

## ASX ANNOUNCEMENT 24 July 2007

# First "Bridge to Recovery" Patient and Clinical Trial Update

HeartWare is pleased to report the first successful "Bridge to Recovery" case using HeartWare's HVAD<sup>TM</sup> left ventricular assist device.

On 18th July, the heart failure team at Royal Perth Hospital led by Prof Gerry O'Driscoll (heart failure cardiologist) and Dr Rob Larbalestier (cardiothoracic surgeon) successfully removed the HVAD<sup>TM</sup> device from one of their patients. The 38-year-old male patient had been implanted with his HVAD<sup>TM</sup> on 23rd October 2006. After 268 days or approximately 9 months of support on the device, the patient's heart function had improved to such an extent that the Royal Perth team decided to explant the pump.

### Professor Gerry O'Driscoll commented:

"This case presents a clear example of the potential for mechanical pumps to recover certain patients from heart failure. The additional blood-flow provided by the implanted pump helps to unload the left ventricle and reverse end-organ dysfunction. Over time, and with appropriate drug therapy, the damaged heart muscle can recover and resume near-normal function. In cases such as these, the potential to remove the pump and avoid heart transplantation is a significant advance.

Less than one year ago, this patient was critically ill. He would not have survived without either a mechanical pump or a heart transplant. Today, at 38 years of age, he has largely overcome his heart failure and faces the real prospect of a long and productive life."

The prospect of pumps being used for "bridge-to-recovery" has the potential to significantly expand the market for these devices. Studies are currently underway to establish how best to identify potential recovery patients and to more clearly understand the bridge to recovery opportunity.

### **Clinical Trial Update**

Following two implants last week at St Vincent's Hospital (Sydney) and Vienna General Hospital respectively, the HeartWare HVAD<sup>TM</sup> has now been implanted in 18 patients.

Of these 18 patients, 17 are alive. On a cumulative basis these patients have now been supported on the device for almost 2,600 days, or over 7 years. Of our 18 patients, 7 have successfully passed the primary clinical endpoint of the trial. Three of these patients underwent successful heart transplantations after being supported by their pumps for 427, 348 and 157 days respectively.

We continue to be encouraged by the clinical performance of our pump and we remain on track to completing our twenty patient target enrolment in our CE mark clinical trial over coming weeks.



#### **About HeartWare**

HeartWare is developing a family of proprietary circulatory assist devices to treat patients with heart failure. HeartWare's lead device, the HVAD<sup>TM</sup> pump, is currently progressing through an international clinical trial. With a volume of 45cc, the HVAD<sup>TM</sup> pump is the smallest "3rd generation" pump and the only full output device implantable routinely within the thoracic cavity.

HeartWare's miniaturization platform enables the development of smaller devices, potentially implantable by minimally invasive surgical techniques. Pre-clinical studies are underway for HeartWare's MVAD<sup>TM</sup> pump, a pump one-third the size of the HVAD<sup>TM</sup> pump. HeartWare's IV-VAD, a pump one-tenth the size of the HVAD<sup>TM</sup> pump, is at early prototype stage.

For further information:

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