ASX ANNOUNCEMENT

8 March 2006

Approval from the Therapeutic Goods Administration

HeartWare is pleased to announce that the Australian Therapeutic Goods Administration ("TGA") has approved the commencement of human implants of the HVAD Left Ventricular Assist Device.

The approval by the TGA follows the recent receipt of Ethics Approval from the Royal Perth Hospital. The HVAD implant program at the Royal Perth Hospital will be led by Dr Rob Larbalestier, cardiac surgeon, and Dr Gerry O'Driscoll, heart failure cardiologist. The Royal Perth Hospital has a well established and internationally recognized mechanical circulatory support program. Both Dr Larbalestier and Dr O'Driscoll have extensive experience with a wide range of implantable mechanical assist devices. Dr O'Driscoll is also a member of HeartWare's Medical Advisory Board.

HeartWare now has approval from the regulatory authorities in both Austria and Australia to initiate human implants of the HVAD. As announced on 31 January 2005, the Company has also completed its surgeon training program. The training sessions were conducted at the Texas Heart Institute and were attended by the surgical teams from all four hospitals participating in the first phase of the trial, including the Vienna General Hospital (Austria), the Royal Perth Hospital (Australia), the Hannover Medical Centre (Germany) and Harefield Hospital (UK).

HeartWare CEO, Mr Stuart McConchie, commented:

"HeartWare's primary stated objective since our IPO in January 2005 has been to commence human implants of the HVAD during the first quarter of 2006. Having now received regulatory approvals in two key jurisdictions, we remain confident of achieving this important milestone. A critical issue for HeartWare over coming weeks will be to select an appropriate candidate to receive the first HVAD implant. Subject to patient availability, we expect to conduct our first procedure before the end of March."

The forthcoming implants of the HVAD device form part of HeartWare's CE mark trial. The trial protocol calls for the implantation of the HVAD in twenty patients with advanced heart failure. With a minimum of four leading international centres enrolling patients in parallel, HeartWare's objective is to complete all twenty implants before the end of 2006. Subject to successfully completing enrollment within this timeframe, HeartWare expects to receive CE mark for the HVAD in the third quarter of 2007, at which time commercial sales in Europe and Australia can commence.

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 parallel with the HVAD clinical development, HeartWare has accelerated its MVAD program, aimed at developing a family of miniaturized cardiac assist devices, implantable by minimally invasive techniques. The current MVAD prototype, approximately one tenth the volume of the HVAD, is currently undergoing long term animal studies.

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