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Abiomed Impella® Therapy Receives FDA Approval for Cardiogenic Shock After Heart Attack or Heart Surgery

Entire Family of Impella Left Side Heart Pumps FDA Approved To Enable Heart Recovery

DANVERS, Mass., April 07, 2016 (GLOBE NEWSWIRE) -- Abiomed, Inc. (NASDAQ:ABMD), a leading provider of breakthrough heart support technologies, today announced that it has received U.S. Food and Drug Administration (FDA) Pre-Market Approval (PMA) for its Impella 2.5™, Impella CP®, Impella 5.0™ and Impella LD™ heart pumps to provide treatment of ongoing cardiogenic shock. In this setting, the Impella heart pumps stabilize the patient's hemodynamics, unload the left ventricle, perfuse the end organs and allow for recovery of the native heart. This latest approval adds to the prior FDA indication of Impella 2.5 for high risk percutaneous coronary intervention (PCI), or Protected PCI™, received in March 2015.

With this approval, these are the first and only percutaneous temporary ventricular support devices that are FDA-approved as safe and effective for the cardiogenic shock indication, as stated below:

> The Impella 2.5, Impella CP, Impella 5.0 and Impella LD catheters, in conjunction with the Automated Impella Controller console, are intended for short-term use (≤4 days for the Impella 2.5 and Impella CP and ≤6 days for the Impella 5.0 and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (<48 hours) following acute myocardial infarction (AMI) or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures with or without an intra-aortic balloon pump. The intent of the Impella system therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

The product labeling also allows for the clinical decision to leave Impella 2.5, Impella CP, Impella 5.0 and Impella LD in place beyond the intended duration of four to six days due to unforeseen circumstances.

The Impella products offer the unique ability to both stabilize the patient's hemodynamics before or during a PCI procedure and unload the heart, which allows the muscle to rest and potentially recover its native function. Heart recovery is the ideal option for a patient's quality of life and as documented in several clinical papers, has the ability to save costs for the healthcare system[1,2,3].

Cardiogenic shock is a life-threatening condition in which the heart is suddenly unable to pump enough blood and oxygen to support the body's vital organs. For this approval, it typically occurs during or after a heart attack or acute myocardial infarction (AMI) or cardiopulmonary bypass surgery as a result of a weakened or damaged heart muscle. Despite advancements in medical technology, critical care guidelines and interventional techniques, AMI cardiogenic shock and post-cardiotomy cardiogenic shock (PCCS) carry a high mortality risk and has shown an incremental but consistent increase in occurrence in recent years in the United States.

"This approval sets a new standard for the entire cardiovascular community as clinicians continue to seek education and new approaches to effectively treat severely ill cardiac patients with limited options and high mortality risk," said William O'Neill, M.D., medical director of the Center for Structural Heart Disease at Henry Ford Hospital. "The Impella heart pumps offer the ability to provide percutaneous hemodynamic stability to high-risk patients in need of rapid and effective treatment by unloading the heart, perfusing the end organs and ultimately, allowing for the opportunity to recover native heart function."

"Abiomed would like to recognize our customers, physicians, nurses, scientists, regulators and employees for their last fifteen years of circulatory support research and clinical applications. This FDA approval marks a significant milestone in the treatment of heart disease. The new medical field of heart muscle recovery has begun," said Michael R. Minogue, President, Chairman and Chief Executive Officer of Abiomed. "Today, Abiomed only treats around 5% of this AMI cardiogenic shock patient population, which suffers one of the highest mortality risks of any patient in the heart hospital. Tomorrow, Abiomed will be able to educate and directly partner with our customers and establish appropriate protocols to improve the patient outcomes focused on native heart recovery."

Abiomed Data Supporting FDA Approval

The data submitted to the FDA in support of the PMA included an analysis of 415 patients from the RECOVER 1 study and the U.S. Impella registry (cVAD Registry™), as well as an Impella literature review including 692 patients treated with Impella from 17 clinical studies. A safety analysis reviewed over 24,000 Impella treated patients using the FDA medical device reporting ("MDR") database, which draws from seven years of U.S. experience with Impella.

In addition, the Company also provided a benchmark analysis of Impella patients in the real-world Impella cVAD registry vs. these same patient groups in the Abiomed AB5000/BVS 5000 Registry. The Abiomed BVS 5000 product was the first ventricular assist device (VAD) ever approved by the FDA in 1991 based on 83 patient PMA study. In 2003, the AB5000 Ventricle received FDA approval and this also included a PMA study with 60 patients.

For this approval, the data source for this benchmark analysis was a registry ("AB/BVS Registry") that contained 2,152 patients that received the AB5000 and BVS 5000 devices, which were originally approved for heart recovery. The analysis examined by the FDA used 204 patients that received the AB5000 device for the same indications. This analysis demonstrated significantly better outcomes with Impella in these patients.

The Company believes this is the most comprehensive review ever submitted to the FDA for circulatory support in the cardiogenic shock population.

1. Maini B, Gregory D, Scotti DJ, Buyantseva L. Percutaneous cardiac assist devices compared with surgical hemodynamic support alternatives: Cost-Effectiveness in the Emergent Setting. *Catheter Cardiovasc Interv*. 2014 May 1;83(6):E183-92.
2. Cheung A, Danter M, Gregory D. TCT-385 Comparative Economic Outcomes in Cardiogenic Shock Patients Managed with the Minimally Invasive Impella or Extracorporeal Life Support. *J Am Coll Cardiol*. 2012;60(17_S):. doi:10.1016/j.jacc.2012.08.413.
3. Gregory D, Scotti DJ, de Lissovoy G, Palacios I, Dixon, Maini B, O'Neill W. A value-based analysis of hemodynamic support strategies for high-risk heart failure patients undergoing a percutaneous coronary intervention. *Am Health Drug Benefits*. 2013 Mar;6(2):88-99

ABOUT IMPELLA

Impella 2.5 received FDA PMA approval for high risk PCI in March 2015, is supported by clinical guidelines, and is reimbursed by the Centers for Medicare & Medicaid Services (CMS) under ICD-9-CM code 37.68 for multiple indications. The Impella RP® device received Humanitarian Device Exemption (HDE) approval in January 2015. The Impella product portfolio, which is comprised of Impella 2.5, Impella CP, Impella 5.0, Impella LD, and Impella RP, has supported over 35,000 patients in the United States.

ABOUT ABIOMED

Based in Danvers, Massachusetts, Abiomed, Inc. 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.

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