

## ASX ANNOUNCEMENT 31 March 2009

# First International Sales of HeartWare® Ventricular Assist System and US Clinical Trial Enrolment Update

**Framingham, MA and Sydney, Australia, 31 March 2009** – HeartWare International, Inc. (NASDAQ: HTWR - ASX: HIN) today announced that it had commenced international sales of the HeartWare<sup>®</sup> Ventricular Assist System, with the Company having sold systems in both Europe and Australia over recent weeks.

In Europe, receipt of CE Mark allows the system to be sold as an approved medical device. In Australia, prior to the system being approved by the Therapeutic Goods Administration (TGA), the system is being made available to hospitals at normal commercial pricing under the TGA's Special Access Scheme. The first international sale was made to St Vincent's Hospital in Sydney, Australia in mid February. The first sale in Europe was to Hannover Medical Center, Germany.

The company's U.S. clinical trial has now enrolled 17 patients. Implants have been conducted at 7 centers, including Washington Hospital Center, Jewish Hospital Louisville, Northwestern Memorial Hospital, The University of Michigan Medical Center, The Cleveland Clinic, Ohio State Medical Center and Penn State Hershey Medical Center.

"It is pleasing to witness momentum building in our U.S. clinical trial in concert with our first international commercial revenues," said HeartWare CEO, Doug Godshall. "We expect to see revenues continue to build month to month as we accelerate international commercial activity and as the number of active U.S. clinical sites continues to increase."

#### **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<sup>®</sup> Ventricular Assist System features the HVAD<sup>™</sup> 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.