



## ASX ANNOUNCEMENT

24 March 2006

### First Human Implant of HeartWare's HVAD

On 22 March 2006, a 48 year old male patient suffering NYHA Class IV Heart Failure became the first recipient of HeartWare's HVAD mechanical circulatory assist device. The implant was conducted at the Vienna General Hospital and the surgical team was led by Dr Georg Wieselthaler, Clinical Director of Mechanical Circulatory Support at the University of Vienna.

The successful implant marks the start of HeartWare's CE mark clinical study. The trial protocol calls for the implantation of the device in twenty patients suffering advanced heart failure. The implants are to be conducted at the Vienna General Hospital (Austria), the Royal Perth Hospital (Australia), the Hannover Medical Centre (Germany) and Harefield Hospital (UK). HeartWare expects to complete patient enrolment in the trial by the end of 2006.

Commenting on the first implant, Dr Wieselthaler said:

*"Our first clinical experience of the HVAD was extremely positive. The procedure was completed quickly and without incident, and our patient's early post-operative recovery has been excellent."*

*The device's small size and configuration facilitated a relatively fast implant procedure. The surgery took only 85 minutes, significantly less than the time typically required to implant other devices. The patient was moved from the operating theatre into the post operative recovery area, conscious and off ventilation within seven hours. He continues to recover quickly and has met with his family. We are very pleased with these results."*

HeartWare CEO, Mr Stuart McConchie, commented from Vienna:

*"The performance of the HVAD continues to support our high expectations for its clinical potential. The early success of this first implant marks the culmination of many years of effort in conceiving, designing, developing and testing what we believe to be the world's leading mechanical circulatory assist device."*

*The HVAD is the smallest 3<sup>rd</sup> generation circulatory assist device available. It is the only full-output pump implantable in the pericardial space and the only centrifugal pump implantable above the diaphragm. The pump's impeller design, together with its integrated inflow cannula, help to ensure optimal blood flow characteristics which should, over time, allow reduction of the anticoagulant levels typically required for LVAD recipients."*

*The HVAD's unique design should allow long term device durability – providing the genuine prospect of "lifelong" therapy. We are extremely encouraged by the early results of our first implant and look forward to confirming and replicating these results through the course of the clinical trial."*

*I would particularly like to recognise the efforts of the dedicated teams at HeartWare and at Vienna General Hospital who together have made this initial implant possible."*



## Clinical Trial Reporting

HeartWare provides the following guidance in relation to its CE mark clinical trial.

1. As previously advised, the combined EU/Australian clinical trial calls for the implantation of the device in twenty patients with advanced heart failure who are listed for a heart transplant. The endpoint for the study is survival to 180 days or transplantation. Implants will be conducted at a minimum of four centres, located in Austria, Australia, Germany and the UK. HeartWare anticipates completing enrolment in the trial before the end of 2006. This is expected to enable regulatory submissions to be made during the first half of 2007, with regulatory approvals anticipated during the second half of next year.
2. HeartWare has adopted the ASX's *Code of Best Practice for Reporting by Life Science Companies* and will follow the recommended guidelines set out in that Code.
3. HeartWare's primary responsibility is for the wellbeing and privacy of the patients agreeing to participate in the HVAD clinical trial. At no time will HeartWare or any clinician or participating hospital disclose any personal details concerning any of these patients.
4. HeartWare will continue to advise the market as each new participating centre commences implants and may provide details regarding the specific experience of the implanting surgeons.
5. HeartWare will continue to comply with its disclosure obligations under the ASX Listing Rules and will, in addition, provide periodic updates advising of the status of the study. These updates are expected to include information concerning the total number of implants completed, a breakdown across participating implant centres and clinical outcomes across the study population. Specific announcements will not be made in relation to each new patient implanted or the ongoing status of individual patients.

## About HeartWare

HeartWare is developing a family of proprietary circulatory assist devices to treat patients with heart failure. HeartWare's lead device, the HVAD, commenced human clinical trials in March 2006. First sales are anticipated in late 2007. With a volume of 45cc, the HVAD is the smallest "3rd generation" pump and the only full output device implantable within the pericardial space.

In parallel with the HVAD clinical development, HeartWare is pursuing its MVAD program, aimed at developing a family of miniaturized cardiac assist devices, implantable by minimally invasive surgical techniques. The current MVAD prototype, approximately one tenth the volume of the HVAD, is currently undergoing animal studies.

For further information:

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