



Abiomed Announces European Approval (CE Marking) for Impella 5.5™ and First Patient Treated at University Heart Center Hamburg

DANVERS, Mass., April 4, 2018 (GLOBE NEWSWIRE) -- Abiomed, Inc. (NASDAQ:ABMD), a leading provider of breakthrough heart recovery and support technologies, announced today that the Impella 5.5™ heart pump received CE marking¹ approval in Europe and the first patient was treated at University Heart Center in Hamburg, Germany. The Impella 5.5 heart pump further enhances Abiomed's product portfolio and provides physicians a 30-day, ambulatory, wean-able, forward flow heart pump.

Under the leadership of Professor Hermann Reichenspurner, MD, PhD, Alexander Bernhardt, MD treated the first patient, who presented with ischemic cardiomyopathy, severe mitral regurgitation and an ejection fraction of 18%. The patient currently remains stable on Impella 5.5 support.

The Impella 5.5 heart pump has the ability to provide peak flows of greater than 6.0 liters per minute. It is designed to be implanted in the axillary artery, avoiding the need for a sternotomy and allowing for patient ambulation. The Impella 5.5 is approved in Europe for up to 30 days of support and can be adjusted to nine power levels that regulate flow to optimize weaning protocols. The Impella 5.5 device includes the new SmartAssist technology with optical sensor, which will enable the integration of clinical data informatics including Left Ventricular Pressure (LVP), End-Diastolic Pressure (EDP) and Cardiac Power Output (CPO) on the Impella console as well as real-time, exact positioning of the Impella device. Over the next fiscal year, Abiomed plans to launch the Impella 5.5 heart pump through a controlled roll-out at German hospitals with established heart recovery protocols. Abiomed will continue to collect data on Impella 5.5 user experience and patient outcomes through our German hospitals submitting clinical data in the global cVAD Registry study.

Data Supporting CE Marking Approval

The data submitted for this CE marking approval included pre-clinical data on the Impella 5.5 and incorporates the clinical experience from over 3,000 patients, most all with axillary implants treated with the Impella 5.0 device. The submission also included an analysis of 68 patients from Abiomed's FDA reviewed cVAD Registry study treated with Impella 5.0® or Impella LD® heart pumps and a literature review of eight papers identifying patients treated with the Impella 5.0. Additionally, Abiomed submitted an analysis of 17 patients enrolled in the RECOVER I prospective, multicenter FDA IDE study.

"The Impella 5.5 device is an easy to implant, minimally-invasive device that provides full cardiac flow and stabilizes the patient by increasing cardiac power output, unloading the left ventricle and perfusing the coronaries and end organs," said Hermann Reichenspurner, MD, PhD, Professor and Chief, Department of Cardiovascular Surgery, University Heart Center Hamburg. "This approval gives our cardiovascular community a new option for effectively treating severely ill patients."

"We are excited about the Impella 5.5 and the impact of fully unloading the left ventricle," said Michael R. Minogue, President, Chairman and Chief Executive Officer of Abiomed. "We commend the dedication of the team at University Heart Center Hamburg. The addition of the Impella 5.5 to the Impella platform of devices will further address the clinical needs of patients and physicians as we advance the field of heart recovery."

1. The CE marking approval for Impella 5.5 intended use is:
The Impella 5.5 heart pump is an intracardiac pump for supporting the left ventricle. It is intended for clinical use in cardiology and in cardiac surgery for up to 30 days for the following indications, as well as others: The Impella 5.5 is a cardiovascular support system for patients with reduced left ventricular function, e.g., post-cardiotomy, low output syndrome, cardiogenic shock after acute myocardial infarction; The Impella 5.5 may also be used as a cardiovascular support system during coronary bypass surgery on the beating heart, particularly in patients with limited preoperative ejection fraction with a high risk of postoperative low output syndrome.

ABOUT IMPELLA HEART PUMPS

The Impella 5.5 heart pump is not approved for use or sale in the United States.

The Impella 2.5[®], Impella CP[®], Impella CP[®] with SmartAssist, 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.

The ABIOMED logo, ABIOMED, Impella, Impella 2.5, Impella 5.0, Impella LD, Impella CP, Impella RP, and Recovering Hearts. Saving Lives. are registered trademarks of ABIOMED, Inc. in the U.S. and in certain foreign countries.

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 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.

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