



ASX ANNOUNCEMENT

1 August 2008

First Institutional Review Board Approval in the United States Washington Hospital Centre Approval for HeartWare Trial

Framingham, MA and Sydney, Australia, August 1, 2008: HeartWare Limited (ASX: HTW) today announces that the Institutional Review Board (“IRB”) of Washington Hospital Center (“WHC”) has approved WHC’s participation in the clinical trial of the HeartWare[®] Left Ventricular Assist System. WHC is the first U.S. center to approve the Company’s study. Once the requisite contracts are signed, WHC will be able to begin implanting the HeartWare[®] device.

The Principle Investigator at WHC is Dr. Leslie Miller, one of the world’s most renowned heart failure cardiologists. The lead surgeon is Dr. Steven Boyce, who is one of the highest volume cardiac surgeons in the United States.

“We are delighted to have received this approval and are fortunate to be associated with such exceptional physicians and their top flight support team,” said HeartWare CEO and President, Mr Doug Godshall.

“We have worked with Dr.’s Miller and Boyce for many years. As members of our Medical Advisory Board, their insight and guidance have been invaluable. We look forward with great anticipation to them starting to implant the HeartWare pump, allowing them to experience first-hand the benefits of our system that our international physicians have observed.”

HeartWare has received conditional approval of its investigational device exemption (“IDE”) from the United States Food & Drug Administration (“FDA”). This allows our investigational centers to proceed with their internal approval processes and to begin implanting the device. While several centers are actively working through contract arrangements, others have chosen to wait until HeartWare’s approval becomes “unconditional”. We continue to work closely with the FDA to address the few remaining conditions.

Washington Hospital Center has this week completed its training on the HeartWare systems and are our fourth US center to complete the training program. A number of additional sites will complete training 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 that 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. The device is currently the subject of an international clinical trial involving five investigational centres in Europe and Australia. The Company has received conditional approval from the US FDA to commence a pivotal clinical trial in the United States for a Bridge-to-Transplant indication.

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