ASX ANNOUNCEMENT
30 January 2009

HeartWare Receives CE Mark Approval for Miniaturized Heart Pump System

Company to Initiate Commercial Sales in Europe

Framingham, MA and Sydney, Australia, 30 January 2009 - HeartWare International, Inc. (ASX: HIN) today announced that it has received Conformite Europeene (CE) Mark approval for its HeartWare® Ventricular Assist System. The system features a miniaturized, full-output, implantable heart pump designed to treat patients suffering from advanced heart failure. Receipt of CE Mark enables HeartWare to initiate commercial sales of the system throughout the European Union.

HeartWare's submission for CE Mark was based on data from the first 25 patients to have been implanted in the Company's international clinical trial. Of these 25 patients, 23 patients (92 percent) survived to 180 days or to heart transplantation, the primary endpoint of the trial. A total of 50 patients were enrolled in the trial. Within this broader group, the survival rate has remained above 90 percent.

"It has been a great pleasure to be involved in the HeartWare trial," said Dr. Georg Wieselthaler of the Medical University of Vienna, the clinical trial's principal investigator. "The Vienna team was the first to implant the HeartWare device and our enthusiasm for this pump has grown during the trial. This miniature centrifugal pump has distinct design features that give rise to important clinical advantages. I expect the HeartWare® System to play an important role in the future management of heart failure."

Dr. Martin Strueber, principal investigator at Hannover Medical School, the highest enrolling center in the HeartWare clinical trial, said: "We have implanted the HeartWare device in 19 patients and these patients have been supported by the system for an average of over 300 days each. We have been impressed with the pump's performance and are delighted to be able to offer it to our heart failure patients now that it is approved."

As previously advised, HeartWare has begun to establish the necessary infrastructure in Europe to drive a commercial rollout of the system and to support new customers on the continent. HeartWare will focus initially on its existing trial sites and will expand to key new target hospitals over the ensuing months.

About HeartWare International

HeartWare International develops and manufactures miniaturized implantable heart pumps, or Left Ventricular Assist Devices (LVADs), to treat patients suffering from advanced heart failure. The HeartWare® Ventricular Assist System features the HVAD™ pump, the only full-output pump designed to be implanted next to the heart, avoiding the abdominal surgery generally required to

implant competing devices. HeartWare has completed an international clinical trial for the device involving five investigational centres in Europe and Australia. The device is currently the subject of a 150-patient clinical trial in the United States for a Bridge-to-Transplant indication.

For further information:

www.heartware.com
Howard Leibman
Director Corporate Development
HeartWare Limited
Email. howard.leibman@heartware.com.au
Tel. +61 2 9238 2064

U.S. Investor Relations
Matt Clawson
Partner
Allen & Caron, Inc.
Email. matt@allencaron.com
Tel. +1 949 474 4300

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, 2008, and those described in other reports filed from time to time with the SEC.