



ASX ANNOUNCEMENT

28 April 2006

HVAD Clinical Trial Update

In accordance with the guidelines set out in HeartWare's ASX announcement of 24 March 2006, we are pleased to provide the following update with regards the status of the HVAD clinical trial.

On 22 March 2006 a 48 year old male patient became the first to receive an implant of the HVAD circulatory assist device. The procedure was carried out at the Vienna General Hospital, by a surgical team led by cardiothoracic surgeon Dr Georg Wieselthaler, Clinical Director of Mechanical Circulatory Support. The patient's post operative progress has met expectations and there have been no adverse events. The hospital policy is to discharge all mechanical support patients to a rehabilitation facility and this is expected to occur this week.

On 19 April 2006, with the first patient approaching 30 days post implant, Dr Wieselthaler implanted an HVAD in a second patient, a 35 year old male suffering from idiopathic cardiomyopathy. The HVAD has performed flawlessly and the patient has made an excellent recovery to date.

HeartWare CEO, Mr Stuart McConchie, commented:

"Although it is too early to draw definitive conclusions, we are extremely encouraged by the clinical performance of the HVAD with over a month of cumulative implant experience in these two patients. In both cases the surgery was completed quickly, highlighting the relative simplicity of the procedure. Both implants were without incident and the patients have followed the expected post-operative course.

We have been particularly pleased by the absence of pump related haemolysis in these two cases. Haemolysis is damage to red blood cells typically observed in patients implanted with a circulatory assist device. A modest level of haemolysis is generally expected and is considered clinically acceptable. In both HVAD patients the haemolysis, determined by the level of plasma-free haemoglobin in the blood, has been in the normal physiological range – suggesting that the HVAD is causing no measurable damage to the blood. While this observation will need to be confirmed over a larger number of patients, it does provide significant and positive validation of the design of the HVAD and has the potential to further set the device apart from competing LVADs."

The two patients implanted in Vienna are the first in a twenty patient study designed to achieve CE mark and TGA approval for the HVAD. 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.

About HeartWare

HeartWare is developing a family of proprietary circulatory assist devices to treat patients with congestive 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, commenced animal studies in August 2005.

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