ASX ANNOUNCEMENT
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HEARTWARE RECEIVES CONDITIONAL APPROVAL OF IDE

Framingham, MA and Sydney, Australia, May 5, 2008 - HeartWare Limited (ASX: HTW) today announced that it had received conditional approval from the United States Food and Drug Administration (FDA) of an Investigational Device Exemption (IDE) for its lead product, the HeartWare® Left Ventricular Assist System (LVAS).

The granting of conditional IDE approval by the FDA enables the Company to immediately commence its US clinical trial for the HeartWare® LVAS for use as a bridge to cardiac transplant in patients suffering from end-stage heart failure. HeartWare's Bridge-to-Transplant (BTT) clinical trial protocol incorporates a number of novel elements, the key aspects of which are as follows:

- The primary endpoint is survival at 180 days. This survival endpoint is specifically defined to include patients who have received a heart transplant, patients who remain alive and supported by the device at 180 days, and "recovery" patients who have survived for a minimum of 60 days following the explant of their device. Patients are not required to be listed for transplant at 180 days in order to be considered a "success" under the study.

- The study is a "pivotal trial" and therefore does not include a feasibility or pilot phase.

- The study includes a contemporaneous control group. Patient outcomes will be compared to those of a matched cohort of patients recorded in the InterAgency Registry for Mechanical Assisted Circulatory Support (INTERMACS). INTERMACS is a US national registry of patients implanted with an FDA approved circulatory support device.

- The trial requires the enrolment of up to 150 patients across a maximum of 28 centres.

- HeartWare is permitted to open up to 10 centres immediately. Once 10 patients have been enrolled and supported with the HeartWare® LVAS for a mean period of 90 days, the Company will submit a clinical safety report to the FDA for review. Enrolment will continue unabated at the initial 10 centres during this review period. Subject to FDA approval of the clinical safety report, enrolment can then be expanded to all 28 centres.

- Patients enrolled in the HeartWare trial will be eligible for discharge from hospital immediately following their implant.

"Receipt of this conditional approval of an IDE represents one of the most significant milestones since HeartWare's inception," said HeartWare Chief Executive Officer and President, Mr Doug Godshall.

"We believe that the HeartWare® LVAS is poised to make a significant impact on the US mechanical circulatory support market. This is reinforced by the high level of interest we are receiving from US physicians, many of whom already anticipate the potential clinical advantages associated with our device's small size, pericardial placement and advanced peripheral systems. We are confident that these advantages, combined with the innovative structure of our trial and the FDA's consent to immediate patient discharge, will help encourage significant clinician support of the study.

It is also pleasing that we are now within a month or two of generating our first revenue. As previously indicated, we expect to be able to charge for our system during the course of our US clinical trial. We expect to supplement this revenue through commercial sales in Europe once we receive CE Mark later this year."

HeartWare will commence training for our initial US clinical sites later this week and, in parallel, will seek investigational review board (IRB) approval for these sites while working towards satisfying the few conditions to our IDE. The Company expects to shortly release details regarding our initial sites and lead clinical investigators.

About HeartWare
HeartWare develops and manufactures miniaturized implantable heart pumps, or Left Ventricular Assist Devices (LVADs), designed to treat patients suffering from advanced heart failure. The Company is developing the industry's 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 a full-output pump designed to be implanted in the chest, avoiding the abdominal surgery generally required to implant competing devices. The pump is currently the subject of an international clinical trial involving five investigational centres in Europe and Australia. A clinical trial in the U.S. is expected to commence shortly following the receipt of conditional IDE approval in May 2008.

For further information:

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