



## **ASX ANNOUNCEMENT**

**11 October 2005**

### **Independent Endorsement from HeartWare's Medical Advisory Board**

HeartWare is pleased to advise that the Company's Medical Advisory Board has provided a strong endorsement of HeartWare's decision to proceed to human clinical trials in the first quarter of 2006.

The meeting of the Company's Medical Advisory Board was addressed by Professor Fred Clubb of the Department of Pathology and Laboratory Medicine at the University of Texas Medical School. Professor Clubb was responsible for the pathology tests conducted on the sheep implanted with HeartWare's HVAD during the Company's Good Laboratory Practice ("GLP") study. Following review of the pathology data, the Medical Advisory Board provided unanimous support for HeartWare's decision to progress the HVAD towards a human clinical study as soon as the regulatory process allows.

During the meeting, HeartWare also presented the Company's clinical and regulatory plans for the HVAD. The Advisory Board conducted a detailed review of HeartWare's draft clinical study protocol, including interim comments received from the US Food and Drug Administration.

HeartWare CEO, Mr Stuart McConchie, commented:

"The results of our GLP study conclusively demonstrate that the HVAD has performed according to design. The level of haemolysis (*blood damage*) was minimal and there was no evidence of pump-related thrombogenesis (*blood clotting*). It is very gratifying that, following detailed discussion of these results, our Medical Advisory Board has provided unanimous support for our clinical programme.

HeartWare's Medical Advisory Board includes prominent cardiac surgeons and heart failure cardiologists from around the world. Their support for our clinical and regulatory plans provides a strong independent endorsement of HeartWare's achievements to date. We remain on track to commence a combined European/Australian human clinical trial for the HVAD in the first quarter of 2006 and are confident of the prospects for the device."



### **HeartWare's Medical Advisory Board Members**

Bud Frazier, MD (Chairman)	Chief of Transplant Services and Director Cardiovascular Research, Texas Heart Institute, USA
Steven Boyce, MD	Director of Heart Transplantation and Cardiac Assist Device Programmes, Washington Hospital Centre, USA
Laman A. Gray, Jr., MD	Professor of Surgery and Director of Thoracic and Cardiovascular Surgery, University of Louisville School of Medicine, USA
Leslie Miller, MD	Professor of Medicine and Director of Heart Failure Program, University of Minnesota, USA
Gerry O'Driscoll, MD	Head of Heart Failure and Cardiac Transplantation, Royal Perth Hospital, Australia
Stephen Westaby, MD	Cardiothoracic Surgeon, John Radcliffe Hospital, UK ( <i>not present at MAB Meeting</i> )
Georg Wieselthaler, MD	Clinical Director of Mechanical Circulatory Support, Vienna General Hospital, Austria

### **About HeartWare**

HeartWare is developing a family of proprietary circulatory assist devices to treat patients with congestive heart failure. Heart failure affects 10 million people globally, with over one million new patients diagnosed every year. Some 100,000 patients per year are expected to be eligible for device based treatment.

HeartWare's first left ventricular assist device, the HVAD, is expected to commence human clinical trials in early 2006, with first sales planned for 2007. With a volume of 45cc, the HVAD is substantially smaller than other "third generation" full output pumps in development, giving rise to significant potential clinical advantages.

For further information:

[www.heartware.com.au](http://www.heartware.com.au)

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