Impella SmartAssist Platform Launches at SCAI, Designed to Further Improve Patient Outcomes

May 16, 2019

DANVERS, Mass.--(BUSINESS WIRE)--May 16, 2019-- Abiomed (NASDAQ:ABMD) announces today that the Impella CP with SmartAssist, which is designed to improve patient outcomes with advanced algorithms and simplified patient management, will be commercially available beginning at the 2019 Society for Cardiovascular Angiography & Interventions (SCAI) Scientific Sessions through a controlled launch process at select sites. The majority of Impella CP heart pumps in the U.S. will be transitioned to SmartAssist over the next fiscal year.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20190516005223/en/

Abiomed announces today that the Impella CP with SmartAssist, which is designed to improve patient outcomes with advanced algorithms and simplified patient management, will be commercially available beginning at the 2019 SCAI Scientific Sessions through a controlled launch process at select sites.(Graphic: Abiomed, Inc.)

Abiomedreceived U.S. FDA approval for Impella CP with SmartAssist in March 2018. During a limited market release over the past year, more than 1,000 patients at 70 sites have been treated with the SmartAssist platform. These advances in Impella forward-flow heart pump technologies and software are designed to improve ease-of-use and patient management to optimize both survival and heart recovery:

- **Weaning Algorithms to Optimize Survival and Native Heart Recovery**: Real-time displays of critical hemodynamic metrics including left ventricular end-diastolic pressure (LVEDP), mean arterial pressure (MAP), and cardiac power output (CPO). Impella CP with SmartAssist is the only mechanical circulatory support device that calculates and displays LVEDP, MAP and CPO.
- **Easier Management and Repositioning:** SmartAssist sensor allows for precise positioning in the aorta and left ventricle and repositioning in the ICU without the need for catheterization lab or ultrasound imaging.
- **Greater Hemodynamic Support**: Allows for sustained peak flows of up to 4.3L/minute (>85% of a normal cardiac cycle).
- **Faster, Simplified Impella Console Set Up**: Less than 90 seconds.

“Access to real-time clinical data has allowed our team to identify best practices for patient management and weaning,” said Hiram Bezerra, interventional cardiologist, University Hospitals, Cleveland, and a participant in the limited market release. “Metrics such as LVEDP, MAP and CPO and the ability to monitor trends on the Impella console allow physicians to utilize this hemodynamic information to optimize heart recovery with objective and quantifiable data to enable clear communication within the shock team.”

The SmartAssist platform is complemented by Abiomed’s industry-leading on-site and on-call support, including the Clinical Support Center, which provides 24x7 expert evaluation of Impella data and collaborative patient care to help improve outcomes.

“The SmartAssist platform represents the next generation of heart recovery products,” said Michael R. Minogue, Chairman, President and CEO of Abiomed. “SmartAssist represents Abiomed’s continued commitment to provide world-class innovation and unparalleled service to help physicians, nurses and ICU staff improve patient outcomes for both survival and native heart recovery.”

ABOUT IMPELLA HEART PUMPS

The Impella 2.5® and Impella CP® devices are U.S. FDA PMA 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 U.S. 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 RP® is U.S. FDA approved to treat right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

In Europe, the Impella 2.5, Impella CP and Impella CP with SmartAssist are CE marked for treatment of high-risk PCI and AMI cardiogenic shock patients for up to 5 days. Impella 5.0 and Impella LD are CE marked to treat heart attack or cardiomyopathy patients in cardiogenic shock for up to 10 days. The Impella 5.5™ heart pump is CE marked to treat heart attack or cardiomyopathy patients in cardiogenic shock for up to 30 days. The Impella RP is CE marked to treat right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, open-heart surgery, or refractory ventricular arrhythmia.

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.impella.com.

ABOUT ABIOMED

Based in Danvers, Massachusetts, USA, 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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Source: Abiomed, Inc.

Tom Langford
Director, Communications and Public Relations
978-882-8408
tlangford@abiomed.com

Ingrid Goldberg Ward
Director, Investor Relations
978-646-1590
igoldberg@abiomed.com