Impella Connect Achieves Regulatory Milestone

January 31, 2019

Cloud-based monitoring platform gains CE Mark, adding to FDA PMA approval

DANVERS, Mass.--(BUSINESS WIRE)--Jan. 31, 2019-- Abiomed (NASDAQ:ABMD) has achieved CE Mark for Impella Connect, the first-of-its kind cloud-based technology that enables secure, real-time, remote viewing of the Impella console for physicians and hospital staff from anywhere with Internet connectivity. European CE Mark adds to Impella Connect's previous U.S. FDA PMA approval.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20190131005297/en/

Impella Connect allows medical professionals to view the Impella console, in real-time, from any Internet-connected computer or mobile device. (Photo: Abiomed, Inc.)

Impella Connect uses real-time intelligence to help improve patient outcomes. In addition to allowing medical professionals to view their hospital's consoles remotely, Impella Connect allows highly-trained staff at Abiomed's 24x7 Clinical Support Center to provide medical professionals with expert evaluation of Impella data and real-time collaborative patient management.

"Impella Connect is an extremely valuable resource that allows me, as well as allied health professionals and nursing staff, to have direct visualization of data from the Impella console and to closely monitor patients on hemodynamic support, in real time," said Rajeev L. Narayan, MD, Assistant Director of Structural Heart Intervention and Director Interventional Mechanical Circulatory Support, Vassar Brothers Medical Center.

Based on the previous FDA PMA approval, Impella Connect, which is fully HIPAA compliant, is in a limited market release in the United States. 36 hospital sites are currently using the technology on a regular basis to provide enhanced real-time support for their patients. Abiomed will launch Impella Connect in Europe this quarter through a controlled roll-out at hospital sites with established heart recovery protocols. The first hospital will be University Heart Center in Hamburg, Germany.

"Impella Connect is a technological advancement which represents the next frontier of heart recovery products," said Michael R. Minogue, President, Chairman and CEO of Abiomed. "Impella Connect, along with our 24x7 onsite and on-call support, enables physicians, nurses and ICU staff to increase productivity, improve patient outcomes, and help patients return home with their native heart."

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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