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New Study with Abiomed's Impella 2.5® Heart Pump Demonstrates Potential Survival with Pre-PCI Insertion in Heart Attacks with the Left Main Coronary Artery

DANVERS, Mass., June 30, 2017 (GLOBE NEWSWIRE) -- Abiomed, Inc. (NASDAQ:ABMD), a leading provider of breakthrough heart support and recovery technologies, announced today the recent publication of a peer-reviewed retrospective study on hemodynamic support with the Impella 2.5® heart pump. The study analyzed patients with acute myocardial infarction complicated by cardiogenic shock (AMICS) undergoing a percutaneous coronary intervention (PCI) on an unprotected left main coronary artery (ULMCA)[1]. The study was published in the *Journal of Interventional Cardiology*. Results of the study suggest that initiation of Impella 2.5 heart pump prior to the start of a PCI on an ULMCA culprit lesion is associated with significant survival benefit in patients supported for cardiogenic shock following an AMI. Patients supported with the Impella 2.5 heart pump post-PCI appear to have very poor survival at 30 days. This study adds to the existing body of clinical data supporting the early placement of Impella heart pumps before PCI for patients in cardiogenic shock.

A heart attack in the left main is sometimes referred to as the "mother of all widow makers" because it carries a mortality rate of over 80%[2,3]. The left main coronary artery and its branches supply oxygenated blood to 75% of the heart's left ventricular muscle mass[4]. This important artery is the only source of blood and oxygen to the left side of the heart, thereby deemed ‘unprotected' when there is no history of heart surgery to bypass the left main coronary artery.

Perwaiz Meraj, MD, and colleagues reported for the first time the real-world outcomes of Impella 2.5 use in PCI on a ULMCA culprit lesion in patients with AMICS. This multicenter, retrospective study included 36 patients from 19 U.S. sites participating in the cVAD Registry™[4] in order to assess whether the initiation of hemodynamic support before PCI would have a survival benefit compared to initiation of support after the PCI. The majority of these patients (average age 69) were in cardiogenic shock at the time of hospital admission (73%) and had a low mean ejection fraction of 25%.

Increased Survival and Heart Recovery Demonstrated

The study demonstrated a significant hospital survival benefit when Impella 2.5 was initiated prior to PCI.

	Impella pre-PCI (n=20)	Impella after PCI (n=16)	p Value
Survival to Discharge	55%	19%	0.041
Survival at 30 Days	48%	13%	0.004

"Patients with cardiogenic shock complicating an acute myocardial infarction due to an unprotected left main coronary artery culprit lesion are some of the sickest and most clinically challenging patients admitted in the cath lab," said Dr. Meraj, of Northwell Health and first author of this manuscript published in the *Journal of Interventional Cardiology*. "Our data suggests that early placement of Impella before PCI is vital to survival."

Reproducible Results Support the Benefit of Impella® Placement Pre-PCI

These new data support prior publications with percutaneous heart pumps (such as Impella) supporting cardiogenic shock patients published in *Journal of the American College of Cardiology* (*National trends in the utilization of short-term mechanical circulatory support*)[5] and the *Journal of Interventional Cardiology* (*Use of Impella 2.5 in Acute Myocardial Infarction complicated by Cardiogenic Shock*)[6] representing nearly 12,000 Medicare/insurance patients and 154 cVAD Registry patients respectively. Additional data from Abiomed's observational IQ Database of 15,259 AMICS patients and data from the Detroit Cardiogenic Shock Initiative[7,8] reinforce the best practice of placing Impella heart pump before PCI in cardiogenic shock patients.

"We commend Dr. Meraj and his coauthors on this application of real-world evidence," said Seth Bilazarian, MD, Chief Medical Officer of Abiomed. "We are pleased that this adds to the body of research showing the benefit of placing Impella early and before PCI in the setting of cardiogenic shock."

To learn more about the study from Dr. Meraj, visit www.protectedpci.com.

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 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® 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.

1. Meraj, P. Impella 2.5 initiated prior to unprotected left main PCI in acute myocardial infarction complicated by cardiogenic shock improves early survival. J Interv Cardiol. 2017 Apr 17. doi: 10.1111/joic.12377. [Epub ahead of print]

2. De Luca G, Suryapranata H, Thomas K, van 't Hof AW, de Boer MJ, Hoorntje JC, Zijlstra F. Outcome in patients treated with primary angioplasty for acute myocardial infarction due to left main coronary artery occlusion. Am J Cardiol. 2003 Jan 15;91(2):235-8.

3. Lee MS, Tseng CH, Barker CM, Menon V, Steckman D, Shemin R, Hochman JS. Outcome after surgery and percutaneous intervention for cardiogenic shock and left main disease. Ann Thorac Surg. 2008 Jul;86(1):29-34Kalbfleisch H, Hort W. Quantitative study on the size of coronary artery supplying areas postmortem, Am Heart J , 1977, vol. 94 (pg. 183-188)

4. The cVAD Registry (formerly known as the U.S. Impella registry) contains nearly 3,000 patient records and includes Institutional Review Board (IRB) approval, complete data monitoring and Clinical Events Committee adjudication. It is subject to FDA definitions and audits.

5. 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.

6. 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.

7. O'Neill, W. Outcomes for 15,259 US Patients With Acute MI Cardiogenic Shock (AMICS) Supported With Impella; data presented also included early findings from the Detroit Cardiogenic Shock Initiative (DCSI). Presented at the 66th Annual Scientific Session of the American College of Cardiology, Washington, DC. 2017 March.

8. 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.

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