# ASX ANNOUNCEMENT
# 23 September 2008

## US FDA Grants Full Approval of HeartWare's IDE

**Framingham, MA and Sydney, Australia, 23 September 2008** - HeartWare Limited (ASX: HTW) announces that it has received full approval from the United States Food and Drug Administration (FDA) of an Investigational Device Exemption (IDE) for the HeartWare® Left Ventricular Assist System (LVAS).

HeartWare announced on 5 May 2008 that it had received conditional approval from the FDA for a US clinical trial of the HeartWare® LVAS for use as a bridge to cardiac transplant in patients suffering from end-stage heart failure. This conditional approval permitted the Company to start its US trial but included several "conditions" which HeartWare was required to address to the FDA's satisfaction. The Company has now satisfactorily addressed all of these conditions.

"We were very pleased to announce in August that Washington Hospital Center had received approval from its Institutional Review Board (IRB) and had enrolled the first patient into our US clinical trial," said HeartWare CEO and President, Mr Doug Godshall.

"We are currently finalizing the contractual arrangements with a number of additional centers. We have completed surgical training at seven centers and have training sessions scheduled at a number of additional sites. Further, a number of centers which previously elected not to begin their internal reviews until our IDE became unconditional can now progress their IRB approval processes. We look forward to several new centers gaining approvals and beginning implants over coming weeks."

**About HeartWare**

HeartWare develops and manufactures miniaturized implantable heart pumps, or Left Ventricular Assist Devices (LVADs), to treat patients suffering from advanced heart failure. The Company is developing smaller and less invasive pumps which it believes will be the key to unlocking the potential of a large and underserved market. The HeartWare® LVAD is the only full-output pump designed to be implanted in the chest, 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.

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