

# **DRAFT**

**FDA Questions for Circulatory System Devices Panel  
June 23, 2005  
H040006  
Abiomed AbioCor Implantable Replacement Heart**

## **Evaluation of Patient Selection and Inclusion/Exclusion Criteria**

A clinical Feasibility Study for the AbioCor was approved in January 2001 for up to 15 patients. This study was to assess the safety and probable benefit of the AbioCor as a potential therapy for those cardiac patients whose therapeutic options had been exhausted.

- 1. The Feasibility Study was designed to include up to 6 sites. Most of the patients (12/14) were implanted at two centers (University of Louisville/Jewish Hospital with 7 patients and Texas Heart Institute with 5 patients). Please discuss whether there is reasonable assurance that the results from Jewish Hospital and Texas Heart Institute can be generalized to United States transplant centers that would implant this device.**
- 2. Please discuss whether the Feasibility Study inclusion criteria defined the patient population who should be candidates for the device.**

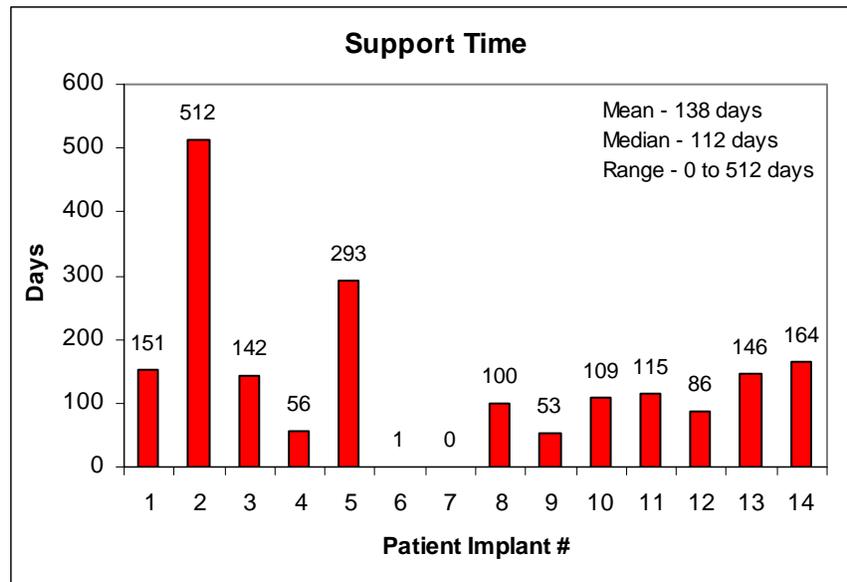
## **Evaluation of Safety**

- 3. Does the frequency of any serious adverse events (e.g., neurological or bleeding) in Table 2.11 Adverse Event Rate (page 21, section 2.3.5, Clinical Summary) raise significant clinical concerns?**
- 4. Considering the bleeding and stroke complication rates seen in the Feasibility Study, please discuss whether you think that the proposed anticoagulation protocol (page 71, section 3.31, Post Approval Study) is appropriate for the intended population.**

## **Evaluation of Probable Benefit**

An HDE application must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

Patients implanted with the Abiomed AbioCor were ineligible for cardiac transplantation for various reasons (e.g. age, renal insufficiency, pulmonary hypertension, etc). The chart below shows the time on device for each patient.



5. **The study design did not prospectively include a formal measurement of health status. Of the 14 patients enrolled in the Feasibility Study, 2 died in the operating room, 10 did not leave the hospital (except for day passes for 4 patients), 1 was discharged to a nearby hotel and 1 was discharged home. Please discuss whether you believe the activities that patients undertook equate to meaningful improvement in quality of life.**
  
6. **Please discuss whether you believe the probable benefits of the AbioCor Implantable Replacement Heart outweigh the observed and potential risks associated with the device.**

### **Labeling**

One aspect of the pre-market evaluation of a new product is the review of its labeling. The labeling must define which patients are appropriate for treatment, identify potential adverse events with the use of the device, and explain how the product should be used to maximize clinical benefit and minimize adverse events. If you recommend approval of the device, please address the following questions regarding product labeling.

The proposed indication for use of this device is for use in severe end stage heart disease patients who:

- are less than 75 years old,
- are not transplant candidates at the time of assessment,
- require multiple inotropic support,

- are in biventricular failure not treatable by LVAD destination therapy,
- are not weanable from biventricular support if on such support and not awaiting transplant.

**7. With regards to the Indications for Use, labeling, and clinical experience, please comment on the following:**

- a. Do the Indications for Use adequately define the patient population studied and for which the device will be marketed? If not, how should the Indications for Use be modified?**
- b. Are there any additional warnings, precautions, or contraindications that you think should be included in the labeling to assist practitioners in determining the need for biventricular support?**

### **Training**

The sponsor has included a summary of their proposed physician training program in section 10 of the Instructions for Use. The physician's Training Manual will be used for all new physicians who will be implanting the AbioCor Implantable Replacement Heart.

- 8. Please comment on the adequacy of the proposed physician training plan, as described in the panel package (page 39, section 10, Instructions for Use). Are there additional recommendations that should be included in the proposed physician training plan or to a transplant cardiologist on the selection of patients?**

### **Postmarket Approval Study**

The sponsor has proposed a Post Approval Study to continue to monitor the safety and probable benefit of the AbioCor while it is being introduced commercially into qualified centers. Safety parameters such as frequencies of neurological events, infection, bleeding, renal dysfunction, liver dysfunction, and respiratory events would be tracked. Probable benefit parameters to be evaluated include duration of support, number of patients discharged from the hospital, frequency of excursions while in the hospital, and normal life activities for discharged patients. The sponsor proposes to follow 20 patients for a 6-month period.

- 9. Please comment on the proposed plan for postmarket data collection submitted by the Sponsor (page 65, Post Approval Study). In addition to survival and serious adverse events should data on quality of life or functional status be collected using formal instruments; if so, which instruments would be appropriate?**