Data Presented at TCT Connect Finds Pre-PCI Use of Impella for AMI Cardiogenic Shock is Associated with Higher Survival, Particularly in Women

October 16, 2020

DANVERS, Mass.--(BUSINESS WIRE)--Oct. 16, 2020-- Two studies of AMI cardiogenic shock (AMICS) patients found higher survival when Impella was placed pre-PCI, compared to when Impella was placed after PCI. The findings were presented at TCT Connect, the 32nd annual scientific symposium of the Cardiovascular Research Foundation.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20201016005118/en/

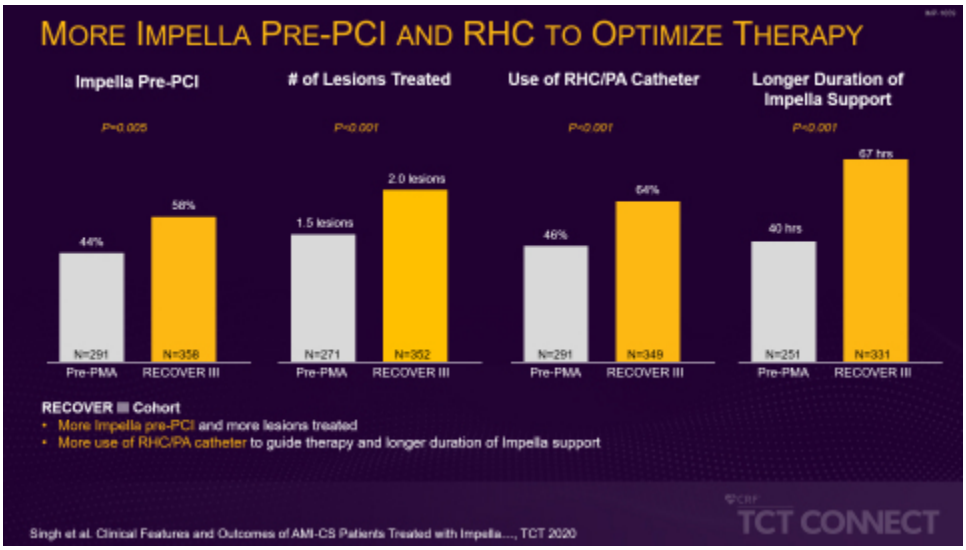

Figure 1 (Graphic: Business Wire)

In the first study, presented by Hemindermeet Singh, MD, of Ascension St. John Hospital, researchers compared 649 patients from two cohorts: a recent cohort (2017–2019) from the RECOVER III post-market approval (PMA) study, after the widespread adoption of the best practice of placing Impella pre-PCI, and a cohort from before PMA (2008–2014) when the practice of placing Impella pre-PCI was not yet widely adopted. Researchers found an 18% relative improvement in overall survival in the recent cohort, indicating an associated benefit to placing Impella pre-PCI. The recent cohort also had lower incidences of peri-PCI acute kidney injury (AKI) and major bleeding or vascular complications. This is despite a higher prevalence of hypertension, smoking, stroke, and New York Heart Association (NYHA) class III/IV heart failure in the recent cohort. (*see figure 1*)

“This data shows increased adoption of the cardiogenic shock best practices over the last three years has led to an improvement in overall survival rates,” said Amir Kaki, MD, the study’s senior author, an interventional cardiologist and director of mechanical circulatory support at Ascension St. John Hospital. “In order to improve outcomes for our patients, it is important for practitioners to apply these best practices, which include early identification of shock, use of a right heart cath, reduction of toxic inotropes and use of Impella prior to the PCI.”

“Our study demonstrates growing physician and institutional experience. The implementation of standardized cardiogenic shock protocols and the increasing use of strategies to reduce vascular and bleeding complications are associated with better survival. In-depth understanding of these factors has significant potential of improving outcomes in cardiogenic shock patients in the community at large,” said Dr. Singh.

The second study, presented by Tayyab Shah, MD, of the Yale School of Medicine, analyzed data collected from the RECOVER III trial between 2017-2019. It found that placing Impella pre-PCI in AMICS patients is associated with higher survival than placing Impella post-PCI, especially in women. Study investigators determined women had a 74% relative survival benefit with Impella use pre-PCI as compared to post-PCI. The study authors conclude early implantation of Impella provides a significant survival benefit, particularly to women. (*see figure 2*)

“This study suggests that the early use of the Impella device to support patients in cardiogenic shock, before PCI and inotrope/vasopressor usage, may provide a survival benefit particularly to females,” said Dr. Shah. “This is an interesting result from an observational study with meaningful clinical implications, which need to be further explored in the upcoming RECOVER IV randomized controlled trial.”

Since FDA PMA approval, Abiomed (NASDAQ: ABMD) has collected data on nearly 100% of U.S. Impella patients in the observational Impella Quality (IQ) Database. This clinical data, combined with the FDA post-approval studies, such as RECOVER III, that are embedded in Abiomed’s prospective, IRB approved, catheter-based Ventricular Assist Devices (cVAD) Study, helped identify and validate best practices for Impella use associated with improved survival and native heart recovery. These best practices, including use of Impella pre-PCI, early identification of shock, reduction of inotropes, and hemodynamic monitoring with pulmonary artery catheters, have now been validated in multiple publications. (*see figure 3*)

Additionally, independent physician-led studies with best practice protocols that include placing Impella pre-PCI, such as the National Cardiogenic Shock Initiative Study (NCSI), the Inova Study (Tehrani et al), and the Japanese P-VAD Study (J-PVAD), have demonstrated significant increases in survival compared to historic cardiogenic shock survival rates. (*see figure 4*) These best practices will inform the study protocol for the upcoming RECOVER IV Randomized Controlled Trial of Impella in AMICS.

To share best practices in AMI cardiogenic shock treatment, Abiomed is hosting a symposium at TCT Connect on Sunday, October 18, 2020 at 10:00 a.m. EDT, titled *Achieving >70% AMI-CS Survival: Best Practices from Around the World*. The symposium is chaired by William O’Neill, MD, medical director of the Center for Structural Heart Disease at Henry Ford Hospital.

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 reopen blocked coronary arteries. The Impella 2.5, Impella CP, Impella CP with SmartAssist®, Impella 5.0®, Impella LD®, and Impella 5.5® with SmartAssist® 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. The Impella RP is also authorized for emergency use by healthcare providers (HCPs) in the hospital setting for providing temporary right ventricular support for up to 14 days in critical care patients with a body surface area ≥1.5 m2, for the treatment of acute right heart failure or decompensation caused by complications related to coronavirus disease 2019 (COVID-19), including pulmonary embolism (PE). The Impella RP has not been cleared or approved for the treatment of acute right heart failure or decompensation caused by complications related to COVID-19. Impella Left Ventricular (LV) Support Systems are also authorized for emergency use by HCPs in the hospital setting for providing temporary (≤ 4 days for Impella 2.5, Impella CP, and Impella CP with SmartAssist; and ≤ 14 days for Impella 5.0 and Impella 5.5 with SmartAssist) LV unloading and support to treat critical care patients with confirmed COVID-19 infection who are undergoing ECMO treatment and who develop pulmonary edema while on V-A ECMO support or late cardiac decompensation from myocarditis while on V-V ECMO support. The authorized Impella LV Support Systems have neither been cleared or approved for the authorized indication for use. The Impella RP and Impella LV Support Systems have been authorized for the above emergency use by FDA under an EUA and have been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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 with SmartAssist 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. Abiomed, Impella, Impella 2.5, Impella 5.0, Impella 5.5, Impella LD, Impella CP, Impella RP, SmartAssist and Impella Connect are registered trademarks of Abiomed, Inc., and are registered in the U.S. and certain foreign countries. Impella BTR, Impella ECP, CVAD Study and STEMI DTU Study are pending trademarks of Abiomed, Inc.

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 the scope, scale and duration of the impact of the COVID-19 pandemic, 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 the filings subsequently filed with or furnished to the SEC. 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20201016005118/en/

Tom Langford
Director of Communication
(978) 882-8408
TLangford@abiomed.com

Source: Abiomed, Inc.