Abiomed Receives CE Mark for Impella RP

New Impella RP Provides Percutaneous Hemodynamic Support for Right Sided Heart Failure

DANVERS, Mass., April 8, 2014 (GLOBE NEWSWIRE) -- Abiomed, Inc. (Nasdaq:ABMD), a leading provider of break-through heart support technologies, today announced it has received CE Marking approval in the European Union to market the Impella® RP device, a new percutaneous Impella heart pump that provides temporary ventricular support for patients with right ventricular failure.

The Impella RP is a percutaneous heart pump that is implanted through a single access site in the patient's leg and deployed through the venous system, across the right side of the heart without requiring a surgical procedure.

"We are proud to announce the commercial European availability of the new Impella RP device," said Michael R. Minogue, Chairman, President and Chief Executive Officer, Abiomed. "This exciting news follows our recent announcement of the completion of patient enrollment in the U.S. IDE RECOVER RIGHT trial, which further emphasizes the need for percutaneous support for right sided heart failure in hospitals around the world."

The Impella RP is not currently cleared for sale or use in the United States.

According to the labeling under CE Mark in Europe and other countries, the Impella® RP System (percutaneous pump for right ventricular support) is intended for clinical use in cardiology, in cardiac surgery, and intensive care unit for up to 14 days for the following indications, as well as others: Acute or transient reduction of the right ventricular function (e.g., postcardiotomy low output syndrome); Cardiogenic shock as a consequence of a posterior myocardial infarction with right ventricular heart failure; Right heart support during coronary beating heart bypass surgery, especially for patients with a reduced preoperative cardiac output or for patients having a high risk of developing a postoperative low output syndrome for other reasons; Right ventricular heart failure after implantation of a left ventricular assist device; Therapy unresponsive arrhythmias with a reduction of right ventricular output; Heart failure and/or cardiogenic shock as a consequence of refractory ventricular arrhythmia, as well as a consequence of sustained supraventricular arrhythmias, causing hemodynamic compromise.

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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