FDA Approves First Artificial Implantable Heart

BY ALICIA AULT
Associate Editor, Practice Trends

The Food and Drug Administration has given a limited approval to the first totally artificial implantable heart, Abiomed Inc.'s AbioCor.

The AbioCor was approved under a humanitarian device exemption. Under an HDE, the device has to show a "probable benefit," a less onerous standard than would be required under a premarket approval application, said Dr. Daniel Schultz, director of the FDA's Center for Devices and Radiological Health. The approval limits use of the device to no more than 4,000 patients each year.

Both the FDA and Danvers, Mass.–based Abiomed expect there to be a very limited patient population. The $250,000 device is indicated in patients with severe right and left ventricular failure, who are not eligible for transplant and who have a life expectancy of less than 1 month. Patients also may have pulmonary hypertension refractory to pharmacologic management, significant aortic valve regurgitation, mechanical valve prosthesis, intractable life-threatening arrhythmias, ventricular septal rupture, or failed transplant.

Most likely, only men and larger women would be eligible to receive the 2-pound device.

In Abiomed's 14-patient study, patients were an average 6 feet tall and weighed 170-180 pounds, Dr. Bram Zuckerman, director of FDA's Division of Cardiovascular Devices, said in a briefing with reporters.

The AbioCor is the result of almost 30 years of research and development, much of which was supported by the National Heart, Lung, and Blood Institute.

"The approval of the totally implanted artificial heart is a significant milestone as there are few options for heart failure patients with the most severe form of the disease and who are in critical need," the NHLBI's director, Dr. Elizabeth G. Nabel, said in a statement.

The implanted system consists of an artificial heart, a battery, and two controllers that receive information via radio waves from an external controller and power source. Patients can be away from a power source for up to 1 hour—an important quality-of-life consideration that influenced the FDA's approval decision, Dr. Zuckerman said.

In Abiomed's original study—in 14 patients from 2001 to 2004—6 of the 12 patients who survived surgery were ambulatory and 4 made excursions outside of the hospital. One patient was discharged to home. The mean life span on AbioCor was 5 months, but the range was 53-512 days.

"Just being able to ambulate, to clearly communicate with loved ones, and to celebrate family events is, in the view of many patients and family members, a significant improvement in quality of life," Dr. Zuckerman said.

The FDA approval comes despite a 7-6 vote against approval by an FDA advisory panel in June 2005. The committee had concerns about clotting and stroke risk.

After the first five patients were implanted and died, Abiomed conducted autopsies that led the company to slightly redesign the AbioCor, which was accepted by the FDA, said company chairman and CEO Michael R. Minogue in an interview. Anticoagulation continued to be a challenge in the next nine patients, however.

The company has learned that only patients who can tolerate anticoagulation therapy should receive the AbioCor, Mr. Minogue said. In a planned postapproval study, which will enroll all patients implanted with the device, the company will determine how to best manage patients and whether it can appropriately train surgeons at new clinical sites.

The first implants will occur at Jewish Hospital in Louisville, Ky., where Dr. Laman Gray, director of the division of thoracic and cardiovascular surgery at the University of Louisville, and Dr. Rob Dowling, director of the heart transplant and cardiac assist devices program at Jewish Hospital, have implanted 7 of the original 14 devices since 2001.

Both Johns Hopkins Hospital, in Baltimore, and the Robert Wood Johnson University Hospital, in New Brunswick, N.J., also have entered into letters of intent to implant the AbioCor. Mr. Minogue said he expects training at these facilities to take at least 8-10 months.

The company aims to bring 5-10 centers on line. The AbioCor 2 is currently in development. It will be 30% smaller, have a different pump system, and will last up to 5 years, Mr. Minogue said. ■