HEARTWARE RECEIVES SECOND PATIENT ALLOTMENT UNDER CONTINUED ACCESS PROTOCOL FOR PIVOTAL U.S. BRIDGE-TO-TRANSPLANT CLINICAL TRIAL

Framingham, MA and Sydney, Australia, September 4, 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 approved an IDE (Investigational Device Exemption) Supplement that allows HeartWare to enroll a second allotment of 54 patients in its "ADVANCE" bridge-to-transplant clinical trial under a Continued Access Protocol (CAP). The FDA granted an initial allotment of 54 patients in April 2010 and the final patient was implanted under the initial allotment in August 2010.

HeartWare's ADVANCE clinical trial is an FDA approved IDE study designed to evaluate the HeartWare® Ventricular Assist System as a bridge to heart transplantation for patients with end-stage heart failure. The primary endpoint of the trial is survival at 180-days, defined as alive on the originally implanted device or transplanted or explanted for recovery.

Under the ADVANCE study, 140 patients at 30 U.S. clinical sites received HeartWare HVAD® pumps, making it the largest bridge-to-transplant pivotal trial to date. The final implant in ADVANCE was performed in February 2010, and the last follow-up evaluation at 180-days was in August 2010. Results of the ADVANCE trial are scheduled to be announced as part of a Late-Breaking Clinical Trial session at American Heart Association's upcoming Scientific Sessions 2010 to be held in Chicago, November 13−17, 2010. HeartWare currently anticipates submission to the FDA of a PMA application seeking approval of the HeartWare System for the bridge-to-transplant indication in December of this year.

Patient enrollment under the second CAP can now commence at the 30 centers participating in the ADVANCE clinical trial, subject to Institutional Review Board approvals at these sites.

Destination Therapy

Separately, the FDA has granted HeartWare full approval for enrollment in its IDE destination therapy clinical trial for the HeartWare® Ventricular Assist System. In June 2010, the FDA granted HeartWare conditional approval to begin enrollment in the destination therapy study. 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, clinical trial to evaluate the use of the HeartWare Ventricular Assist System as a destination therapy in advanced heart failure patients.

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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 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, expected timing of FDA regulatory filings and expected timing of presentation of trial results. 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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