



## Abiomed Receives FDA Approval for Impella CP® with SmartAssist™ and Optical Sensor

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DANVERS, Mass., April 02, 2018 (GLOBE NEWSWIRE) -- Abiomed, Inc. (NASDAQ:ABMD), a leading provider of breakthrough heart support and recovery technologies, announced today that it has received U.S. Food and Drug Administration (FDA) Pre-Market Approval (PMA) for its Impella CP® heart pump with SmartAssist™, utilizing an optical sensor. At the forefront of innovation, these advances in technology and software are designed to improve productivity, ease of use, and patient management to ensure optimal patient care.

The addition of Impella CP with SmartAssist represents the next generation for heart recovery products and includes the following features:

- **Simplified Patient Management:** Advanced software and new optical sensor improves understanding of real-time, exact positioning for the Impella heart pump and allows for repositioning without the need for imaging equipment.
- **Integration of Clinical Data Informatics on Impella Console:** Real-time informational displays of Left Ventricular Pressure (LVP), End-Diastolic Pressure (EDP) and Cardiac Power Output (CPO) provides optimal support for patients.
- **Ease of Use:** Faster set-up with fewer steps and connections simplifies patient management for physicians, cath lab staff and ICU staff. New steps further reduce start time by 15%, which is critical for emergency patients in cardiogenic shock.

Abiomed has already received CE marking approval in the European Union to market Impella CP with SmartAssist. To date, over 60 patients at three sites have been treated with Impella CP with optical sensor. Abiomed submitted more than 60 engineering reports and full technical specifications for this expanded PMA approval, which were approved by the FDA. To date, the clinical data informatics has been tested on the Abiomed Impella Controller on 38 patients at two hospitals in the U.S. Over the next fiscal year, Abiomed will launch the Impella CP with SmartAssist through a controlled roll-out at hospital sites with established heart recovery protocols. A simple upgrade to Abiomed's existing installed base will be performed on the routine service cycle.

"The ability to view fundamental hemodynamic data such as LVP, EDP and CPO directly on the Impella console provides critical information for clinical decision-making," said William O'Neill, Medical Director, Center for Structural Heart Disease, Henry Ford Hospital. "Additionally, access to data and real-time pump position improves efficiency for nurses and physicians in the ICU and CCU."

"Abiomed would like to thank our physicians, technologists and nurses for their feedback on how to improve the Impella platform. Our scientists, engineers and clinical team are always looking for ways to improve our ease of use, training and clinical performance," said Michael R. Minogue, President, Chairman and CEO of Abiomed. "Through innovation and research, our clinical team will utilize SmartAssist to help our customers achieve our goal to improve outcomes and enable heart recovery for every patient."

### ABOUT IMPELLA HEART PUMPS

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, Impella CP, Impella CP with SmartAssist, 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](http://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](http://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.

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