ASX MEDIA RELEASE
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U.S. FDA AUTHORIZES EXPANSION TO 40 CLINICAL SITES FOR U.S. BRIDGE-TO-TRANSPLANT CLINICAL TRIAL

Framingham, MA and Sydney, Australia, October 6, 2009 - HeartWare International, Inc. (NASDAQ: HTWR - ASX: HIN) today announced that it has received approval from the U.S. Food and Drug Administration ("FDA") to expand the number of clinical sites participating in its U.S. bridge-to-transplant trial, known as the ADVANCE trial. Pursuant to the FDA approval, HeartWare will be permitted to enroll a total of 40 clinical sites for the purposes of evaluating the Company's Ventricular Assist System (HVAD) in end-stage heart failure patients requiring circulatory support to bridge them to a heart transplant.

"We continue to be encouraged by the number of physicians who believe the HVAD may provide an important benefit for their patients and we hope that the enthusiasm for our system continues to grow as their experience expands," said Doug Godshall, President and CEO of HeartWare.

"While we have had strong interest from high caliber transplant centers that want to join our ADVANCE trial, we could not previously accommodate them due to our existing 28 clinical site limitation. Receipt of FDA approval enabling expansion from 28 to 40 clinical sites allows us to accept many of these additional sites prior to the completion of enrolment which we project will occur in the first half of 2010," continued Godshall.

At present, HeartWare currently has 22 clinical sites initiated in the United Sites with 69 patients implanted in the 150 patient study.

About End Stage Heart Failure - Heart failure is one of the leading causes of death in the developed world. According to the American Heart Association, congestive heart failure (CHF) afflicts approximately 5 million people in the US with approximately 550,000 new cases diagnosed each year. Despite new treatment strategies for patients with end-stage heart failure, the number of patients who die with this disease is of epidemic proportion. Cardiac transplantation is currently the most effective therapy for the treatment of advanced end stage heart failure, however, its application is limited due to the lack of available donor organs.

Over the last decade, bridging to cardiac transplantation with implantable left ventricular assist devices (LVADs) has gained wider clinical acceptance and LVADs are used to extend life expectancy for patients with end-stage heart failure who might otherwise deteriorate while awaiting a donor heart.

About HeartWare International - HeartWare International develops and manufactures miniaturized implantable heart pumps, or left ventricular assist devices, to treat Class IIIb and 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® Ventricular Assist System in the European Union. The device is currently the subject of a 150-patient clinical trial in the United States for a Bridge-to-Transplant indication.

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

For further information:

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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. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. We 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 SEC on February 28, 2009, and those described in other reports filed from time to time with the SEC.