Abiomed Announces Approval in India for the Impella 2.5®, Impella CP® and Impella 5.0® Heart Pumps and First Indian Patient Treated

July 26, 2018

DANVERS, Mass., July 26, 2018 (GLOBE NEWSWIRE) -- Abiomed, Inc. (NASDAQ:ABMD), a leading provider of breakthrough heart recovery and support technologies, announced the Impella 2.5®, Impella CP® and Impella 5.0® heart pumps received Central Drugs Standard Control Organization (CDSCO) approval in India for use during high-risk percutaneous coronary intervention (PCI), cardiogenic shock, and other reduced left ventricular function conditions. The first patient was treated with the Impella 2.5 heart pump at Fortis Escorts Heart Institute in New Delhi.

Ashok Seth, MD treated the first patient, an 86 year old man who was too high risk for heart surgery and presented with severe, recurrent chest pain and multiple comorbidities. A diagnostic catheterization demonstrated blockages of more than 90% in three left coronary arteries as well as distal disease. Dr. Seth performed a Protected PCI procedure including atherectomy with Impella 2.5 support. The patient was weaned off support and after three days was discharged home with an improved quality of life.

Impella heart pumps stabilize the patient's hemodynamics, unload the left ventricle, perfuse the end organs and promote recovery of the native heart. Heart disease is the number one cause of death in India[1] and of those diagnosed with heart failure, 23% die within one year[2].

"We are proud to be the first Heart Recovery Program in India," said Ashok Seth, MD, Chairman, Fortis Escorts Heart Institute and Head, Cardiology Council, Fortis Group. "The Impella heart pump unloads the left ventricle and allows the heart to rest and recover so that patients may gain an improved quality of life. We look forward to providing access to protected revascularization to improve their cardiac function and subsequent quality of life for more patients with heart failure, cardiogenic shock or left ventricular dysfunction."

“Abiomed is committed to expanding access to our heart recovery products around the world. We are moving forward to establish Heart Recovery Programs in India, starting with limited centers of excellence in New Delhi and Jaipur,” said Michael R. Minogue, President, Chairman and Chief Executive Officer of Abiomed. “We commend the dedication of Dr. Seth and his team for providing advanced technology to improve outcomes for patients who now have the opportunity for an improved quality of life.”

Data Supporting CDSCO Approval

Data supporting CDSCO approval included the U.S. FDA studies PROTECT I, PROTECT II RCT and RECOVER I for the Impella 5.0. Additional clinical data was submitted from peer-reviewed publications and the cVAD Registry study, which contains nearly 4,000 patient records. The data collection from the registry includes Institutional Review Board (IRB) approval, complete data monitoring and Clinical Events Committee adjudication.

CDSCO approval for Impella 2.5, Impella CP and Impella 5.0:

The Impella 2.5® and Impella CP® (intracardiac pump for supporting the left ventricle) is intended for clinical use in cardiology and in cardiac surgery for up to five days for the following indications, as well as others: The Impella® 2.5/CP is a circulatory support system for patients with reduced left ventricular function, e.g., post-cardiotomy, low output syndrome, cardiogenic shock after acute myocardial infarction, or for myocardial protection after acute myocardial infarction; the Impella 2.5 and Impella CP 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; support during high risk percutaneous coronary intervention (PCI).

The Impella 5.0 (intracardiac pump for supporting the left ventricle) is intended for clinical use in cardiology and in cardiac surgery for up to 10 days for the following indications, as well as others: The Impella 5.0 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 5.0 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, or post PCI.

1. 2016 Global Burden of Disease Report. 15 Sept, 2017. http://www.healthdata.org/india
2. Lancet Glob Health. Global mortality variations in patients with heart failure: results from the International Congestive Heart Failure (INTER-CHF) prospective cohort study. 2017 Jul;5(7):e665-e672.

ABOUT IMPELLA HEART PUMPS

The Impella 2.5 and Impella CP devices are FDA 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. 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. 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.

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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