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Abiomed Receives FDA PMA Approval for Impella RP® for Right Heart Failure

DANVERS, Mass., Sept. 20, 2017 (GLOBE NEWSWIRE) -- Abiomed, Inc. (NASDAQ:ABMD), a leading provider of breakthrough heart support and recovery technologies, today announced it has received U.S. Food and Drug Administration (FDA) pre-market approval (PMA) for the Impella RP® heart pump. Culminating from five years of research, this approval follows the prior FDA Humanitarian Device Exemption (HDE) received in January 2015 and adds the Impella RP heart pump to Abiomed's platform of PMA approved devices.

With this approval, the Impella RP heart pump is the only percutaneous temporary ventricular support device that is FDA-approved as safe and effective for right heart failure as stated in the indication:

The Impella RP System is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m^2, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

Data submitted to the FDA in support of the Impella RP heart pump PMA included the RECOVER RIGHT[1] FDA-approved, prospective, multicenter, single-arm study, which commenced after the company received FDA investigational device exemption (IDE) approval in November 2012 and concluded in 2014. Since that time, Abiomed completed a Continuous Access Protocol (CAP) as well as a prospective, multicenter post-approval study (PAS). **These data was presented in the plenary session of the 2017 Annual Meeting and Scientific Sessions of the International Society for Heart and Lung Transplantation[2]. The Impella RP heart pump is reimbursed by Medicare and other major payers.** Abiomed will complete a PMA post-approval study with 60 consecutive patients in Abiomed's Institutional Review Board (IRB)-approved, FDA audited prospective cVAD Registry.

Right Ventricular Failure (RVF) is associated with increased mortality, longer lengths of stay in the intensive care unit and potential end-organ dysfunction[1]. The Impella RP heart pump stabilizes the patient's hemodynamics, unloads the right ventricle and allows for native heart recovery. Delivered through a catheter requiring only a small hole in the leg, the Impella RP heart pump is designed to provide the flow and pressure needed to compensate for right heart failure. The device does not require a surgical procedure for insertion, and it provides more than four liters of blood per minute for hemodynamic support.

"The Impella RP has opened up a new era in cardiovascular medicine. With its percutaneous, single vascular access, the Impella RP offers physicians a minimally-invasive procedure for patients who have previously had limited options for treatment of right heart failure," said Mark B. Anderson, M.D., FASC, co-principle investigator for the RECOVER RIGHT trial and vice chair of cardiac surgery services and cardiothoracic surgeon to the Hackensack University Medical Group. "The cumulative data from the FDA studies demonstrate that Impella RP potentially offers survival benefits for these critically ill patients in need of hemodynamic support."

"This latest PMA approval for Impella RP enables physicians for the first time to percutaneously treat a broader population of patients with right heart failure," said Michael R. Minogue, President, Chairman and CEO of Abiomed. "Abiomed would like to recognize the FDA as well as our physicians, scientists and employees for the extensive clinical research and review that allowed this FDA PMA approval. Abiomed now offers a platform of minimally-invasive devices that support both sides of the heart to enable heart recovery and we are committed to education and training for the entire heart team as we move to full commercial availability."

1. Anderson MB, Goldstein J, Milano C, et al. Benefits of a novel percutaneous ventricular assist device for right heart failure: The prospective RECOVER RIGHT study of the Impella RP device. *J Heart Lung Transplant.* 2015; 34 (12):1549-1560.
2. Anderson, MB, et al. Impella RP Post Approval Study: First Multi-Center, Prospective Post Market Approval Results for the Impella RP in Patients with Right Ventricular Failure. *J Heart Lung Transplant.* 2017; 36(4):S64-S65.

ABOUT IMPELLA HEART PUMPS

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. The Impella 2.5®, Impella CP® and Impella 5.0® are FDA-approved heart pumps used to treat heart attack 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. 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.