# FDA advisors: Benefits trump risks for HeartWare ventricular assist pump

APR 25, 2012 Steve Stiles

**Gaithersburg, MD** – An **FDA** advisory panel voted nine to two that the benefits of the HeartWare ventricular assist system (VAS) outweigh the risks for bridge-to-transplant therapy in patients with intractable heart failure [1]. If the agency goes with the panel's recommendation, it will approve the device, probably later this year.

The device is a portable, self-contained, electrically powered ventricular assist pump, much like the **HeartMate II** (Thoratec), and ultimately intended for the same kind of patients.

The Circulatory System Devices Panel had essentially one major HeartWare VAS trial on which to base its call. The HeartWare device in 140 patients showed itself noninferior ($p<0.001$) to other contemporary pumps in the nonrandomized ADVANCE trial, a comparison with patients predominantly with the Heartmate II device in the INTERMACS registry, as covered by heartwire. The composite rate of survival, explantation, or transplantation at six months reached 92% for the ADVANCE patients and 90% for the INTERMACS controls.

But cautions about clots arose as well: ADVANCE patients plus an additional 110 patients in an extension trial showed a 6.4% rate of thrombus development within the pump. The rate on a per-patient-year basis was 9.2%.

The morning's presentation by the FDA made it clear that reviewers were concerned about that possible elevated thrombosis risk but also that the agency might be willing to go ahead with approving the HeartWare pump. An agency representative stated to the panel that it was "interested in a rigorous postapproval study" and outlined three pitches from the company for the design of such a study focusing on safety.

One area of sharp disagreement: whether the still-young INTERMACS registry made for an adequate control group for a safety evaluation. A number of panelists said they were comfortable moving forward with the data available. **Dr Jeffrey Borer** (SUNY Downstate Medical Center, New York NY), for example, felt that the stroke rates were similar to HeartWare data in the literature outside of ADVANCE and perhaps data from the HeartMate II and seemed satisfied with that.

But others slammed the lack of a real, contemporaneous comparator group in ADVANCE and seemed ready to send the device maker (also called HeartWare) back to get more direct comparative-safety data. **Dr John C Somberg** (Rush University Medical Center, Lake Bluff, IL), said the admittedly small stroke rate in ADVANCE was still "worrisome" and "you can't judge safety" without a direct comparator group.

He and panelist **Dr Scott Evans** (Harvard School of Public Health, Boston, MA), were the only nay votes on the panel.

Acting panel chair **Dr Richard L Page** (University of Wisconsin School of Medicine and Public Health, Madison) called the HeartWare device "a real advance in technology" and said its "safety signal is okay." But he slammed what he and others saw as a poorly conducted ADVANCE trial, calling its data "a mess."

And panelist **Dr Gregory Dehmer** (Texas A&M University, Temple) said the trial's data "have more holes than Swiss cheese."

A destination-therapy trial of the HeartWare device, called ENDURANCE, is under way with **Dr Mariell Jessup** (University of Pennsylvania School of Medicine, Philadelphia) and **Dr Francis Pagani** (University of Michigan, Ann Arbor) as co-principal investigators.

**Source**

1. HeartWare. FDA advisory committee votes in favor of HeartWare ventricular assist system as bridge to transplant for patients with end-stage heart failure [press release]. April 25, 2012. Available here.

**Related links**

- Life on a 12-hour charge: Seeking community in the LVAD age
  [*heartwire* > *Features*; Mar 19, 2012]
- 3B or not 3B? Should patients get an LVAD before reaching end-stage HF?
  [*Heart failure* > *Heart failure*; Jan 30, 2012]
- Pumped about LVADs: Many eligible HF patients would "definitely" consider one
  [*Heart failure* > *Heart failure*; Sep 20, 2011]
- Change in anticoagulation reduces thrombi in HeartWare trials
  [*Heart failure* > *Heart failure*; Oct 07, 2011]