Medtronic News

HeartWare Completes Enrollment In HVAD® System LATERAL Study™

- Clinical Trial Evaluates Less-Invasive Thoracotomy Implant Technique of the HVAD System in Patients with Advanced Heart Failure -

FRAMINGHAM, Mass., April 27, 2016 /PRNewswire/ -- HeartWare International, Inc. (NASDAQ: HTWR), a leading innovator of less-invasive, miniaturized circulatory support technologies that are revolutionizing the treatment of advanced heart failure, today announced completion of enrollment in the HeartWare® Ventricular Assist System (HVAD® System) LATERAL Study™.

LATERAL is a U.S. Investigational Device Exemption (IDE) prospective clinical trial designed to study the clinical outcomes of patients with end-stage heart failure who are awaiting a heart transplant, and are implanted with the HVAD® Pump through a less-invasive thoracotomy procedure.

Currently, commercially available ventricular assist devices (VADs) are approved by the U.S. Food and Drug Administration (FDA) for use with implantation via median sternotomy– a common approach in cardiac surgery that utilizes a vertical incision through the center of the patient's chest. The HVAD System features the HVAD Pump, which is smaller than other commercially available devices, which more easily enables implantation through a small, lateral thoracotomy incision between the patient's ribs on the left side of the chest.

"We are pleased to have completed enrollment in this important study, which has the potential to allow for easier, less-invasive implantation while leading to faster patient recovery than the traditional median sternotomy approach," said Ed McGee, M.D., head of the heart transplant and assist device program and a professor in the Department of Thoracic and Cardiovascular Surgery at Loyola University Stritch School of Medicine in Illinois, and a co-principal investigator for the HVAD LATERAL Study. "This less invasive surgical technique also benefits patients by delaying the need for full sternotomy until cardiac transplantation, enabling an easier surgical procedure at the time of transplant. We look forward to monitoring patients through the six-month follow-up period and then reviewing the trial results to help inform the medical community about the potential benefits of the thoracotomy implantation technique."

The first clinical trial of a full-support VAD using an implant technique other than sternotomy, the HVAD LATERAL Study is a prospective, multicenter, single-arm clinical trial that was designed to enroll up to 145 patients at more than 30 hospitals in North America. The study population includes patients with end-stage heart failure who have not responded to standard medical management and who are eligible for cardiac transplantation.

"This study will not only provide the medical community with clinical data on patient outcomes following implantation via thoracotomy, but it also will help to develop best practices for surgical implantation of the HVAD via a minimally invasive approach," said Anson Cheung, M.D., Surgical Director of the Cardiac Transplantation Program of British Columbia and Clinical Professor of Surgery at the University of British Columbia, Department of Surgery, Division of Cardiovascular Surgery and a co-principal investigator of the trial. "Clinical data from the LATERAL Study have the potential to confirm the observations from prior, single-center studies evaluating the thoracotomy technique and to help facilitate a discussion of innovative surgical implantation techniques to achieve optimal patient outcomes."

"The LATERAL study represents one of our key initiatives to leverage the versatility of the HVAD Pump's compact size into clinical benefits for the physician, patient and payer," said Doug Godshall, President and Chief Executive Officer at HeartWare. "We would like to thank the investigators, coordinators and entire heart team at each hospital site participating in this trial, as well as the cardiovascular surgeons for investing the resources necessary to learn and implement a new, promising surgical implant technique."

About the HeartWare® Ventricular Assist System

The HVAD System is HeartWare's flagship product and features the world's smallest full-support circulatory assist device, the HVAD Pump, which is designed to be implanted next to the heart, avoiding the abdominal surgery generally required to implant other devices. The HeartWare System received CE Marking 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. The device is also currently the subject of a U.S. clinical trial for destination therapy. Today, more than 10,000 patients with advanced heart failure in 47 countries around the world have received the HVAD System.

About HeartWare International

HeartWare International develops and manufactures miniaturized implantable heart pumps, or ventricular assist devices, to treat patients around the world suffering from advanced heart failure. Dedicated to developing new, minimally invasive technologies to revolutionize the treatment of patients with end-stage heart failure, HeartWare has multiple technologies in development to offer progressively less-invasive mechanical circulatory support options. HeartWare's corporate headquarters are located in Framingham, Massachusetts, and the company has technology, operations, manufacturing and distribution centers inMiami Lakes, Florida; Arden Hills, Minnesota; and Hannover, Germany. For additional information about the company, please visit www.heartware.com.

Forward-Looking Statements

This announcement contains forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to the: commercialization of the HeartWare HVAD System; timing, progress and outcomes of clinical trials; potential benefits of alternative implantation techniques; and regulatory submissions. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. HeartWare does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by federal securities laws and the rules and regulations of the Securities and Exchange Commission (SEC). HeartWare may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation those described in Part I, Item 1A. "Risk Factors" in HeartWare's Annual Report on Form 10-K filed with theSEC. HeartWare may update risk factors from time to time in Part II, Item 1A. "Risk Factors" in Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, or other filings with the SEC.

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