HeartWare Receives FDA Approval for HeartWare® Ventricular Assist System as a Bridge to Heart Transplantation for Patients with Advanced Heart Failure

– First full-support, miniaturized ventricular assist device approved in U.S designed to be placed in the pericardial space–

– HeartWare Management to Host Investor Conference Call Today at 3:00 pm ET –

Framingham, MA and Sydney, Australia, November 20, 2012 – HeartWare International, Inc. (Nasdaq: HTWR; ASX: HIN), a leading innovator of less invasive, miniaturized circulatory support technologies that are revolutionizing the treatment of advanced heart failure, today announced that it has received approval from the United States Food and Drug Administration (FDA) for the HeartWare® Ventricular Assist System as a bridge to heart transplantation in patients with end-stage heart failure.

The HeartWare® Ventricular Assist System features the HVAD® pump, a small full-support circulatory assist device (up to 10L/min flow) designed to be implanted next to the heart, avoiding the abdominal surgery generally required to implant competing devices. The HVAD pump, with sintered inflow cannula, weighs approximately 5 ounces and displaces a volume of approximately 50 milliliters. The HeartWare System is intended for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure.

The HeartWare System is currently the leading ventricular assist device implanted in patients outside of the United States, having received CE Marking in the European Union in 2009, and Australian Therapeutic Goods Administration (TGA) approval in 2011. Today, more than 2,500 advanced heart failure patients globally have received the HVAD® pump.

"FDA approval marks the culmination of an extensive clinical effort and represents an exciting advance in the treatment of late-stage heart failure patients," said Doug Godshall, President and Chief Executive Officer of HeartWare. "We wish to extend our most sincere thanks to the patients, and to their families, for participating in the study of this innovative device, and we also are grateful to each of the nurses, coordinators, surgeons and cardiologists who provided care to those patients."

Achieving long-standing goals

"I've had the opportunity to work on the HVAD® project since its conception over a decade ago. The goal was to develop a miniaturized device with an integrated inflow cannula that could be placed within the pericardial sac, avoiding the necessity of creating a pump pocket with its attendant infection risks, as well as simplifying the surgical insertion," stated O.H. "Bud" Frazier, MD; Chief, Center for Cardiac Support; Director, Cardiovascular Surgery Research; and Co-Director, Cullen Cardiovascular Research Laboratories, at Texas Heart Institute and a global pioneer in mechanical circulatory support. "A second goal was elimination of mechanical bearings to suspend the impeller, designed to enhance durability and blood handling characteristics. Those of us who treat these

challenging end-stage heart failure patients are fortunate to have this pericardial, wearless system available for our patients."

Commencing Commercialization

"Our team is positioned to commence the commercial rollout of the HeartWare System immediately, first facilitating broad use by the 50 U.S. hospitals that participated in our clinical studies, and then with training and expansion to additional U.S. hospitals," added Mr. Godshall. "As always, HeartWare remains committed to enhancing outcomes for patients with end-stage heart failure and we will continue working to improve the overall clinical experience with the HVAD."

HeartWare's pre-market approval (PMA) submission included data from the Company's pivotal ADVANCE clinical trial, an FDA approved Investigational Device Exemption (IDE) study designed to evaluate the HeartWare System as a bridge to heart transplantation for patients with end-stage heart failure. Under ADVANCE, 140 patients at 30 hospitals in the U.S. received the HeartWare investigational device between August 2008 and February 2010. The ADVANCE study achieved a 94% survival at 6 months and successfully met its primary endpoint of establishing non-inferiority between the investigational device and comparator arm of the study, which was derived from contemporaneous patients from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) [$p<0.0001$]. Four supplemental allotments of patients have been granted by the FDA under a Continued Access Protocol (CAP), encompassing more than 250 additional patients.

To help assure the continued safety and effectiveness of an approved device, FDA requires a post-approval study (PAS) as a condition of approval under 21 CFR 814.82(a)(2) to assess device performance in a real-world setting. HeartWare's PAS is a registry consisting of 600 patients who receive an HVAD and an additional 600 control patients derived from a contemporaneous group of continuous flow, intra-corporeal LVAD patients entered into the INTERMACS database. The data for both arms of the study will be entered into the INTERMACS registry by the implanting centers. Other post approval commitments include the transfer of patients from the ADVANCE IDE study into a post approval database as well as an obligation to continue training sites in accordance with an approved training program.

In other clinical development for the HeartWare Ventricular Assist System, HeartWare has completed enrollment of a 450-patient destination therapy study at 50 U.S. sites. The final patients were implanted in May 2012, with a two-year, primary endpoint follow-up period. HeartWare has requested a Continued Access Protocol allocation for destination therapy from the FDA.

Conference Call

HeartWare will host a conference call today at 3:00 p.m. U.S. Eastern Time to discuss approval of the HeartWare® Ventricular Assist System as a bridge to heart transplantation in patients with end-stage heart failure. The call may be accessed by dialing 1-855-235-2089 five minutes prior to the scheduled start time and referencing "HeartWare." For callers outside the U.S., please dial +1-778-327-3988.

A live webcast of the call will also be available at the Company's website (www.heartware.com) by selecting "HeartWare FDA Approval Conference Call" under the section titled "Corporate Presentations" on the Home Page. A replay of the conference call will be available through the above weblink immediately following completion of the call.

About HeartWare International

HeartWare International 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 designed to be implanted next to the heart, avoiding the abdominal surgery generally required to implant competing devices. The HeartWare System is approved in the United States for the intended use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure, and has received CE Marking in the European Union and has been used to treat patients in 27 international countries. The device is also currently the subject of a U.S. clinical trial for destination therapy. For additional information, please visit the Company's website at 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.

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 progress of clinical trials and post-approval studies, regulatory approvals, research and development activities and commercialization strategies. 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 those described in Part I, 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:

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