

HeartWare Completes Enrollment In 450-Patient Pivotal Destination Therapy Clinical Trial

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FRAMINGHAM, Mass. and SYDNEY, May 8, 2012 /PRNewswire/ -- HeartWare International, Inc. (Nasdaq: [HTWR](#) [1]; ASX: HIN), a leading innovator of less invasive, miniaturized circulatory support technologies that are revolutionizing the treatment of advanced heart failure, today announced that enrollment is complete in ENDURANCE, the Company's pivotal Destination Therapy clinical study to evaluate the use of the HeartWare® Ventricular Assist System in patients with end-stage heart failure.

"Completing enrollment in this, the largest head-to-head ventricular assist device clinical trial to date, is a major achievement and we look forward to following this Destination Therapy patient population to primary endpoint over the next two years," said Doug Godshall, President and Chief Executive Officer. "We are thankful for the diligence of the investigators and site coordinators at the 50 U.S. hospitals in the ENDURANCE study. With enrollment of the study complete, we are pleased to report that more than 2,000 end stage heart failure patients globally have received the HeartWare Ventricular Assist System."

ENDURANCE is a randomized, controlled, unblinded, multi-center clinical trial to evaluate the use of the HeartWare Ventricular Assist System as a Destination Therapy in advanced heart failure patients. The non-inferiority study enrolled 450 patients with end-stage heart failure who have not responded to standard medical management and who are ineligible for cardiac transplantation. Patients were randomly selected to receive either the HeartWare Ventricular Assist System or, as part of a control group, any alternative LVAD approved by the FDA for Destination Therapy, in a 2:1 ratio. Each patient receiving the HeartWare Ventricular Assist System or control LVAD will be followed to the primary endpoint at two years, with a subsequent follow-up p

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[1] <http://studio-5.financialcontent.com/prnews?Page=Quote&Ticker=HTWR>

[2] <http://www.bio-medicine.org/medicine-technology-1/HeartWare-Completes-Enrollment-In-450-Patient-Pivotal-Destination-Therapy-Clinical-Trial-25413-1/>

