



HEARTWARE COMPLETES GLP STUDIES OF NEXT GENERATION MVAD[®] PUMP; DATA PRESENTED TODAY AT ISRBP CONGRESS

– Successful GLP study provides confidence to progress to human clinical trials –

Louisville, Kentucky, September 9, 2011 – Data presented today at the 19th Congress of the International Society for Rotary Blood Pumps (ISRBP) demonstrated that the HeartWare MVAD[®] Pump attained the objectives for system performance, hemocompatibility and biocompatibility in Good Laboratory Practice (GLP) animal studies, a significant step prior to commencement of human clinical studies.

HeartWare's MVAD Pump is a development-stage miniature ventricular assist device, approximately one-third the size of HeartWare's HVAD[®] Pump. The MVAD is based on the same proprietary impeller suspension technology used in the HVAD Pump, with its single moving part held in place through a combination of passive-magnetic and hydrodynamic forces. Like the HVAD Pump, the MVAD Pump is designed to support the heart's full cardiac output, yet also has the capability for partial support.

“The MVAD was successfully implanted via a left thoracotomy, without cardio-pulmonary bypass, and exhibited excellent blood handling characteristics during the course of the study,” said Edwin C. McGee, Jr., M.D., Surgical Director, Heart Failure, Heart Transplantation, and Mechanical Assistance; Bluhm Cardiovascular Institute, Northwestern Memorial Hospital and Associate Professor, Northwestern University's Feinberg School of Medicine, Chicago. “At the 90-day explant date, there was no evidence of device wear or thrombus, and end-organ gross and histological results were positive.”

“We're pleased with these results and are appreciative of the efforts of Dr. McGee and our investigators,” stated Doug Godshall, President and Chief Executive Officer of HeartWare International. “Based on these successful outcomes, we remain on track to commence human clinical studies of the MVAD System, with a newly designed controller, early next year. We look forward to exploring the potential of the MVAD Pump for both left and right ventricular support, as well as the potential to benefit smaller-sized patients or those with smaller hearts, including pediatric patients.”

- more -

About the MVAD System

The MVAD Pump is designed to require less invasive surgery than that required to implant currently available devices. In particular, the MVAD Pump is expected to be implanted without the need for a median sternotomy of the rib cage, as was demonstrated during the preclinical study presented today. By reducing the invasiveness of the surgery, HeartWare hopes to be able to treat a greater proportion of heart failure patients.

The MVAD Pump has been shown over a series of pre-clinical studies to have comparable blood flow characteristics to the Company's HVAD Pump.

More than 750 patients across Europe have received the HeartWare Ventricular Assist System, which features the HVAD Pump, a left ventricular assist device designed to provide circulatory support for patients in the advanced stage of heart failure. A proprietary continuous flow pump, the HVAD Pump is capable of delivering up to 10 litres of blood per minute and is designed to be implanted adjacent to the heart, avoiding the abdominal surgery generally required to implant similar devices.

Highlighting HVAD at ISRBP

“In addition to Dr. McGee’s presentation on the MVAD GLP studies, there were four other presentations on the HeartWare Ventricular Assist System. These highlighted many of the novel attributes of the HVAD platform such as wave form capabilities, flow estimation advances, self-regulating behavior and pump performance during exercise,” added Mr. Godshall. “The broad spectrum of presentations demonstrate both the Company’s technology leadership in mechanical circulatory support, which extends beyond the HVAD Pump, and also the breadth of HVAD System adoption outside the United States.”

About HeartWare International

HeartWare International, Inc. (NASDAQ: HTWR; ASX: HIN), develops and manufactures miniaturized implantable heart pumps, or ventricular assist devices, to treat Class IIIB / IV patients suffering from advanced heart failure. The HeartWare® Ventricular Assist System features the HVAD® Pump, a small full-output circulatory support device (up to 10L/min flow) designed to be implanted next to the heart, avoiding the abdominal surgery generally required to implant competing devices. HeartWare has received CE Marking for the HeartWare System in the European Union and TGA approval in Australia. The device is currently the subject of United States clinical trials for two indications: bridge-to-transplant and destination therapy. For additional information, please visit www.heartware.com.

HeartWare International, Inc. is a member of the Russell 2000® and its securities are publicly traded on The NASDAQ Stock Market and the Australian Securities Exchange.

HEARTWARE, HVAD, MVAD and HeartWare logos are registered trademarks of HeartWare, Inc.

- more -

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 timing and progress of, and presentation of data related to, clinical and preclinical trials, expected timing of regulatory filings and approvals, and research and development activities. 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. 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, the possibility the FDA does not approve the marketing of the HeartWare® Ventricular Assist System in the U.S., and those described in "Item 1A. Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission. We may update our risk factors from time to time in "Part II, Item 1A "Risk Factors" in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, or other filings with the Securities and Exchange Commission.

For further information:

Christopher Taylor
HeartWare International, Inc.
Email: ctaylor@heartwareinc.com
Phone: +1 508 739 0864

###