ASX ANNOUNCEMENT
11 September 2008

HeartWare Files for CE Mark for the HeartWare® Left Ventricular Assist System

Framingham, MA and Sydney, Australia, 11 September, 2008 - HeartWare Limited (ASX: HTW) today announced that it has filed for approval to CE Mark its HeartWare® Left Ventricular Assist System ("LVAS"). Approval of the submission would allow the commercial launch of the system throughout the European Union.

HeartWare's submission for European approval is based on data from the first 25 patients to have been implanted with the HeartWare® Left Ventricular Assist Device (LVAD) in the Company's international clinical trial. Of the 25 patients, 23 patients (92%) successfully met the primary endpoint of the clinical trial, namely survival to 180 days or heart transplantation.

"Our application seeks approval to sell the HeartWare® LVAS in Europe," said HeartWare President and Chief Executive Officer, Mr Doug Godshall. "We remain encouraged by the results from our international trial and by the enthusiasm being expressed by surgeons and cardiologists globally. We hope to be approved for CE Mark before the end of the year and to commence sales in the European Union soon thereafter."

As previously advised, HeartWare has continued to enrol patients into the international trial. To date a total of 43 patients have been implanted with the device in Europe and Australia. HeartWare will cease enrolment under the international clinical trial once a total of 50 patients have been implanted across the five participating centers.

HeartWare is currently running a Bridge-to-Transplant clinical trial in the United States under conditional IDE approval. The trial will enrol 150 patients across a maximum of 28 centers.

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.

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.

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