



## **ASX ANNOUNCEMENT 21 August 2008**

### **First US Implant of the HeartWare<sup>®</sup> Left Ventricular Assist System**

**Framingham, MA and Sydney, Australia, August 21, 2008** - HeartWare Limited (ASX: HTW) today announced that the first patient in the United States received the HeartWare<sup>®</sup> Left Ventricular Assist System (“LVAS”) at Washington Hospital Center (“WHC”) in Washington, DC. This marks the start of HeartWare’s US Bridge-to-Transplant clinical trial, under which 150 patients awaiting heart transplantation will be enrolled at up to 28 participating centers. The HeartWare<sup>®</sup> LVAS features a miniature blood pump that can be placed adjacent to the patient’s heart, and is designed to avoid potentially more complicated abdominal implantation. The system is designed to provide circulatory support for patients with advanced heart failure. The HeartWare<sup>®</sup> LVAS is limited to investigational use in the United States.

The Principal Investigator at WHC is Dr. Leslie Miller, one of the world’s most renowned cardiologists and a recognized leader in the use of mechanical circulatory support systems. The surgery was performed by Steven Boyce, MD, Surgical Director, Heart Failure Program at WHC and one of the most progressive and highest volume cardiac surgeons in the United States.

“Like many of our colleagues, we have been closely watching HeartWare’s progress and have been impressed by the results from the international clinical trial,” said Drs. Miller and Boyce in a joint statement. “We at Washington Hospital Center are pleased to have been the first to implant this exciting new device. The surgery was quick and without incident and the patient is recovering well. The novel configuration of the HeartWare device together with its small size allow the pump to be implanted in the pericardial space, potentially reducing the risks associated with more extensive surgery. The pump has one moving part, an impeller that utilizes a passive suspension system designed to minimize mechanical wear and friction while pumping. We look forward to Washington Hospital Center’s continued use of the device through the course of this trial.”

HeartWare President and CEO, Doug Godshall said “The start of our US clinical trial is one of the most important milestones in the Company’s history. While we have much work ahead, this important achievement takes HeartWare one step closer to our long term objective of market leadership in the mechanical circulatory support arena. We are encouraged by the enthusiasm expressed by so many of the physicians who are joining our trial and it is particularly gratifying to be working alongside the likes of Drs. Miller and Boyce.”

“We expect a number of additional centers to complete their internal review processes and to begin enrolling patients over the next several months,” continued Godshall. “We will provide specific updates to the market as the first five centers join the study. In addition, we will continue to provide periodic updates regarding the overall status of enrolment in the trial.”



## About HeartWare

HeartWare develops and manufactures miniaturized implantable heart pumps designed to treat patients suffering from advanced heart failure. The Company believes these smaller pumps, designed to allow less invasive implantation, will be the key to unlocking the potential of a large and underserved advanced heart failure market. HeartWare is conducting an international clinical trial for the device involving five investigational centers in Europe and Australia. Over 40 patients have been enrolled to date. The device is also 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 redomiciliation in the United States. 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.

For further information:

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