ASX ANNOUNCEMENT

22 May 2006

Regulatory Approval to Commence HVAD Implants in the UK

HeartWare is pleased to announce that it has received regulatory approval from the Medicines and Healthcare Products Regulatory Agency ("MHRA") to commence implants of its HVAD circulatory assist device in the United Kingdom. HeartWare's submissions to the MHRA followed receipt of Ethics Committee Approval from Harefield Hospital, one of the four hospitals that will be participating in the clinical trial currently underway for the HVAD.

The HVAD implant program in the UK will be led by Mr Asghar Khaghani, Consultant Cardiac Surgeon at the Royal Brompton and Harefield Hospital Trust. Mr Khaghani is in charge of the cardiac transplantation and mechanical circulatory assist programs at Harefield Hospital and has extensive experience with a wide range of implantable circulatory assist devices. Mr Khaghani is also a member of HeartWare's Medical Advisory Board.

HeartWare now has approvals to implant the HVAD in Austria, Australia and the UK. In addition, HeartWare has received approval from the Ethics Committee at the Hanover Medical Centre in Germany and has completed its submissions to the German regulatory authority. Approval to implant in Germany is anticipated in coming months.

With implants of the HVAD now underway at the Vienna General Hospital in Austria, HeartWare's key priority for 2006 is the enrolment of all twenty patients across the four participating centres. As previously advised, Royal Perth Hospital will be the second centre to begin implanting the HVAD. Royal Perth will be followed by Harefield Hospital and finally by Hanover Medical Centre, subject to receipt of regulatory approval in Germany.

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, commenced human clinical trials in March 2006. First sales are anticipated in late 2007. With a volume of 45cc, the HVAD is the smallest "3rd generation" pump and the only full output device implantable within the pericardial space.

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

For further information:

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