

FOR IMMEDIATE RELEASE
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ABIOMED gets OK from FDA to begin human implants of artificial heart

(Danvers, Mass.) -- ABIOMED Inc. (NASDAQ:ABMD), a leader in heart assist and replacement technology, announced today that it has received permission from the Food and Drug Administration (FDA) to begin the initial clinical trial of its AbioCor (TM) Replacement Heart.

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

The investigational device exemption 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. FDA's letter authorizing the trial requires ABIOMED to respond to a number of questions within 45 days, but initiation of the trial is not contingent upon those responses.

"This is a great day for everyone who has worked with so much dedication and spirit to make the AbioCor a reality," said Dr. David M. Lederman, ABIOMED's president and chief executive officer. "Dozens and dozens of people have been major contributors to ABIOMED's effort, under the leadership of chief scientific officer Dr. Robert T.V. Kung, chief regulatory officer Janice T. Piasecki, and AbioCor program director and chief engineering officer William J. Bolt. We will take a moment to celebrate, but only a moment. This FDA action will further energize us as we make final preparations, at ABIOMED and at the collaborating centers, for the initial human implants of the AbioCor.

"Our IDE submission for the AbioCor clinical trial was extraordinarily comprehensive," Dr. Lederman continued, "totalling thousands of pages of highly technical material in 18 volumes. It is a testimony to the commitment and professionalism of the FDA staff that they reviewed this materials,

submitted to them just before the December holiday, so quickly, thoroughly and expertly. Our interactions with members of FDA's Office of Device Evaluation over the past several years have given us important direction in improving our testing protocols and have thereby helped us to reach this landmark point in AbioCor's development.

"We have benefited immensely from the enthusiastic support and the many contributions of all of our collaborating centers and the members of our medical replacement heart advisory board. Special mention needs to be made of Dr. O.H. (Bud) Frazier of the Texas Heart Institute, who has lent his clinical insight to the AbioCor program for over a decade. The team at the University of Louisville and Jewish Hospital in Louisville, Ky., led by Dr. Laman A. Gray and Dr. Robert D. Dowling, has made major contributions over the past three years to the advancement of our preclinical testing program and to our current state of preparedness."

He concluded: "We thank and acknowledge the vital support and encouragement from the National Heart, Lung and Blood Institutes, who have sponsored the development of AbioCor since 1988."

Based in Danvers, Mass., ABIOMED Inc. is a leading developer, manufacturer and marketer of medical products designed to assist or replace the pumping function of the failing heart. The company's AbioCor implantable replacement heart is in an advanced stage of development and preparing for initial human trials. ABIOMED currently manufactures and sells the BVS(R), a temporary heart assist device, for the support of all patients with failing but potentially recoverable hearts.

The company's AbioCor performance, timing and results may differ materially based on a number of factors, including uncertainty of successfully meeting product development milestones, manufacturing milestones in light of complex manufacturing processes, obtaining and maintaining regulatory approvals for clinical trials, ability to train the clinical teams on a timely basis and to obtain IRB approvals from the participating institutions, unproven markets for products under development, dependence on key personnel, competition and technological change, uncertainty in the ability to recruit required personnel on a timely basis, government regulations, dependence on limited sources of supply, dependence on third-party reimbursement, potential inadequacy of product liability insurance, dependence on patents and proprietary rights and other risks detailed in the company's filings with the Securities and Exchange Commission. Investors are cautioned that all such statements involve risks and uncertainties. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. The company undertakes no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

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