

## ASX ANNOUNCEMENT 2 November 2005

## **Successful Completion of Animal Studies**

HeartWare is pleased to announce the completion of animal studies for the HVAD, the Company's lead mechanical assist device for the treatment of patients in cardiac failure.

In the second quarter of 2005 HeartWare commenced its final series of animal studies for the HVAD, conducted at the Texas Heart Institute under Good Laboratory Practice (GLP) conditions. As previously detailed to the market, this study required the implantation of the device in six sheep, each for a period of 90 days.

We are pleased to advise that surgeons at the Texas Heart Institute last week explanted the sixth device, marking the end of the GLP study. As with the previous implants, pathology analysis has confirmed that the device performed exceptionally well during the implant period. Specifically, the level of haemolysis (blood damage) was minimal and there was no evidence of pump-related thrombogenesis (blood clotting).

HeartWare CEO, Mr Stuart McConchie, commented:

"Early this year we made the decision to conduct our entire GLP study in sheep, without the use of anticoagulants, thereby subjecting the pumps to a particularly rigorous test protocol. Despite this, all six pumps have achieved the 90 day implant period and performed according to design. The results of this final explant confirm the HVAD's exceptional performance characteristics.

The completion of our GLP study marks a significant transition for HeartWare. Data from the study form a critical component of HeartWare's submissions to various regulatory authorities to commence our human clinical trial. We expect to lodge these submissions within weeks and remain confident of achieving our first human implant within the first quarter 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, is expected to commence human clinical trials in early 2006, with first sales planned for 2007. With a volume of 45cc, the HVAD is the smallest "third generation" full output pump in development.

For further information:

## www.heartware.com.au

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