May 9, 2017

Abiomed Introduces 3rd Generation Impella CP® Heart Pumps at SCAI 2017

Designed to Enable Ease of Use in High-Risk Percutaneous Coronary Interventions and in the ICU

DANVERS, Mass., May 09, 2017 (GLOBE NEWSWIRE) -- Abiomed, Inc. (NASDAQ:ABMD), a leading provider of breakthrough heart support and recovery technologies, announced the debut of the 3rd Generation Impella CP heart pump at the Annual meeting of the Society for Cardiovascular and Angiography Interventions (SCAI 2017) in New Orleans, LA. The technology offers new features for optimal care during a percutaneous coronary intervention (PCI) in high-risk patients known as a Protected PCI, and for patients being treated with Impella in the intensive care unit (ICU). The 3rd Generation Impella CP is a member of the Impella family of heart pumps which have the unique ability to unload the heart and enable native heart recovery, potentially allowing patients to return home with their own hearts. As the world's smallest heart pump, the Impella platform has supported more than 50,000 patients in the U.S. alone, and is the only Food and Drug Administration (FDA)-approved percutaneous ventricular assist device (pVAD) indicated as safe and effective for PCI in high-risk patients[1] and patients with Acute Myocardial Infarction complicated by Cardiogenic Shock (AMICS)[2].

A photo accompanying this announcement is available at http://www.globenewswire.com/NewsRoom/AttachmentNg/2c12e27d-b221-4a86-95d9-a2a8db4b4fac

Higher flows and ability to maintain access to arteriotomy

There are several new features on the Impella CP 3rd Generation that simplify patient management:

- To maximize unloading of the heart in the cath lab, this next generation heart pump enables higher flow. Clinicians could see peak flows above 4 liters/minute for patients whose hearts need additional pumping support
- New guide wire re-access sheath allows clinicians to re-access the femoral artery which enables the clinician to rapidly escalate care if needed
- For ease of use, the insertion kit contains a new, proprietary, 25 cm introducer sheath to facilitate the insertion of the device in challenging or tortuous femoral vessels, thus increasing the number of patients who could benefit from percutaneous hemodynamic support. This unique, long introducer sheath can be removed after pVAD insertion with a simple peel-away technique that is not possible with any other kind of introducer

"The ability to introduce the Impella device simply and swiftly even in the presence of challenging femoral or iliac arteries will be valuable for interventional cardiologists caring for high-risk patients during PCI and for those in cardiogenic shock," explained Seth Bilazarian M.D., FACC, FSCAI, Chief Medical Officer of Abiomed and experienced interventional cardiologist. He continued, "Enhanced flows will be very useful, as will the new guide wire repositioning unit which expands the options for access site closure or device exchanges."

Fewer steps for the heart team

The ability to maintain access to the arteriotomy is particularly vital to the care of patients supported by the Impella device in the ICU long-term, such as those in cardiogenic shock. In addition, the Impella CP 3rd Generation heart pump offers fewer steps when flushing the system as part of standard maintenance.

"It's intuitive and user-friendly," said Christiana Gartner, RN, a Nurse Educator and experienced ICU nurse with extensive Impella experience at Greenville Health System who had the opportunity to test features of the 3rd Generation CP. She continued, "It's a time saver; you don't question what's coming next. This software will make it easier to take care of your patient in the ICU."

Like all Impella heart pumps for the left side, the 3rd Generation CP® devices are designed for optimal positioning in the left ventricle and feature a flexible catheter, radiopaque marker, cannula shape and pigtail. The 3rd Generation Impella CP devices are now available in the U.S.

Real-world data suggest improvement in outcomes, but also significant underuse of Impella Technology

Since the Impella® platform received Pre-Market Approval (PMA) from the United States FDA for AMICS in April, 2016[2], Abiomed has continued tracking best practice data in the Impella Quality (IQ) Assurance Program, a real-world collection of clinical information derived from the treatment of patients with Impella devices since 2008. Results reveal that across sites using Impella devices to treat AMICS:

- There has been an observed 14 percent relative improvement in survival as compared to the year before the FDA approval
- In 2016, there were 89,000 AMICS cases nationwide with only 6 percent, or approximately 5,000, treated with Impella heart pumps.
- For more real-world evidence on the use of Impella, please see the Presentation on Abiomed's Impella® Quality (IQ) Assurance Program and Importance of Treatment Protocols to Improve Patient Survival and Heart Recovery.

"These additions to the Impella CP represent the continuous innovation and commitment to patients that you've known since Impella was first introduced nine years ago," said Abiomed President, Chairman and Chief Executive Officer Michael R. Minogue. "We continue to believe that data-driven insights and clinical expertise, along with our 24x7 onsite and on-call support, can help hospitals improve patient outcomes and reduce costs."

Abiomed at SCAI 2017

The 3rd Generation Impella CP® heart pumps will be available for viewing at Booth # 404 beginning on May 10. During SCAI, we anticipate the opportunity to view three live cases that feature use of the Impella device.

As part of the conference agenda, experienced users of Impella devices will also lead discussions on critical industry challenges including:

- **Protected PCI — Using Hemodynamic Support for Patient Safety and Improved Outcomes**
  • SCAI 2017 Industry Dinner Symposium featuring Drs. Raj Patel, Michael Flaherty, Anthony Hilliard, Brian Kolski, Dan Burkhoff, Tony DiMartini, and moderated by Seth Bilazarian, MD and Chief Medical Officer, Abiomed
  • Hilton New Orleans Riverside
  • Wednesday, May 10th 7:30 PM-9:30 PM

- **Contemporary Look at the Treatment of Cardiogenic Shock**
  • SCAI 2017 Industry Breakfast Symposium featuring Drs. Michael Lim, Navin Kapur, Theodore Schreiber and Alex Truesdell
  • Hilton New Orleans Riverside
  • Thursday, May 11th 7 AM-8 AM

ABOUT IMPELLA HEART PUMPS

The Impella 2.5®, Impella CP® and Impella 5.0® are FDA-approved heart pumps used to treat heart attack patients in cardiogenic shock, and have the unique ability to enable native heart recovery, allowing patients to return home with their own hearts. The Impella 2.5 and Impella CP 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 approved to treat certain patients experiencing right heart failure. 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.

Footnotes:

1. The Impella 2.5 heart pump received FDA PMA approval to treat certain elective and urgent high risk PCI patients in March of 2015. The Impella CP heart pump was subsequently approved to treat that patient population in December 2016. The data underpinning the FDA's approval of the Impella 2.5 device included U.S. clinical trial data from the PROTECT I FDA safety study and the PROTECT II randomized clinical trial. Additionally, the PMA submission for the Impella 2.5 device included an analysis of 637 high risk patients, from 49 separate centers, enrolled in the cVAD Registry (formerly known as the U.S. Impella registry), which now contains nearly 3,000 patient records and includes Institutional Review Board (IRB) approval, complete data monitoring and Clinical Events Committee adjudication. The Impella 2.5 PMA submission also included clinical and scientific supporting evidence from more than 215 publications, totaling 1,638 Impella 2.5 patients and incorporated a medical device reporting (MDR) analysis from 13,981 Impella 2.5 patients. In additional to this comprehensive data set, the FDA's PMA approval for the Impella CP device included its consideration of 72 high risk Impella CP patients from the CVAD Registry, as well as an additional 637 Impella 2.5 device patients.

2. The entire family of left side Impella® heart pumps received FDA approval for cardiogenic shock in April, 2016. Impella® remains the only percutaneous temporary ventricular support device that is FDA approved as safe and effective for the cardiogenic shock indication. The Company believes this is the most comprehensive review ever submitted to the FDA for circulatory support in the cardiogenic shock population.
    a. The data submitted to the FDA in support of the PMA included an analysis of 415 patients from the RECOVER 1 study and the U.S. Impella registry (cVAD Registry™), as well as an Impella literature review including 692 patients treated with Impella from 17 clinical studies. A safety analysis reviewed over 24,000 Impella treated patients using the FDA medical device reporting ("MDR") database, which draws from seven years of U.S. experience with Impella.
    In addition, the Company also provided a benchmark analysis of Impella patients in the real-world Impella cVAD registry vs. these same patient groups in the Abiomed AB5000/BVS 5000 Registry. The Abiomed BVS 5000 product was the first ventricular assist device (VAD) ever approved by the FDA in 1991 based on 83 patient PMA study. In 2003, the AB5000 Ventricle received FDA approval and this also included a PMA study with 60 patients.
    For this approval, the data source for this benchmark analysis was a registry ("AB/BVS Registry") that contained 2,152 patients that received the AB5000 and BVS5000 devices, which were originally approved for heart recovery. The analysis examined by the FDA used 204 patients that received the AB5000 device for the same indications. This analysis demonstrated significantly better outcomes with Impella in these patients.
    b. A recent analysis of 15,259 Acute Myocardial Infarction Cardiogenic Shock (AMICS) patients from the Impella Quality (IQ) Assurance Database found that the use of best practice protocols including unloading the left ventricle of the heart (Door to Unload or DTU) with Impella before percutaneous coronary intervention (pre-PCI) in the setting of cardiogenic shock appears to improve outcomes.

**For further information please contact:

Adrienne Smith
Senior Director, Public Relations and Corporate Communications
781-277-1170 Cell
adsmith@abiomed.com

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