Abiomed Impella 2.5™ and Impella 5.0™ Heart Pumps Receive Regulatory Approval From Japan Ministry of Health, Labor & Welfare

First ever percutaneous heart pump approval in Japan

DANVERS, Mass., Sept. 27, 2016 (GLOBE NEWSWIRE) -- Abiomed, Inc. (NASDAQ:ABMD), a leading provider of breakthrough heart support technologies, announced today that the Impella 2.5 and Impella 5.0 heart pumps received Pharmaceuticals and Medical Devices Agency (PMDA) approval from the Japanese Ministry of Health, Labor & Welfare (MHLW) for the treatment of drug-resistant acute heart failure.

With this approval, these are the first and only percutaneous temporary ventricular support devices that are PMDA-approved in Japan deemed safe and effective in the indication, as stated:

This product is a catheter-styled blood pump, used for drug-resistant acute heart failure, such as cardiogenic shock, to support systemic circulation by placing the device at left ventricle from a femoral artery insertion and expelling blood directly from left ventricle to ascending aorta.

Acute heart failure is a sudden and temporary morbid state in which various factors such as acute myocardial infarction, ischemic heart disease and/or reduced cardiac function may prevent the delivery of oxygen to the heart and other vital organs, resulting in the rapid deterioration of heart function. In Japan, it is estimated that 50,000 acute heart failure patient opportunities exist in the country. In the United States, this patient population is included in the high risk urgent PCI and cardiogenic shock indications. The Japanese indication states that the pump can be used for a duration determined by the physician based on the clinical needs of the patient.

Japanese researchers and physicians have studied hemodynamic science and heart recovery for decades and have been leaders in the field for high-risk revascularization in the cath lab. Due to cultural and quality of life expectations and an aging society, Japan is the second largest medical device market in the world. Percutaneous options for revascularization are preferred over sternotomy or heart transplant alternatives because of the cultural interest in treating patients minimally invasively. For chronic heart failure patients, implantable LVAD devices or heart transplant remain an option at very limited sites for patients that do not have the ability to achieve native heart recovery.

Abiomed is opening a larger office in Tokyo, recruiting for clinical support staff, and submitting for Japanese reimbursement in the near future. A rigorous on-site training and certification program is planned including physician proctoring. Abiomed plans to start supporting patients in Japan during the fourth quarter of FY ‘17 and will be investing in distribution, but does not expect material revenue until FY ‘18 given the controlled roll-out. Additionally, the Company is planning future discussions with the PMDA relating to potential regulatory reviews of the Impella CP and Impella RP later this fiscal year.

"This approval marks a significant milestone to provide Impella hemodynamic support for heart failure patients. We commend the dedication of Japanese physicians and regulatory bodies in searching for new treatment options to improve patient outcomes and quality of life, and enable cost-effective solutions," said Michael R. Minogue, President, Chairman and Chief Executive Officer of Abiomed. “We are pleased that the field of heart recovery with percutaneous heart pumps has begun in Japan.”

ABIOMED DATA SUPPORTING APPROVAL
Impella clinical data supported an overall high safety profile and recovery of acute heart failure with improved quality of life. The supporting data includes an FDA study and randomized controlled trial which demonstrated improvement in hemodynamics vs. IABP. The company will conduct a post-market surveillance on Impella usage.

ABOUT IMPELLA
The Impella products offer the unique ability to stabilize the patient's hemodynamics and unload the heart, which allows the muscle to rest and potentially recover its native function. Impella 2.5 received FDA PMA approval for high risk PCI in March 2015. Impella 2.5, Impella CP, and Impella 5.0 received FDA PMA approval for cardiogenic shock in the setting of acute myocardial infarction/heart attack or after heart surgery. These are the first and only percutaneous temporary ventricular support devices that are FDA-approved as safe and effective for the cardiogenic shock indication. The Impella product portfolio, which is comprised of Impella 2.5, Impella CP, Impella 5.0, Impella LD, and Impella RP, has supported over 40,000 patients in the United States.
The ABIOMED logo, ABIOMED, Impella, Impella CP, and Impella RP are registered trademarks of Abiomed, Inc. in the U.S.A. and certain foreign countries. Impella 2.5, Impella 5.0, Impella LD, and Protected PCI are trademarks of Abiomed, Inc.

ABOUT ABIOMED
Abiomed, Inc. based in Danvers, Massachusetts, with offices in Tokyo, Japan, is a leading provider of medical devices that provide circulatory support. Our products are designed to enable the heart to rest by improving blood flow and/or performing the pumping of the heart. For additional information, please visit: www.abiomed.com.

FORWARD-LOOKING STATEMENTS
This release includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "plan," "could," "may," "will," "believe," "estimate," "forecast," "goal," "project," and other words of similar meaning. These forward-looking statements address various matters including, the Company's guidance for fiscal 2016 revenue. Each forward-looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, uncertainties associated with development, testing and related regulatory approvals, including the potential for future losses, complex manufacturing, high quality requirements, dependence on limited sources of supply, competition, technological change, government regulation, litigation matters, future capital needs and uncertainty of additional financing, and the risks identified under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended March 31, 2015 and the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, each filed with the Securities and Exchange Commission, as well as other information the Company files with the SEC. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this release and the Company undertakes no obligation to update or revise any of these statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

For more information, please contact:

Ingrid Goldberg
Director, Investor Relations
978-646-1590
ir@abiomed.com