# ASX ANNOUNCEMENT

**11 April 2007**

## First HVAD™ Implant at St Vincent's Hospital, Sydney

HeartWare is pleased to announce that on 4 April 2007, the cardiothoracic team at St Vincent's Hospital in Sydney, Australia conducted their first implant of HeartWare's HVAD™ Left Ventricular Assist Device. The device was implanted in a 60 year old male patient with familial cardiomyopathy. The procedure was completed quickly and without incident and the patient continues to recover well from the surgery.

The surgical team was led by Dr Paul Jansz, cardiothoracic and transplant surgeon. Dr Jansz commented:

*"Our first clinical experience with the Heartware device was extremely positive. The device was the smallest device we have used and consequently implantation was remarkably easy. The pump has worked seamlessly. Our patient has made a relatively straightforward recovery and has now been discharged from the Intensive Care Unit to the ward. The fact that the pump, once implanted, is totally contained within the chest cavity means that there is no need for the abdominal surgery associated with other devices. I am convinced that this pump marks a significant step forward in the treatment of end stage heart failure."*

### Clinical Trial Update

To date, thirteen patients have been implanted with the HVAD™, including five at Vienna General Hospital, three at Royal Perth Hospital, two at Hannover Medical Centre, two at Harefield Hospital and one at St Vincent's Hospital. On a cumulative basis, these patients have been supported for a total of over 1,500 days.

Sadly, we also report the death on Monday 10th April of one of the patients enrolled in the HeartWare clinical trial. Despite a successful implant of the HVAD™ device, the patient suffered a series of operative complications that the implanting surgeon feels were entirely unrelated to the pump. As a company, our goal is to preserve and extend the lives of the patients who receive our implant so we are deeply saddened by this outcome even though this type of event is common to every LVAD trial.

Now that all of our five centers are open and implanting, we will be providing periodic updates of the progress of our clinical trial and, as previously disclosed, will not be providing patient-by-patient implant details or progress. We will however provide relevant details regarding the outcome of our entire clinical trial following the endpoint of our clinical trial.

The primary endpoint for the HVAD™ clinical trial is patient survival to 180 days or transplantation. Of the thirteen patients enrolled to date, three have successfully met the trial endpoint. These include HeartWare's first patient, who has been supported by his pump for 385 days, and HeartWare's second and third patients who received heart transplants after 348 and 157 days respectively.

**About HeartWare**

HeartWare is developing a family of proprietary circulatory assist devices to treat patients with heart failure. HeartWare's lead product, the HVAD™ Left Ventricular Assist Device, is currently progressing through an international clinical trial. With a volume of 45cc, the HVAD™ device 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™ pump, a device one third the size of the HVAD™ pump. HeartWare's IV-VAD, a pump one tenth the size of the HVAD™ device, is at early prototype stage.

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