



## ASX ANNOUNCEMENT

7 July 2006

### German Regulatory Approval and Clinical Trial Update

#### Regulatory Update

HeartWare is pleased to advise that it has received regulatory approval to commence implants of its HVAD<sup>TM</sup> left ventricular assist device in Germany. Approval from the German Institute of Medical Documentation and Information follows receipt of Ethics Committee Approval from Hanover Medical Centre.

HeartWare has previously confirmed the receipt of regulatory approvals in Austria, Australia and the United Kingdom. With regulatory approval being obtained in Germany, HeartWare now has approval to implant the HVAD<sup>TM</sup> device at all four centres participating in its CE mark clinical trial, namely Vienna General Hospital (Austria), Royal Perth Hospital (Australia), Harefield Hospital (UK) and Hanover Medical Centre (Germany).

#### Clinical Trial Update

HeartWare initiated its clinical trial of the HVAD<sup>TM</sup> device with two implants at the Vienna General Hospital in Austria. Both patients are recovering well. They have been discharged to their respective homes and both patients are indicating continued improvement in their exercise capacities. With six months of cumulative implant experience, there have been no adverse events and the HVAD<sup>TM</sup> has performed as expected.

HeartWare CEO, Mr Stuart McConchie, commented:

*“With six months of cumulative implant experience (being the combined implant duration for both patients), there have been no adverse events and the HVAD<sup>TM</sup> has performed as expected. We now look forward to accelerating our implant rate with the successive introduction of our three remaining clinical trial centres. We intend to open our second centre before the end of July. Our objective remains to complete enrolment of all twenty patients 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<sup>TM</sup> left ventricular assist device, commenced human clinical trials in March 2006. First sales are anticipated in late 2007. With a volume of 45cc, the HVAD<sup>TM</sup> device is the smallest “3rd generation” pump and the only full output device implantable routinely within the thoracic cavity.

In parallel with the clinical development of the HVAD<sup>TM</sup> device, HeartWare is pursuing its MVAD<sup>TM</sup> program, aimed at developing a family of miniaturized circulatory assist devices, implantable by minimally invasive surgical techniques. The current MVAD<sup>TM</sup> prototype, approximately one tenth the volume of the HVAD<sup>TM</sup> device, commenced animal studies in August 2005.



For further information:

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

Howard Leibman

Director Corporate Development

HeartWare Limited

+61 2 8215 7604 / 0402 440644

Stuart Barton

Gavin Anderson & Company

+61 2 9552 4499 / 0404 054 857