

First Implant at Royal Perth Hospital

On 19 October 2006, the cardiothoracic team at Royal Perth Hospital implanted HeartWare's HVADTM left ventricular assist device in a 35 year old female patient suffering advanced heart failure. The patient had failed all conventional medical therapy and needed mechanical support. The procedure was completed quickly and without incident. The HVADTM has performed as expected and the patient continues to recover well from the surgery.

Professor Gerry O'Driscoll, Consultant Cardiologist at Royal Perth Hospital and Medical Head of West Australian Advanced Heart Failure and Cardiac Transplant Services, commented:

"Our first experience with HeartWare's HVADTM has been extremely encouraging. The implant procedure was short and relatively simple and the patient was discharged from the intensive care unit in less than 24 hours. The pump's small size facilitates implantation above the diaphragm, eliminating the need for abdominal surgery and minimizing both bleeding and infection risks. These factors should translate into improved outcomes for our patients. Furthermore, this pump's design will allow for implantation without cardiopulmonary bypass (off-pump) and its size will allow smaller patients, including children, to be supported."

Royal Perth Hospital is the second centre to begin implanting the HVADTM left ventricular assist device. Two implants have been conducted previously at the Vienna General Hospital. These first two patients have now been supported for a cumulative period of approximately 13 months, with both having successfully passed the 180 day primary end-point of the clinical trial. In each case, the HVADTM has performed very effectively and the patients continue to enjoy a significantly improved quality of life.

HeartWare Chief Executive Officer, Mr. Doug Godshall commented:

"It is extremely gratifying to have completed a third implant and to welcome Royal Perth as our second trial site. This implant signals an important step forward for the company. Our focus on operational and manufacturing processes over recent months has already begun to yield benefits. We now have a steady flow of devices coming through manufacturing and have product inventory at our first two investigational sites. We look forward to a speedy recovery for this patient and we anticipate further implants at Royal Perth and Vienna General in the near future. Our plan is to open our third trial site before the end of the year."



About HeartWare

HeartWare is developing a family of proprietary circulatory assist devices to treat patients with congestive heart failure. HeartWare's lead product, the HVADTM left ventricular assist device, commenced human clinical trials in March 2006. Regulatory approval in Europe is anticipated in late 2007. With a volume of 45cc, the HVADTM is the smallest "3rd generation" pump and the only full output device implantable routinely within the thoracic cavity.

HeartWare's miniaturization platform allows the development of smaller devices, potentially implantable by minimally invasive surgical techniques. Pre-clinical studies are underway for a prototype pump approximately one tenth the volume of the HVADTM.

For further information:

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