HeartWare Receives 54-Patient Allotment From FDA Under Continued Access Protocol for Pivotal U.S. Bridge-to-Transplant Clinical Trial

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FRAMINGHAM, Mass. and SYDNEY, March 16, 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 the U.S. Food and Drug Administration (FDA) has approved an IDE (Investigational Device Exemption) Supplement that allows HeartWare to enroll a fourth allotment, of 54 additional patients, in its "ADVANCE" bridge-to-transplant clinical trial under a Continued Access Protocol (CAP). In three prior CAP allotments granted by FDA, 202 patients were enrolled between April 2010 and December 2011.

HeartWare's ADVANCE clinical trial is an FDA approved IDE study designed to evaluate the HeartWare® Ventricular Assist System as a bridge to heart transplantation for patients with end-stage heart failure. Under the ADVANCE study, 140 patients at 30 U.S. clinical sites received HeartWare HVAD® pumps, making it the largest bridge-to-transplant pivotal trial to date. HeartWare submitted to the FDA a Pre-Market Approval (PMA) application seeking approval of the HeartWare System for the bridge-to-transplant indication in December 2010, and an FDA Circulatory System Devices Panel will review the PMA application on April 25, 2012.

Patient enrollment under the new CAP can now commence at the 30 centers participating in the ADVANCE clinical trial, subject to Institutional Review Board approvals at those sites.

About HeartWare International
HeartWare International develops and manufactures miniaturized implantable heart pumps, or ventricular assist devices, to treat Class IIIB / IV patients suffering from advanced heart failure. The HeartWare® Ventricular Assist System features the HVAD® pump, a small full-output circulatory support de
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