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## **First-Ever Presentation on Abiomed's Impella® Quality (IQ) Assurance Program and Importance of Treatment Protocols to Improve Patient Survival and Heart Recovery at the 2017 American College of Cardiology Scientific Session**

- Real-World Data Representing 15,259 Patients

WASHINGTON, March 19, 2017 (GLOBE NEWSWIRE) -- Data from Abiomed's (NASDAQ:ABMD) Impella® Quality (IQ) Assurance Program, which includes the IQ Database and cVAD Registry, was presented today as late-breaking Featured Clinical Research at the American College of Cardiology (ACC) 66<sup>th</sup> Annual Scientific Session in Washington, D.C. These data were derived from the IQ Database documenting the real-world treatment of approximately 50,000 U.S. patients, with a subset of 15,259 Acute Myocardial Infarction Cardiogenic Shock (AMICS) patients. The Impella heart pump results indicate an association between the use of best practice protocols and improved survival and native heart recovery, as compared to inconsistent treatment or inexperienced hospitals.

The Abiomed IQ Assurance Program is a real-world collection of clinical information derived from the treatment of patients with Impella devices since 2008. Trends in the observational IQ Database, combined with information from Abiomed's Institutional Review Board (IRB)-approved cVAD Registry have helped identify best practices and protocols that are associated with improved survival and native heart recovery in hospitals using Impella devices.

Best practice protocols include:

- | 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
- | Reducing the escalation of inotrope therapy
- | Utilizing hemodynamic monitoring for escalation and weaning during support
- | Experienced physicians implanting Impella heart pumps

Results from the IQ Database reveal that since the Impella line of heart pumps received Pre-Market Approval (PMA) from the United States Food and Drug Administration (FDA) in April 2016 for use in treating AMICS<sup>5</sup>, there has been an observed 14 percent relative improvement in survival as compared to the prior year. In 2016, there were 89,000 AMICS cases nationwide, and approximately 5,000 or about 6 percent, were treated with Impella heart pumps. This compares with approximately 35,600 or 40 percent treated with the intra-aortic balloon pump (IABP), even though randomized controlled trials show no hemodynamic augmentation or survival benefit for IABP patients in AMICS<sup>1,2</sup>. Though First 510(k) cleared in 1976 as a result of already being on the market, the IABP is not FDA approved as safe and effective for the AMICS indication.

"The FDA deemed Impella devices safe and effective in the U.S. for cardiogenic shock less than one year ago, which has allowed us to collaborate with hospitals to expand education on hemodynamic science and share best practices to achieve native heart recovery across the country. We are pleased to see improvements of 14 percent this year and recognize the opportunity to further impact and improve the outcomes of thousands of patients with the lessons learned by the most advanced centers and physicians," said Seth Bilazarian, MD, FACC, FSCAI, Chief Medical Officer, Abiomed.

The data presented today also included new data from the Detroit Cardiogenic Shock Initiative (DCSI), which is an unprecedented collaboration between five heart hospitals in Detroit. The presentation by study principal investigator William W. O'Neill, MD, FACC, FSCAI, Medical Director of the Center for Structural Heart Disease at Henry Ford Hospital, Detroit, highlighted the treatment of 37 patients utilizing these best practices and protocols derived from Abiomed's IQ Assurance Program and our most experienced heart hospitals.

- | Applying these systematic best practices, DCSI hospitals showed an increase in cardiogenic shock survival rates from 51 percent baseline to 84 percent, with 100 percent of survivors discharged home with their native heart.

"These results validate earlier studies from the cVAD Registry that early circulatory support is critical for survival and heart recovery in cardiogenic shock," said Dr. O'Neill. "We are proud of the positive results of our unprecedented collaboration. By sharing our best practice protocols, we remain committed to improving shock outcomes in Detroit and around the world."

	Impella Sites	Survival	Survival Improvement (Absolute %)	Survival Improvement (Relative %)	Standardized Protocols for Heart Recovery
IQ Database n=15,529	1,010 Hospitals	58%	7%	14%	No
Top 20% IQ n=3051	158 Hospitals	76%	25%	50%	Yes
Detroit CSI n=37	5 Hospital Systems	84%	33%	65%	Yes

*For mobile viewers, please scroll right to view the complete table.*

These new data support prior publications with percutaneous heart pumps (such as Impella) supporting cardiogenic shock patients published in *JACC (National trends in the utilization of short-term mechanical circulatory support)*<sup>3</sup> and the *Journal of Interventional Cardiology (Use of Impella 2.5 in Acute Myocardial Infarction complicated by Cardiogenic Shock)*<sup>4</sup> representing nearly 12,000 Medicare/insurance patients and 154 cVAD Registry patients respectively.

The mission of the IQ Assurance Program is to improve real-world outcomes in Protected PCI and cardiogenic shock patients through training, education and utilization of clinical guidelines, protocols and best practices derived from observational quality assurance data (IQ), IRB approved registry data (cVAD) and IDE approved FDA studies. The points reflected specifically in the IQ Database, as compared to the IQ Program, which includes the cVAD Registry and FDA studies, are not statistically-powered or pre-specified, and no statistical conclusions can be drawn from the observational database.

"Abiomed has invested to create the largest high-risk PCI<sup>6</sup> and cardiogenic shock database of real-world evidence," said Michael R. Minogue, Abiomed President, Chairman and Chief Executive Officer. "We believe that by sharing our data-driven insights and clinical expertise, along with our 24x7 onsite and on-call support, we can help hospitals improve outcomes and reduce costs for the sickest patients in the system."

## **ABOUT IMPELLA HEART PUMPS**

The Impella 2.5<sup>®</sup>, Impella CP<sup>®</sup> and Impella 5.0<sup>®</sup> 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 heart. 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<sup>®</sup> 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](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).

**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.

1. Wayangankar, S. et. al *J Am Coll Cardiol*. Int CATH-PCI Registry.
2. Prondzinsky R. et al. *Jn Critical Care Medicine* IABP-SHOCK I 2010 — Clinicaltrial.gov # NCT00469248.
3. Stretch, R. National trends in the utilization of short-term mechanical circulatory support: incidence, outcomes, and cost analysis. *J Am Coll Cardiol*. 2014 Oct 7;64(14):1407-15. doi: 10.1016/j.jacc.2014.07.958.
4. O'Neill, W. The current use of Impella 2.5 in Acute Myocardial Infarction complicated by Cardiogenic Shock: Results from the USpella Registry. *J Interv Cardiol*. 2014 Feb; 27(1): 1—11. doi: 10.1111/joic.12080.
5. 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 BVS 5000 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. The Company believes this is the most comprehensive review ever submitted to the FDA for circulatory support in the cardiogenic shock population.
6. 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 addition 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.

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