February 14, 2018

Abiomed Receives Approval for Expanded FDA Indication for High Risk Percutaneous Coronary Intervention (PCI) Procedures

DANVERS, Mass., Feb. 14, 2018 (GLOBE NEWSWIRE) -- Abiomed, Inc. (Nasdaq:ABMD), a leading provider of breakthrough heart support and recovery technologies, today announced that it has received an expanded U.S. Food and Drug Administration (FDA) Pre-Market Approval (PMA) for the Impella 2.5® and Impella CP® heart pumps during elective and urgent high risk percutaneous coronary intervention (PCI) procedures. This expanded indication confirms Impella support as appropriate in patients with severe coronary artery disease, complex anatomy and extensive comorbidities, with or without depressed ejection fraction (EF).

Impella's initial approval for High Risk PCI was based on two FDA studies (PROTECT I and PROTECT II), that treated the sickest and most severe patients in the catheterization lab with the majority being denied open heart surgery. This change broadens the appropriate use of Impella support and eliminates the requirement for depressed ejection fraction in the presence of severe coronary artery disease or complex anatomy (e.g., left main, multi-vessel, or requiring rotational atherectomy). With this expanded approval, the FDA has further validated this "first of its kind" indication for High Risk PCI and the benefit of percutaneous hemodynamic support in treating severely complex patients with mild, moderate and severely depressed ejection fraction. Clinical society guidelines from the ACC/HFSA/SCAI/STS consensus publication support the use of Impella in patients with reduced or normal left ventricular function and severe coronary artery disease for treatment of anticipated technically challenging or prolonged PCI patients[1,2].

The Impella 2.5 and Impella CP heart pumps are the only percutaneous temporary ventricular support devices FDA-approved as safe and effective for High Risk PCI, with the new indication stated below:

> The Impella 2.5 and Impella CP are indicated for providing temporary (< 6 hours) ventricular support during elective or urgent high risk percutaneous coronary interventions (PCI) performed in hemodynamically stable patients with severe coronary artery disease, when a heart team, including a cardiac surgeon, has determined high risk PCI is the appropriate therapeutic option. Use of the Impella 2.5 and the Impella CP in these patients may prevent hemodynamic instability which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

Data Supporting Expanded FDA Approval

The data submitted to the FDA in support of this expanded PMA indication included an analysis of 229 consecutive patients with mild to moderately reduced ejection fraction from the cVAD Registry study. In this cohort, the majority of patients were turned down for open heart surgery (CABG) due to their surgical risk factors and remaining minority refused surgery. On average, these patients were older, more often female, had more lesions treated, experienced more hypertension and presented with higher ejection fraction than patients in the CVAD registry cohort with ejection fraction less than 35% (n=464). This comparison demonstrated that high risk PCI with Impella support was feasible, safe and achieved favorable outcomes in patients with mild to moderately reduced ejection fraction.

The data collection from the cVAD registry includes Institutional Review Board (IRB) approval, complete data monitoring and Clinical Events Committee adjudication. This clinical data reinforces prior FDA studies demonstrating the safety and effectiveness of Impella support in elective, urgent and emergent patient populations.

"This expanded FDA approval with moderately reduced ejection fraction validates our real-world experience using hemodynamic support in patients turned down for surgery with severe coronary artery disease," said Ehtisham Mahmud, MD, FACC, FSCAI, Division Chief, Cardiovascular Medicine and Director, Sulpizio Cardiovascular Center, UC San Diego. "These patients who have often been managed medically in the past may have a new option for treatment."

"Our patients are increasingly more complex, requiring higher levels of operator skill and protocol driven use of hemodynamic support in the cath lab," said Tony DeMartini, MD, FACC, Interventional Cardiologist, Edward-Elmhurst Health. "These patients often experience improved quality of life and with complete revascularization can have improved ejection fraction following Protected PCI."

"Abiomed would like to thank the physician community, caregivers, employees and regulators involved in the FDA clinical

trials and cVAD post market approval studies," said Michael R. Minogue, President, Chairman and CEO of Abiomed. "Abiomed takes great satisfaction in knowing that our significant investment in clinical research over the last 12 years has helped thousands of patients, identified best practices and expanded our regulatory indications in both high risk PCI and cardiogenic shock."

1. Society for Cardiovascular Angiography and Interventions (SCAI), American College of Cardiology (ACC), Heart Failure Society of America (HFSA), Society of Thoracic Surgeons (STS)
2. Rihal, C. Naidu, S, et al. 2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care. J Am Coll Cardiol. 2015 May 19;65 (19):e7-e26. doi: 10.1016/j.jacc.2015.03.036. Epub 2015 Apr 7.

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.

For further information please contact:
Ingrid Goldberg Ward
Director, Investor Relations
978-646-1590
igoldberg@abiomed.com

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.