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FOR MORE INFORMATION:
Linda McGinity Jackson, Jewish Hospital:
502-561-5447
Kathy Keadle, University of Louisville: 502-561-5447
Tess Donovan, Brodeur Worldwide for ABIOMED:
617-587-2981

LOUISVILLE PHYSICIANS DISCUSS FDA APPROVAL FOR ABIOMED TO BEGIN HUMAN IMPLANTS OF ARTIFICIAL HEART

(LOUISVILLE, Ky.) -- Physicians from the University of Louisville and Jewish Hospital gathered today to discuss the recent announcement by ABIOMED, Inc., that it had received permission from the Food and Drug Administration (FDA) to begin the initial clinical trial of its AbioCor Replacement Heart.

Jewish Hospital, in partnership with the University of Louisville, is among a select group of five U.S. medical centers that have been working with ABIOMED to further develop the totally implantable replacement device.

"We have been working with ABIOMED for the last three years on this project. We believe this device is very reliable and are pleased that the FDA has approved the next phase of this project," said Laman A. Gray, Jr., M.D., Co-Principal Investigator. "While we have received the go-ahead, we do not know when the first procedure will occur because there are still several minor steps that must be taken internally before the first procedure takes place. This is the most sophisticated medical device that has ever been developed for implantation. We have been extremely methodical and cautious in our research to date and will continue to exercise the same restraint as we approach an actual implantation."

The AbioCor, the world's first implantable artificial heart, is intended as a permanent replacement, not a bridge, for end-stage heart failure patients who are at risk of imminent death, are not transplantable, and cannot be helped by other available therapies. These patients are not candidates for transplant and cannot be helped by any other available therapy.

"This technology could be the next critical step in saving patients with end-stage heart disease and no other chance for survival," Robert Dowling, M.D., Co-Principal Investigator explains. "The AbioCor heart replacement device could be a permanent solution for these patients, giving them another opportunity for an extended life."

The Investigational Device Exemption (IDE) granted by the FDA allows for the implantation of the AbioCor in the first five patients of the clinical trial. Success of the trial will be based upon periodic review of the survival of AbioCor patients and their quality of life as measured by a variety of assessment instruments previously validated for end stage heart failure patients.

"Jewish Hospital is proud to continue being part of ground breaking research which will impact patients in this region and around the world," said John Oldfather, Ph.D., Vice President and Administrator of the Jewish Hospital Heart and Lung Institute. "Our commitment to this type of research is unparalleled, as evidenced by our long relationship with the University of Louisville."

Jewish Hospital is one of the top ten cardiac centers in the United States, and along with the University of Louisville, is dedicated to excellence in clinical care, research and education. Jewish Hospital is one of only a few facilities in the world offering a complete range of surgical treatments for end-stage heart failure, including transplantation, ventricular assist devices, cardiomyoplasty and ventricular remodeling.

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