

ASX ANNOUNCEMENT 24 April 2009

HeartWare International Clinical Trial Shows 90% Survival at 180 Days

Framingham, MA and Sydney, Australia, 24 April 2009 – HeartWare International, Inc. (NASDAQ: HTWR - ASX: HIN) today announced updated results for its international clinical trial of the HeartWare[®] Left Ventricular Assist System. The results were presented by Dr. Martin Strueber, cardiothoracic surgeon at Hannover Medical School, at the annual meeting of the International Society for Heart and Lung Transplantation (ISHLT) held in Paris this week. A full copy of the presentation is attached to this announcement.

The data presented at ISHLT includes all 50 patients enrolled in the trial across 5 participating centers. The data show a survival rate of 90% at 6 months and a survival rate of approximately 86% at 12 months post implant*. On average, the patients were supported by the HeartWare[®] System for 300 days each. The cumulative duration of support across the group exceeded 41 years. The patients' quality of life showed significant improvement at all points post-implant and the rates of adverse events were relatively low despite the unusually long average duration of pump support across the patient group.

"These results appear again to confirm the benefits we believe to be inherent in the design of this device," said HeartWare CEO, Mr. Doug Godshall. "At the ISHLT meeting 12 months ago we reported a 90% survival among our initial patient cohort. It is pleasing to observe that this success rate has been maintained over a far larger patient group and over a longer period of time. We anticipate these positive data providing a meaningful stimulus as we make the system more broadly available in our International markets and as we accelerate enrolment in our US Bridge to Transplant clinical trial."

* The data includes all patients through February 26, 2009. As of today, 3 patients have yet to pass the endpoint of the international clinical trial and the last of these is expected to do so in early June.

About HeartWare International

HeartWare International develops and manufactures miniaturized implantable heart pumps, or Left Ventricular Assist Devices (LVADs), to treat patients suffering from advanced heart failure. The HeartWare[®] Ventricular Assist System features the HVAD[™] pump, the only full-output pump designed to be implanted next to the heart, avoiding the abdominal surgery generally required to implant competing devices. HeartWare has completed an international clinical trial for the device involving five investigational centres in Europe and Australia. The device is currently the subject of a 150-patient clinical trial in the United States for a Bridge-to-Transplant indication.



For further information:

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Forward-Looking Statements

This announcement contains forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to the progress of clinical trials. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. We may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation those described in "Item 1A. Risk Factors" in our Annual Report on Form 10-K filed with the SEC on February 28, 2008, and those described in other reports filed from time to time with the SEC.

Clinical Results of the International HeartWare[®] Ventricular Assist System Bridge to Transplant Trial



M. Strueber, A. Khaghani, P. Jansz, G. O'Driscoll and G. Wieselthaler

The HeartWare[®] Ventricular Assist System

- HVAD[™] miniaturized implantable blood pump
 - > 50cc / 140g, 50mm outside diameter
- 10 liters of flow
- Advanced Impeller is the only moving part
 - > Hybrid magnetic / hydrodynamic
 - Wear-less system
- Two motors designed to provide power redundancy
- Thin (4.2 mm), flexible driveline with fatigue resistant cables





HeartWare Peripheral Equipment

Touch screen Hospital Monitor with pump parameters & flow waveforms



Controller with LCD display, audible alarms and 30 day data storage

2 small, Lithium ION Batteries last12 hours



Pericardial Placement – a Key Advantage



- No abdominal surgery Low blood loss ightarrow
- •
- 3 step implant ullettechnique
- No pump pocket Potential for short

CPB implant time







First Human Clinical Trial Overview

- First human trial of HVAD[™] Pump also served as CE mark study
- Primary endpoint is survival to transplantation, on the device, or explanted to recovery at 180 days
- Secondary study endpoints include:
 - Pre-implant cardiac index vs. pump index
 - Incidence of all reported adverse events
 - Incidence of all device failures and device malfunctions
- Quality of life and neurocognitive scores were collected
- 50 patient enrollment completed in December 2008
- Data cut-off February 25, 2009; 3 patients remain on support at less than 180 days

International HeartWare BTT Trial

| | Centers | # Patients |
|---|---|------------|
| • | Harefield Hospital, UK Asghar Khaghani, Emma Birks | 3 |
| • | Royal Perth Hospital, Australia Gerry O'Driscoll, Rob Larbalestier, Lawrence Dembo | 8 |
| • | St. Vincent's Hospital, Australia Paul Jansz, Philip Spratt | 10 |
| • | Vienna General Hospital, Austria Georg Wieselthaler, Heinrich Schima | 10 |
| • | Hannover Medical School, Germany | 19 |
| | Martin Strueber, Anna Myer | 50 |

Competing Outcomes (n = 50)



Patient Demographics (n=50)

General: • Age: 48.5 ± 13.6 years • BSA: 1.51 to 2.56 m² (mean 1.97 m²)

• Weight: 78.4 <u>+</u> 18 kg



Preoperative Hemodynamics (n = 50)

| Parameter | HeartWare | HM II* |
|--------------------------|--------------|-------------|
| Cardiac Index (L/min/m2) | 1.94 ± 0.54 | 2.0 ± 0.6 |
| LVEF (%) | 18.7 ± 5.9 | 16.3 ± 5.7 |
| BP Systolic (mmHg) | 101.5 ± 13.9 | 95.8 ± 14.6 |
| BP Diastolic (mmHg) | 64.2 ± 10.9 | 61.7 ± 11.3 |
| Mean BP (mmHg) | 76.7 ± 10.6 | 73 |
| PCWP (mmHg) | 23.7 ± 6.5 | 26.1 ± 7.9 |
| PA Systolic (mmHg) | 47.6 ± 15.7 | 53 ± 14.1 |
| PA Diastolic (mmHg) | 27.7 ± 9.3 | 28.2 ± 8.8 |
| CVP (mmHg) | 12.3 ± 5.9 | 13.5 ± 7.8 |

* Use of a Continuous Flow Device in Patients Awaiting Heart Transplantation. Miller LW et al NEJM 357;9

Clinical Trial Highlights (n = 50)

| Overall survival at 180 days | 90% |
|--|---------------------------------|
| Total duration of pump support | 41.1 years |
| Average pump support | 300 days |
| Average days on pump at time of transplant | 294 days |
| Patients transplanted at 180 days | 14% |
| Six month survival after transplant | 94% |
| Survival in 60 and older subgroup (n =14) | 93% |
| Significant improvements pre-implant vs. post implant hemodynamic parameters | PAP, PCWP, CI/VAD Flow Index |



Data cut-off February 25, 2009.

Device Performance Highlights (n = 50)

| Successful pericardial placements | 100% |
|---|----------------|
| Reduction in re-hospitalizations post implants* | 80% |
| Average pump flow and power | 6.2 L 4.8 w |
| Recorded single Battery support time | 6 hrs |
| Peri-operative survival | 96% |
| Shortest cardiac bypass time | 21 min |
| Mechanical pump failures | 0% |
| Driveline cable fractures | 0% |



* compared admissions during12 months pre-implant versus 12 months post-implant

Spring 2007 Device Impeller Issue

- Pump thrombus and high AE rates in 6 patients
- Diagnosis pointed towards distorted thrust bearings
- Revised manufacturing processes
 and testing
- New devices began shipping in June 2007
- No reoccurrences





Normal Flow

Reduced Outer Shroud Height Allows Flow to Divert off Bearing

Serious Adverse Events

| | Event Rate per Patient Year | | |
|---|--------------------------------|---------------|---------------|
| Event | n=6 w/ MFG defect | n=44 | n=50 |
| All infection | 0.78 | 0. 39 | 0.44 |
| Bleeding requiring operation (% of patients) | 0.39 (33%) | 0.17 (14%) | 0.19 (16%) |
| Respiratory dysfunction | 0.39 | 0.19 | 0.22 |
| Right heart failure | 0.20 | 0.11 | 0.12 |
| Ventricular arrhythmias: cardioversion / defibrillation | 0.20 | 0.03 | 0.05 |
| Renal dysfunction | 0.20 | 0.03 | 0.05 |
| VAD thrombus | 1.57 | 0.00 | 0.19 |
| Ingested VAD thrombus | 0 | 0.08 | 0.07 |
| Hemolysis without thrombus | 0.00 | 0.00 | 0.00 |

Device Exchanges

- 4 exchanges (excluding 2 exchanges from impeller manufacturing issue)
 - Reasons:
 - Ingest pre-implant LV thrombus: 1
 - RVAD flow and mitral apparatus occlusion: 1
 - Ingest LV thrombus: 2 (patients not on anti-platelet therapy)
 - ➤ All were exchanged to a second HVADTM Pump

All Neurologic Events (n = 50)

| Neurological Event | # Patients (%) | Event Rate (per patient year) |
|---------------------|-------------------|----------------------------------|
| Ischemic CVA (2) | 2 (4%) | 0.05 |
| TIA (1) /PRIND (2) | 2 (4%) | 0.07 |
| Hemorrhagic CVA (2) | 2 (4%) | 0.05 |

Summary of Deaths (n = 50)

| Cause | Number of Patients |
|---------------------|--------------------|
| Multi-organ failure | 6* |
| Hemorrhagic stroke | 1 |

*3 deaths prior to discharge

Quality of Life is Significantly Improved



Kansas City Cardiomyopathy Questionnaire

Neurocognitive Evaluation (n = 44)



Conclusions From First BTT Trial

- Promising results with 90% survival at 180 days in first human study
- Successful implant in the pericardial space without surgical pump pocket
- Patient implant days unusually long for a BTT trial without adversely impacting AE rates
- Excellent survival post transplantation
- Quality of life is significantly improved at all points post-LVAS implantation
- Improvements in measured neurocognitive function
- Identified and solved important manufacturing specification issue early in trial (June 2007)