relations
+1-763-505-4626
