



Source: ABIOMED, Inc.

October 26, 2017 07:03 ET

Abiomed Announces First Patient Treated with Impella® in Japan

DANVERS, Mass., Oct. 26, 2017 (GLOBE NEWSWIRE) -- Abiomed, Inc. (NASDAQ:[ABMD](#)), a leading provider of breakthrough heart support technologies, announced today the first patient treated with the Impella heart pump in Japan. The Impella 2.5® and Impella 5.0® heart pumps are approved for the treatment of drug-resistant acute heart failure and are the first and only percutaneous temporary ventricular support devices Pharmaceuticals and Medical Devices Agency (PMDA) approved in Japan.

The first patient in Japan was treated with the Impella 5.0 heart pump after suffering from acute heart failure. The patient was treated at Osaka University Hospital under the leadership of Professor Yoshiki Sawa, M.D., Ph.D. of the Department of Cardiovascular Surgery, Osaka University's Graduate School of Medicine. According to Professor Sawa, "In acute heart failure, such as cardiogenic shock, initial treatment is very important because of its impact on subsequent cardiac functions and the patient's general condition. Impella, which provides minimally invasively mechanical support for the circulatory system, makes it possible to carry out safe and effective treatment even in the case of severe heart failure, which had been difficult until now. This is a very fortunate development for both patients and their families, so we look forward to using Impella and supporting its popularization in the medical field."

Japanese researchers and physicians have studied hemodynamic science and heart recovery for decades. Japan is the second largest medical device market in the world and Japanese physicians have been leaders in the field for high-risk revascularization in the surgery suite and cath lab. In Japan, percutaneous options for hemodynamic support are limited and Impella fills the need for a more contemporary device that promotes heart recovery.

"Treating the first Japanese Impella patient marks a significant milestone for our Company," said Michael R. Minogue, President, Chairman and Chief Executive Officer of Abiomed. "We are pleased to launch the Field of Heart Recovery in Japan and we commend the dedication of Japanese physicians and the regulatory body for seeking out new and cost-effective solutions for improving patient outcomes and quality of life."

The Impella 2.5 and Impella 5.0 heart pumps received Pharmaceuticals and Medical Devices Agency (PMDA) approval from the Japanese Ministry of Health, Labor & Welfare (MHLW) in September 2016 and received reimbursement, effective September, 2017. Abiomed has opened an office in Tokyo and plans to launch at 10 Japanese hospitals by the end of the fiscal year, in March 2018.

IMPELLA 2.5 AND 5.0 HEART PUMP INDICATION IN JAPAN

In Japan, the Impella heart pump is used for the following indication: In the treatment of drug-resistant acute heart failure attributable to causes such as cardiogenic shock, a catheter is inserted percutaneously/transvascularily without chest-opening surgery, and blood is aspirated via the tip of a catheter inserted/placed into the left ventricle and pumped out via the outlet port located in the ascending aorta, thereby assisting with antegrade blood circulation in the body. It aims to improve hemodynamics and the recovery of the heart muscles through prompt assistance of antegrade blood flow in a minimally invasive manner while reducing burden on the heart muscles, allowing for prompt recovery of cardiac function.

ABOUT IMPELLA HEART PUMPS

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.

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.

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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.