ASX ANNOUNCEMENT
1 November 2007

Submission for Investigational Device Exemption ("IDE")

HeartWare has today filed its submission for Investigational Device Exemption ("IDE") with the US Food and Drug Administration ("FDA").

The IDE submission is the key regulatory filing with the FDA and represents the most important regulatory milestone in the Company's history. The submission follows a long period of dialogue with the FDA and amounts to a synthesis of what the Company has learned about the HeartWare® LVAD System, including all pre-clinical, clinical and technical data.

HeartWare's IDE submission relates to the proposed use of the HeartWare® LVAD System in a Bridge to Transplant indication. The purpose of the proposed study is to evaluate the safety and effectiveness of the HeartWare® LVAD System in patients eligible for cardiac transplantation with refractory, advanced heart failure. The proposed primary endpoint is survival to anesthetic induction for heart transplantation, survival to explant for myocardial recovery, or survival to 180 days on device support, whichever occurs first.

Having submitted the IDE, we anticipate a period of communication with the FDA, during which clarification may be sought and additional information requested, a communication process that takes place in 30-day cycles. In advance of the FDA submission, the Company engaged in detailed and open dialogue with the FDA which we hope will have prospectively addressed many of the FDA's questions. Our best estimate at this time is that we would receive IDE approval and be able to start our US clinical trial early in 2008.

For further information:

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