HEARTWARE RECEIVES FDA APPROVAL OF CONTINUED ACCESS PROTOCOL FOR PIVOTAL U.S. BRIDGE-TO-TRANSPLANT CLINICAL TRIAL

Framingham, MA and Sydney, Australia, April 7, 2010 – HeartWare International, Inc. (Nasdaq: HTWR; ASX: HIN), a leading innovator of less invasive, miniaturized circulatory support technologies 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 up to an additional 54 patients in its "ADVANCE" bridge-to-transplant clinical trial under a Continued Access Protocol (CAP).

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. 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.

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 conducted on February 25, 2010, which will result in the final patient reaching the 180-day follow up point by the end of August 2010.

Patient enrollment under the CAP can now commence at the 30 centers participating in the ADVANCE clinical trial, subject to Institutional Review Board approvals at the centers. The CAP patients will be enrolled and followed under a modified protocol of the ADVANCE trial. HeartWare anticipates submission to the FDA of the PMA seeking approval of the HeartWare System for the bridge-to-transplant indication in December of this year.

About HeartWare International

HeartWare International develops and manufactures miniaturized implantable heart pumps, or ventricular assist devices, to treat Class 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 a United States clinical trial for a bridge-to-transplant indication. 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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