

#### ASX ANNOUNCEMENT 14 April 2008

## PRESENTATION OF HEARTWARE CLINICAL RESULTS SURVIVAL RATE OF 91% AMONG FIRST 23 PATIENTS

**Framingham, MA and Sydney, Australia**: HeartWare Limited (ASX: HTW), a developer of miniaturized implantable heart pumps to treat advanced heart failure, today announced initial results from an international clinical trial of the HeartWare<sup>®</sup> Left Ventricular Assist System. The results were presented by Dr. Georg Wieselthaler, cardiothoracic surgeon at Vienna General Hospital, at the annual meeting of the International Society for Heart and Lung Transplantation held in Boston. A full copy of the presentation is attached.

The data presented by Dr Wieselthaler show a 6-month survival rate of 91% among the first 23 patients implanted with the HeartWare device. Of the 23 patients, 21 patients met the primary endpoint of the trial, defined as survival to 180 days or transplantation. These included 19 patients who were supported by the HeartWare system at 180 days and 2 patients who received transplants, after 157 days and 176 days respectively.

Dr. Wieselthaler noted that one of the key features of the pump is its small size, which allows it to be implanted in the chest, thereby avoiding the abdominal surgery generally required to implant competing devices.

HeartWare CEO Mr. Douglas Godshall said the early clinical success of the HeartWare pump is a key outcome for the Company as it accelerates its efforts to make the device available to patients in the United States and around the world.

"These results are very promising," Mr. Godshall said. "Our early data appears to validate the benefits we believe to be inherent in the design of our device – namely its small size, pericardial placement and wearless mechanism. These results give us great confidence as we move towards the start of our U.S. clinical trial and towards commercial release of the product in Europe."

To date a total of 32 patients have been enrolled in HeartWare's international clinical trial. The average duration of support across this patient group exceeds 220 days per patient. The cumulative period of support across the group exceeds 7,000 days or approximately 19 years. 8 of our patients have been supported by the HeartWare system for periods exceeding 12 months, including one patient who has been supported for more than 500 days.

HeartWare plans to commence a U.S. trial in the middle of 2008. In the U.S. alone more than 5 million patients suffer from heart failure and fewer than 3,000 donor hearts become available each year.



#### **About HeartWare**

HeartWare develops and manufactures miniaturized implantable heart pumps, or Left Ventricular Assist Devices (LVADs), designed to treat patients suffering from advanced heart failure. The Company is developing the industry's smallest and least invasive pumps, which it believes will be the key to unlocking the potential of a large and underserved market. The HeartWare LVAD is a full-output pump designed to be implanted in the chest, avoiding the abdominal surgery generally required to implant competing devices. The device is currently the subject of an international clinical trial involving five investigational centres in Europe and Australia. A clinical trial in the U.S. is expected to begin in the first half of 2008.

For further information:

www.heartware.com.au

Howard Leibman
Director Corporate Development
HeartWare Limited

Email. <a href="mailto:howard.leibman@heartware.com.au">howard.leibman@heartware.com.au</a>

Tel. +61 2 9238 2064

US Investor Relations Matt Clawson Partner Allen & Caron, Inc.

Email. matt@allencaron.com Tel. +1 949 474 4300

#### A Report On The First 23 Human Implants

# Experience with the Novel HeartWare® LVAS with Hydromagnetically Levitated Rotor in a Multi-institutional Trial

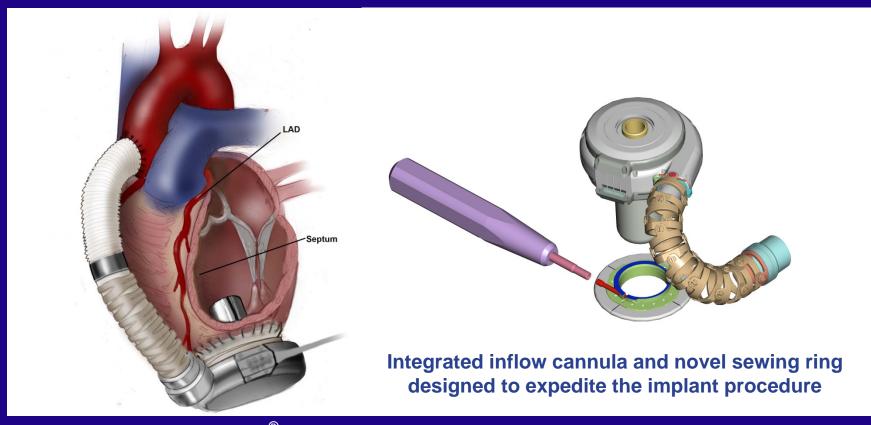
G.M. Wieselthaler, M. Strueber, G.A. O'Driscoll, P. Jansz and A. Khaghani

#### HeartWare Design Features



- One moving part, no mechanical bearings and passive impeller system
- Small centrifugal pump, 50 cc, 140 gms, 2" outside diameter
- Integrated inflow cannula
- 10 mm outflow graft with strain relief
- Dual motor stators for pump power redundancy
- Thin, flexible driveline (4.2 mm)

#### Surgical Implant in the Pericardial Space



HeartWare pump is implanted in the pericardial space

#### International HeartWare BTT Trial

Primary Endpoint: Survival to transplantation or 180 days on the device Enrollment as of November 14, 2007

	Centers	# Patients
•	Vienna General Hospital, Austria Georg Wieselthaler, Henrich Schima	7
•	Royal Perth Hospital, Australia Gerry O'Driscoll, Rob Larbalestier, Lawrence Dembo	4
•	Hannover Medical Center, Germany Martin Strueber, Christian Kuehn, Anna Myer	6
•	Harefield Hospital, UK Asghar Khaghani, Emma Birks, Gilles Dreyfus	2
•	St. Vincent's Hospital, Australia Paul Jansz, Philip Spratt	4
		23

#### Patient Demographics

Patients: 23

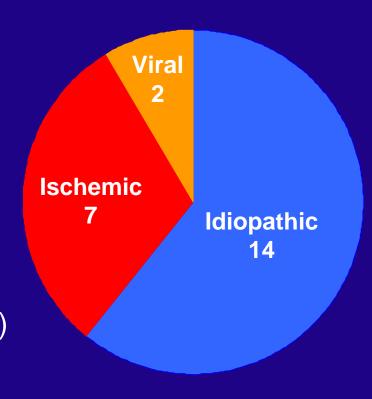
Gender: 20 Males and 3 Females

Age: 26 to 68 years (mean 47.9 yrs)

BSA: 1.51 to 2.56 m<sup>2</sup> (mean 1.98 m<sup>2</sup>)

Weight: 47.8 to 138 kg (mean 83.7 kg)

#### **Etiology of Disease**

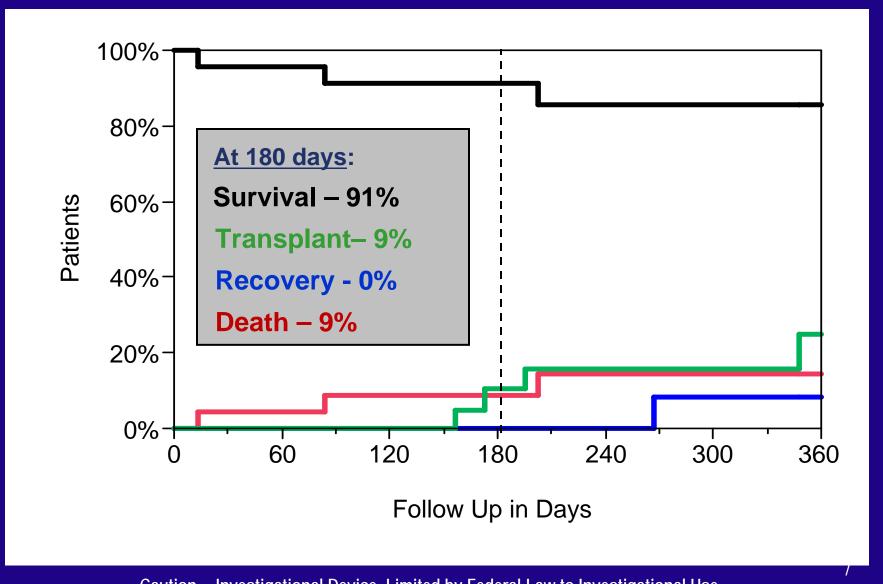


#### Preoperative Hemodynamics

Parameter	HeartWare	HM II*
Cardiac Index (L/min/m²)	1.9 ± 0.5	$2.0 \pm 0.6$
LVEF (%)	$20.6 \pm 7.4$	16.3 ± 5.7
BP Systolic (mmHg)	105 ± 15.8	95.8 ± 14.6
BP Diastolic (mmHg)	67 ± 8.9	61.7 ± 11.3
Mean BP (mmHg)	79 ± 10.2	73
PCWP (mmHg)	23.1 ± 7	26.1 ± 7.9
PA Systolic (mmHg)	52.7 ± 17.2	53 ± 14.1
PA Diastolic (mmHg)	28.1 ± 9.3	28.2 ± 8.8
CVP (mmHg)	13 ± 5.7	13.5 ± 7.8

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

#### Outcomes at 180 Days for First 23 Implants



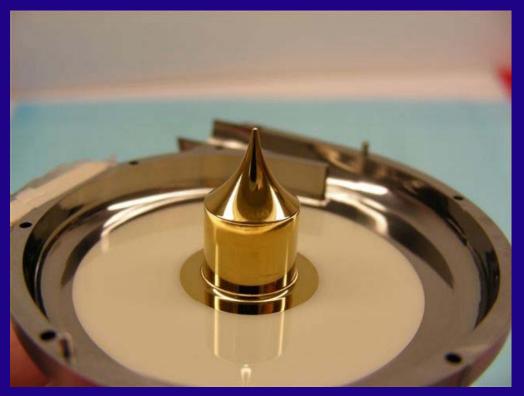
#### Summary of Overall Outcomes of First 23 Implants

#### At 180 days

N = 23		
Ongoing or Transplanted	21	
- Transplanted (earliest POD 157)	2	
- Ongoing		
>180 days	17	
<180 days	2	
Expired	2	
	(13, 84 days)	
- Sepsis	2	

#### **Explanted Pump From First Implant**

#### Pathology pictures after 427 days





Pump housing

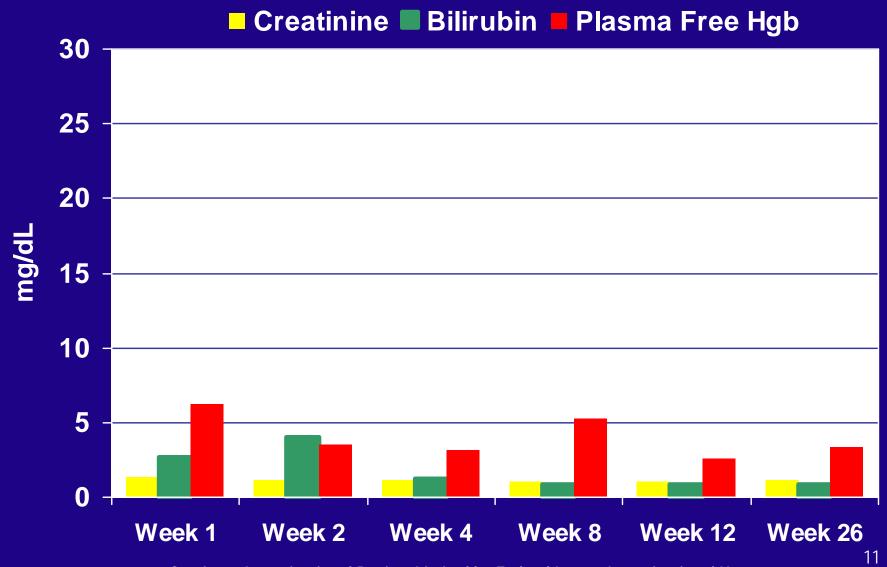
Impeller

Courtesy of Texas A&M University by Dr. Fred Clubb, D.V.M., Ph.D., DACLAM, Clinical Professor

### Hemodynamic Changes After LVAD Implant

Parameter	Pre	POD 1	POD 2
MAP (mmHg)	79 <u>+</u> 10.2	81 <u>+</u> 15.4	75 <u>+</u> 12.2
PAP (mmHg)	37 <u>+</u> 12.2	27 <u>+</u> 7.3	25 <u>+</u> 7.6
PCWP (mmHg)	23 <u>+</u> 7.2	12.2 <u>+</u> 3.1	11.6 <u>+</u> 2.6
RAP (mmHg)	13 <u>+</u> 5.7	12.6 <u>+</u> 2.1	11.4 <u>+</u> 4.2
CI/Flow Index L/min/m <sup>2</sup>	1.9 <u>+</u> 0.5	3.2 <u>+</u> 0.48	2.9 <u>+</u> 0.45

## Key Laboratory Parameters



#### Adverse Events In First 23 Implants

At 180 days

Complication	Patients N	Events N	Event Rate per pt yr
Infections (exit site)	3	3	0.28
Bleeding (requiring re-o	peration) 3	4	0.37
Respiratory Dysfunction	4	4	0.37
Renal Dysfunction	3	3	0.28
Right Heart Failure	1	1	0.09
Device Replaced**	2	2	0.19

<sup>\*\*</sup>Manufacturing change implemented. Both patients received new pumps & ongoing >180 days

#### Neurological Adverse Events In First 23 Implants

At 180 days

Complication	Patients N	Events N	Event Rate per pt yr
TIA (POD 15)	1	1	0.09
Stroke (POD 8, 12)			
-Ischemic*	2	2	0.19
-Hemorrhagic	0	0	0.00
Recovered	3		
Expired	0		

<sup>\* -</sup> one patient with HIT

## Conclusions From First 23 Human Implants (180 days)

- Successful Pericardial Placement of the HeartWare® LVAD
- 91% survival at 180-days (trial endpoint met)
- Comparable Adverse Event profile
- Able to support a broad range of patient needs
  - •Mean flow of 6 liters per minute

# Post-180 Days Summary of Overall Outcomes of First 23 Implants

as of February 22, 2008

N = 23 (mean duration of support 272 days)		
Ongoing or Transplanted	19	
- Transplanted (earliest POD 157)	6	
- Ongoing		
>180 days	11	
<180 days	2	
Longest Duration of Support	466 days	
Recovered / Explanted	<b>1</b> (267 days)	
Expired	<b>3</b> (13, 84 & 203 days)	
- Sepsis	2	
- ICB	<b>1</b>	

Caution -- Investigational Device, Limited by Federal Law to Investigational Use

#### Conclusions From First 23 Human Implants

(data through Feb 22, 2008)

Successful Pericardial Placement of the HeartWare® LVAD

No pump pocket
No intrathoracic infections
No cannula obstructions

- 91% survival at 180-days
- Comparable Adverse Event profile
- Able to support a broad range of patient needs
  - Mean flow of 6 liters per minute
- Potential for long term support

Total duration of support - 17.5 years Mean support - 272 days 8 patients supported > 1 year