HeartWare Files PMA Application for FDA Approval of the HeartWareÃ,® Ventricular Assist System for a Bridge-to-Transplant Indication

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FRAMINGHAM, Mass. and SYDNEY, Dec. 28, 2010 /PRNewswire/ -- HeartWare International, Inc. (Nasdaq: HTWR [1]; ASX: HIN) today announced that it has submitted a Pre-Market Approval (PMA) application to the U.S. Food and Drug Administration (FDA) for the HeartWare® Ventricular Assist System as a bridge to heart transplantation for patients with end-stage heart failure.

The PMA submission includes data from HeartWare's pivotal ADVANCE clinical trial, 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 ADVANCE, 140 patients at 30 hospitals in the U.S. received the HeartWare investigational device between August 2008 and February 2010. The final implant in ADVANCE was performed in February 2010, and the last follow-up evaluation at 180-days was in August 2010.

Previously announced results for ADVANCE showed that 92% of the investigational device patients met the per protocol primary endpoint of the trial, which was defined as alive on the originally implanted device, transplanted or explanted for recovery at 180 days. Additionally, ADVANCE demonstrated that 94% of the investigational device patients enrolled in the study achieved a survival endpoint at 180 days.

Results for the comparator arm of the study, derived from 499 contemporaneous patients from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) demonstrated 90% success of the primary endpoint at 180 days. Based on these results for the primary endpoint of the ADVANCE study, noninferiority of the investigational device was established [p<0.0001].

About HeartWare InternationalHeartWare International develops and manufactures miniaturized implantable heart pumps, or ventricular assist devices, to treat Class IIIB / IV p
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SOURCE [2]

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Links:
[1] http://studio-5.financialcontent.com/prnews?Page=Quote&Ticker=HTWR
[2] http://www.bio-medicine.org/medicine-technology-1/HeartWare-Files-PMA-Application-for-FDA-Approval-of-the-HeartWare-AE-Ventricular-Assist-System-for-a-Bridge-to-Transplant-Indication-13508-1/