HeartWare Receives Conditional Approval From FDA to Enroll Supplemental Patient Cohort in Destination Therapy Trial

PR Newswire

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 granted conditional approval to an IDE (Investigational Device Exemption) Supplement that allows HeartWare to commence enrollment in an additional patient cohort for ENDURANCE, the Company's pivotal, Destination Therapy clinical study.

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 completed enrollment of 450 patients with end-stage heart failure who had not responded to standard medical management and who were 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.

The primary endpoint of the trial is stroke-free (Modified Rankin Score $\geq$ 4) survival at two years, defined as alive on the originally implanted device, transplanted or explanted due to patient recovery. Secondary endpoints include adverse events such as bleeding and infection, as well as functional status, hospitalization, assessment of neuro-cognitive function and patient quality of life. The final implant was conducted in May 2012, which will result in the final patient reaching the two-year follow up point in May 2014.

Supplemental Patient Cohort
FDA granted conditional approval to a protocol designed to confirm observations from ENDURANCE that sites adhering to more regular monitoring and management of patient blood pressure witnessed a notably lower incidence of neurological events.

In this supplemental cohort, HeartWare will enroll up to an additional 240 HeartWare HVAD patients, as well as up to an additional 120 control patients using a randomization scheme consistent with the ENDURANCE protocol. Patients will be followed for 12 months after implant. HeartWare intends to incorporate the data from this new cohort into an anticipated Pre-Market Approval (PMA) Application seeking approval of the HeartWare System for the Destination Therapy indication.

Patient enrollment in this supplemental cohort can commence at the 50 centers participating in the ENDURANCE clinical trial, following edits to the protocol as

prescribed by FDA and Institutional Review Board approvals at each of the centers.

On November 20, 2012, FDA granted approval of the HeartWare System for the Bridge-to-Transplant indication. Concurrent with approval, the Company commenced a post-approval study (PAS) to assess device performance in a real-world setting. HeartWare's PAS is a registry consisting of 600 patients who receive an HVAD and an additional 600 control patients derived from a contemporaneous group of continuous flow, intra-corporeal LVAD patients entered into the INTERMACS database. HeartWare expects enrollment for both arms of the PAS will be complete by year's end.

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-support circulatory assist device designed to be implanted next to the heart, avoiding the abdominal surgery generally required to implant competing devices. The HeartWare System is approved in the United States for the intended use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure, has received CE Marking in the European Union and has been used to treat patients in 30 international countries. The device is also currently the subject of a U.S. clinical trial for destination therapy. For additional information, please visit the Company's website at www.heartware.com [2].

Source URL (retrieved on *03/11/2014 - 7:16pm*):
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