ASX ANNOUNCEMENT

5 January 2006

Regulatory Approval in Europe

HeartWare is pleased to announce the receipt of its first regulatory approval to commence human implants of the HVAD left ventricular assist device. Approval was received from the Austrian Ministry of Health.

The Austrian regulatory approval follows the recent receipt of Ethics Approval from the Vienna General Hospital. The Vienna General Hospital, associated with the University of Vienna, has a well established Mechanical Circulatory Support program and is among the world's leading centres for device based treatment of cardiac failure. Dr Georg Wieselthaler, the Clinical Director of Mechanical Circulatory Support, will lead the HVAD implant program in Vienna. A member of HeartWare's Medical Advisory Board, Dr Wieselthaler is also the Secretary General of the International Society of Rotary Blood Pumps and has extensive experience with a range of mechanical assist devices.

In addition to the Austrian regulatory approval, HeartWare has also been notified of conditional Ethics Approval from the Royal Perth Hospital. HeartWare anticipates receiving full Ethics Approval from Royal Perth over coming weeks, at which time the Company will apply to the Australian Therapeutic Goods Administration to commence human implants in Australia. Within the same timeframe, HeartWare expects to make similar submissions to the regulatory authorities in both Germany and the UK.

In mid January HeartWare will be conducting its surgical training program at the Texas Heart Institute, during which the surgical teams from all hospitals participating in the first phase of the HVAD clinical trial will receive instruction on the HVAD implant procedure.

HeartWare CEO, Mr Stuart McConchie, commented:

"HeartWare's primary objective over the past year has been to initiate our human clinical study during the first quarter of 2006. With receipt of regulatory approval so early in the year, we remain confident of achieving this important milestone. Our surgeon training is scheduled for later this month, and we expect to complete our internal compliance, verification and validation procedures during February. By that stage we expect to have regulatory approval in at least one additional jurisdiction. Subject then only to patient selection, we remain confident of commencing our human implants in March 2006."

Over coming weeks HeartWare will provide regular updates on the status of the Company's Australian, German and UK regulatory submissions and approvals. The Company will provide specific details of the hospitals and the lead investigators at each, following confirmation of regulatory approval in each jurisdiction.

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.

HeartWare's "next generation" device – the MVAD or Miniaturized VAD – is expected to begin clinical trials within two years. The MVAD is one tenth the size of the HVAD and will be implantable via minimally invasive surgical procedures.

For further information:

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