March 9, 2017

New Study Finds Abiomed Impella® Heart Pump Reduces Injury to Kidneys During High-Risk Percutaneous Coronary Intervention

Circulation Research paper supports previously published randomized clinical trial data

DANVERS, Mass., March 09, 2017 (GLOBE NEWSWIRE) -- A new study published in *Circulation Research* finds use of hemodynamic support with Impella® 2.5 heart pump during high-risk percutaneous coronary intervention (HRPCI) can reduce the risk of acute kidney injury (AKI) even when those patients had preexisting kidney disease[1] and low ejection fraction (EF). The new study builds upon earlier data from PROTECT II[2], a randomized clinical trial, which found kidney injury rates were numerically lower when more contrast was used during HRPCI, and adds to the growing body of evidence of the benefits of hemodynamic support with Impella during HRPCI.

For the new retrospective, single-center study, investigators analyzed the procedure and clinical outcomes of 230 patients with an EF of 35 percent or less before undergoing HRPCI. Half of the patients studied were supported with Impella 2.5 during their procedure, and were compared with a matched-controlled cohort of 115 patients undergoing HRPCI without Impella. In the study, Impella-supported patients were more likely to present with co-morbidities at baseline such as left main and three-vessel disease, and lower EF which led to longer median procedure times and greater median volume of contrast in the Impella arm.

Despite these increased risk factors for kidney injury in the Impella arm, the authors found that just 5.2 percent of the Impella-supported patients developed AKI post-procedure, compared to 27.8 percent in the unsupported patients' cohort. Less than one percent of Impella-supported patients required hemodialysis following the intervention, compared with 6.1 percent of unsupported patients; suggesting that patients who did not receive Impella were six times more likely to need dialysis. The mean length of stay was also longer in the unsupported group.

"A substantial number of high-risk PCI patients have both severely reduced left ventricular function and underlying kidney disease[2], and during their procedure, these patients are exposed to high levels of contrast dye, which further compromises kidney function," said Dr. Michael P. Flaherty, Associate Professor of Medicine and Physiology at University of Louisville School of Medicine; Primary Investigator and first and senior author. "We found that, despite severely reduced ejection fractions and baseline chronic kidney disease (CKD), Impella-supported patients were six times less likely to develop acute kidney injury, underscoring the importance of Impella as part of a renal protective strategy during high-risk PCI."

"We believe that kidney injury resulting from episodic decrease in flow during high-risk PCI can be reduced with Impella support and that stagnation of contrast in the renal tubules may be minimized," continued Dr. Flaherty. "The use of Impella, then, is especially important as more patients undergo complete revascularization rather than staged procedures[3], ostensibly improving periprocedural kidney blood flow and reducing the toxic effects of contrast dye despite low ejection fraction, baseline renal insufficiency and longer procedure times."

"Above and beyond the well-known value of cardiac protection, these data show Protected PCI with Impella may also help prevent renal damage which may require dialysis or other costly treatments," said Dr. Seth Bilazarian, MD, Chief Medical Officer for Abiomed. "This is an important finding, because it may allow interventionalists treating high-risk patients to perform more complete revascularization in those with multi-vessel coronary disease. We can potentially reduce the risks and costs associated with multiple PCI procedures performed in stages, which is how many high-risk patients are still treated today."

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1. Flaherty MP, Pant S, Patel SV, et al. Hemodynamic Support with a Micro-Axial Percutaneous Left Ventricular Assist Device (Impella®) Protects Against Acute Kidney Injury in Patients Undergoing High-Risk Percutaneous Coronary Intervention. Circ Res. 2017 Jan 10.

2. O'Neill WW, Kleiman NS, Moses J, et al. A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study. Circulation. 2012 Oct 2;126(14):1717-27.

3. Watkins S, Oldroyd KG, Preda I, et al. Five-year outcomes of staged percutaneous coronary intervention in the SYNTAX

study. EuroIntervention. 2015 Apr;10(12):1402-8.

ABOUT IMPELLA

The Impella 2.5®, Impella CP® and Impella 5.0® are FDA-approved 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® 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®, 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.

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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.

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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