HEARTWARE RECEIVES CONDITIONAL FDA APPROVAL TO COMMENCE PIVOTAL DESTINATION THEORY CLINICAL TRIAL IN THE U.S.

Framingham, MA and Sydney, Australia, June 15, 2010 – 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 the U.S. Food and Drug Administration (FDA) has granted HeartWare conditional approval to begin enrollment in an Investigational Device Exemption (IDE) destination therapy clinical study for the HeartWare® Ventricular Assist System.

Designed to enroll up to 450 patients at 50 U.S. hospitals, the non-inferiority study, which is named “ENDURANCE,” is a randomized, controlled, unblinded, multi-center clinical trial to evaluate the use of the HeartWare Ventricular Assist System as a destination therapy in advanced heart failure patients. The study population will be selected from patients with end-stage heart failure who have not responded to standard medical management and who are ineligible for cardiac transplantation.

“Initiation of this destination therapy study is an important milestone toward our goal of expanding the universe of potential patients that could benefit from less invasive circulatory support systems,” said Doug Godshall, HeartWare President and Chief Executive Officer. “We have been gratified by the support received from all of the prestigious cardiac centers that have participated in our bridge-to-transplant trial and we believe that this study, the largest head-to-head VAD clinical trial to date, will be compelling for cardiologists, surgeons and end-stage heart failure patients.”

Patients in the study will be randomly selected to receive either the HeartWare Ventricular Assist System or, as part of a control group they will be implanted with any alternative LVAD approved by the FDA for destination therapy, in a 2:1 ratio. Each patient receiving the HeartWare Ventricular Assist System or control LVAD will be followed to the primary endpoint at two years, with a subsequent follow-up period extending to five years post implant.

The primary endpoint of the trial is stroke-free survival at two years, defined as alive on the originally implanted device, transplanted or explanted due to patient recovery. Secondary endpoints include adverse events such as bleeding and infection, as well as functional status, hospitalization, assessment of neuro-cognitive function and patient quality of life. There are three minor open questions raised by the FDA which are the ‘conditions’ to approval. Patient enrollment for the ENDURANCE study can commence immediately, subject to Institutional Review Board (IRB) approvals at trial centers.

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Principal Investigators for HeartWare’s ENDURANCE destination therapy study are Mariell Jessup, M.D., Professor of Medicine at the Hospital of the University of Pennsylvania and Francis Pagani, M.D., Ph.D., Surgical Director of the Adult Heart Transplant Program and Director of the Center of Circulatory Support, University of Michigan Medical Center.

“We are fortunate to welcome to the ENDURANCE study two of the most respected, progressive and widely published heart failure physicians in the U.S., Dr. Jessup and Dr. Pagani,” added Mr. Godshall.

In other clinical development initiatives, HeartWare reports that 17 centers have received IRB approval in the past 30 days for participation in the Continued Access Protocol (CAP) for the Company’s U.S. bridge-to-transplant study, making a total of 24 centers which are now able to participate. Since FDA approval of the CAP, 11 patients in the U.S. have been implanted. Enrollment in the bridge-to-transplant study concluded in February, with the six-month follow-up period for patients expected to be completed in August. HeartWare anticipates submission to the FDA of the PMA seeking approval of the HeartWare System for the bridge-to-transplant indication by year end.

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 (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. The device is currently the subject of United States clinical trials for two indications: bridge-to-transplant under a continued access protocol and 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. 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 "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, or other current reports, as filed with the Securities and Exchange Commission.

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