Abiomed Receives Approval for Expanded FDA Indication for Cardiomyopathy with Cardiogenic Shock

DANVERS, Mass., February 13, 2018 (GLOBE NEWSWIRE) -- Abiomed, Inc. (NASDAQ:ABMD), a leading provider of breakthrough heart support and recovery technologies, announced today that it has received an expanded 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 for heart failure associated with cardiomyopathy leading to cardiogenic shock. This approval expands the previous FDA indication for acute myocardial infarction (AMI) cardiogenic shock and post-cardiotomy cardiogenic shock (PCCS), received in April 2016.

The Impella® heart pumps are the only percutaneous temporary ventricular support devices FDA-approved as safe and effective for cardiogenic shock in the setting of cardiomyopathy, as stated below:

> The Impella 2.5, Impella CP, Impella 5.0, and Impella LD Catheters, in conjunction with the Automated Impella Controller, are temporary ventricular support devices 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 or open heart surgery, or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures.* The intent of the Impella Support Systems therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

Abiomed Data Supporting FDA Approval

The data submitted to the FDA in support of this expanded PMA indication included an analysis of 93 patients from Abiomed's FDA reviewed cVAD Registry study, as well as a comprehensive literature review including 109 patients treated with Impella from 32 clinical publications. This clinical data is reinforced by prior FDA studies demonstrating the safety and effectiveness of Impella support in both elective and emergent patient populations. This cardiomyopathy submission includes real world safety data analysis required under FDA's MDR process incorporating over 50,000 patients treated from 2008 to 2017. Additionally, the cVAD registry collects data on more than 1,000 data elements and is guided by an independent physician steering committee.

Prior publications on Impella heart pump utilization in cardiogenic shock patients have been published in *JACC* (National Trends in the Utilization of Short-Term Mechanical Circulatory Support)[1] and the *Journal of Interventional Cardiology* (Use of Impella 2.5 in Acute Myocardial Infarction Complicated by Cardiogenic Shock)[2] representing nearly 12,000 Medicare/insurance patients and 154 cVAD Registry patients respectively.

Cardiomyopathy Facts and Statistics

Cardiomyopathy is a disease of the heart muscle that can lead to cardiogenic shock, a life-threatening condition in which the heart is unable to pump enough blood to support the body's vital organs. In the U.S. alone, cardiomyopathy causes 1.8 million hospitalizations per year and carries a 30% one year mortality rate after hospital admission[3]. Cardiomyopathy has annual Medicare costs of approximately $20 billion[4] and is the number one cause of hospitalizations and length of stay in patients greater than 65 years old[5].

Myocarditis, is an acute form of cardiomyopathy and is sometimes identified as idiopathic cardiomyopathy. Myocarditis impacts a younger population of patients where it is estimated to cause 46% of dilated cardiomyopathy incidents in the United States. Myocarditis can be caused by a virus and

impacts all age groups. It frequently leads to cardiac dysfunction and heart failure, and is responsible for approximately 10%[6] of sudden death cases in young adults. In addition, cardiogenic shock associated with Peripartum and Postpartum Cardiomyopathy (PPCM) has also been included in the expansion of the label.

“In the setting of cardiomyopathy with cardiogenic shock, the Impella heart pump platform stabilizes the patient's hemodynamics and directly unloads the heart providing blood flow to the body’s organs,” said George Batsides, MD, FACC, Chief of Cardiac Surgery & Surgical Director of Mechanical Circulatory Support, Hackensack University Medical Center. “The goal of this therapy is to rest the heart muscle allowing recovery to the patient’s baseline function. This treatment is the ideal solution to restore a patient's quality of life especially for patients older than 65 and not eligible for heart transplant.”

“Abiomed would like to recognize the work of our scientists, physicians, healthcare professionals and regulators for their data collection, clinical research and analysis over the last 9 years,” said Michael R. Minogue, President, Chairman and Chief Executive Officer of Abiomed. “Our ongoing cVAD registry study and IQ commercial database starting from 2008 allows Abiomed to capture real-world evidence on all Impella patients suffering from heart failure associated with hemodynamic instability. As we identify best practices, we remain committed to partnering with heart teams to establish protocols to improve patient outcomes and provide cost effective patient care.”

Learn more about cardiomyopathy patients who have benefited from hemodynamic support and heart recovery at www.heartrecovery.com.

- In March 2017, **Jerome Cole**, 58, collapsed and fell unconscious days after experiencing symptoms of the common cold. Paramedics rushed him to St. Louis University Hospital where physicians Ammar Nasir, Dawn Hui and Tarek Helmy determined that he had cardiomyopathy and his organs were failing. They placed the Impella 5.0 device to support Jerome’s weak heart and he recovered and returned to spending time with his grandchildren.

- In January 2017, **Jenny DeVoe**, 36, drove to the ER with flu-like symptoms and collapsed in the parking lot. Physicians determined that she had myocarditis, caused by a virus, and transferred her to Spectrum Health Heart Center where Dr. David Wohns implanted the Impella CP®. After escalation to the Impella 5.0® implanted by Dr. Marzia Leacche, Jenny made a full recovery and has returned to her active life with two children.

- In October 2015, **Francis “Buddy” Chase**, 44, experienced shortness of breath and stomach pain while at work. Due to worsening symptoms, he went to the Charlton Memorial Hospital emergency room in Fall River, MA. Dr. Adam Saltzman determined that he had cardiomyopathy and placed the Impella CP® device to allow Buddy’s heart to rest. Buddy’s heart recovered and he returned to raising his two children with his wife.

Abiomed will conduct a post-approval study of cardiomyopathy patients for five years using the cVAD Registry study. The cardiomyopathy study will join other post-approval studies from prior FDA indications using the prospective, IRB-approved multi-center cVAD Registry study.

1. Stretch, R. National Trends in the Utilization of Short-Term Mechanical Circulatory Support: Incidence, Outcomes, and Cost Analysis. *J Am Coll Cardiol*. 2014 Oct 7;64(14):1407-15. doi: 10.1016/j.jacc.2014.07.958.
2. O'Neill, W. The Current Use of Impella 2.5 in Acute Myocardial Infarction Complicated by Cardiogenic Shock: Results from the USpella Registry. *J Interv Cardiol*. 2014 Feb; 27(1): 1—11. doi: 10.1111/joic.12080.
3. Am. Journal of Epidemiology, February 19,2016; 183(5): 462-470. Temporal Trends in Hospitalizations for ADHF in the US, 1998-2011.

4. Linden A, Adler-Milstein J. Medicare Disease Management in Policy Context. Health Care Financ Rev. 2008;29(3):1-11.
5. Circulation Heart Failure 2009; 2: 56-62. Loop Diuretics in Acute Decompensated Heart Failure.
6. Fabre A, Sheppard MN. Sudden Adult Death Syndrome and Other Non-Ischaemic Causes of Sudden Cardiac Death. *Heart* 2006;92:316-20.

*Optimal medical management and conventional treatment measures include volume loading and use of pressors and inotropes, with or without IABP.

ABOUT IMPELLA HEART PUMPS

The Impella 2.5®, Impella CP®, Impella 5.0® and Impella LD® are FDA-approved heart pumps used to treat heart attack or cardiomyopathy patients in cardiogenic shock, and have the unique ability to enable native heart recovery, allowing patients to return home with their own heart. The Impella 2.5 and Impella CP devices are also approved to treat certain advanced heart failure patients undergoing elective and urgent percutaneous coronary interventions (PCI) such as stenting or balloon angioplasty, to re-open blocked coronary arteries. Abiomed's right-side heart pump, the Impella RP® device, is FDA approved to treat patients experiencing acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery. To learn more about the Impella platform of heart pumps, including their approved indications and important safety and risk information associated with the use of the devices, please visit: www.protectedpci.com.

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.

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FORWARD-LOOKING STATEMENTS

This release contains forward-looking statements, including statements regarding development of Abiomed's existing and new products, the Company's progress toward commercial growth, and future opportunities and expected regulatory approvals. The Company's actual results may differ materially from those anticipated in these forward-looking statements based upon a number of factors, including 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 other risks and challenges detailed in the Company's filings with the Securities and Exchange Commission, including the most recently filed Annual Report on Form 10-K and Quarterly Report on Form 10-Q. Readers are cautioned not to place undue reliance on any 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 that occur after the date of this release or to reflect the occurrence of unanticipated events.