



**ASX ANNOUNCEMENT  
5 December 2008**

**Successful Completion of International Clinical Trial  
50 Patients Enrolled**

**Framingham, MA and Sydney, Australia, 5 December 2008** – HeartWare International, Inc. (ASX: HIN) today announced the completion of patient enrolment in the international clinical trial of the HeartWare® Ventricular Assist System (HVAD™). A total of 50 patients were enrolled in the trial across 5 participating centres in Europe and Australia.

The 50 patients who have been implanted with the HeartWare® HVAD have been supported by the system for an average of 250 days each. A total of 12 patients have received heart transplants after being supported for an average of 266 days each. Three patients had their device removed after recovery of their heart function. Four patients died on support within the first 180 days of their implant. One additional patient death occurred beyond 180 days. 31 patients have successfully met the endpoint of the trial (180 days or transplant). A further 15 patients remain on support but have yet to reach the 180 day endpoint.

HeartWare President and CEO, Doug Godshall said, “With 50 patients implanted in our international trial, representing a cumulative support period of almost 35 years, we are becoming increasingly confident of the performance of this device given our positive early clinical data. At the ISHLT conference in April this year Dr Georg Wieselthaler presented data from HeartWare’s first 23 patients, showing a survival to endpoint in excess of 90%. It is pleasing that this unusually high rate of success continues to hold true over the larger patient group, particularly in light of the relatively small number of transplants that have occurred.”

HeartWare’s application to apply the CE Mark to the HeartWare® System was based on data from the first 25 patients and this data is presently under independent clinical review. HeartWare reiterates its expectation that CE Mark will be granted in the weeks ahead. With the completion of the international trial, HeartWare’s two core areas of focus are now to manage the Company’s US clinical trial and, in parallel, to drive an effective commercial launch and subsequent rollout in Europe and Australia following receipt of CE Mark.

**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. HeartWare’s HVAD™ pump is the only full-output pump designed to be implanted in the chest, 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.