National Cardiogenic Shock Initiative (NCSI) with Impella Best Practices Demonstrates 72% Survival with 98% Native Heart Recovery

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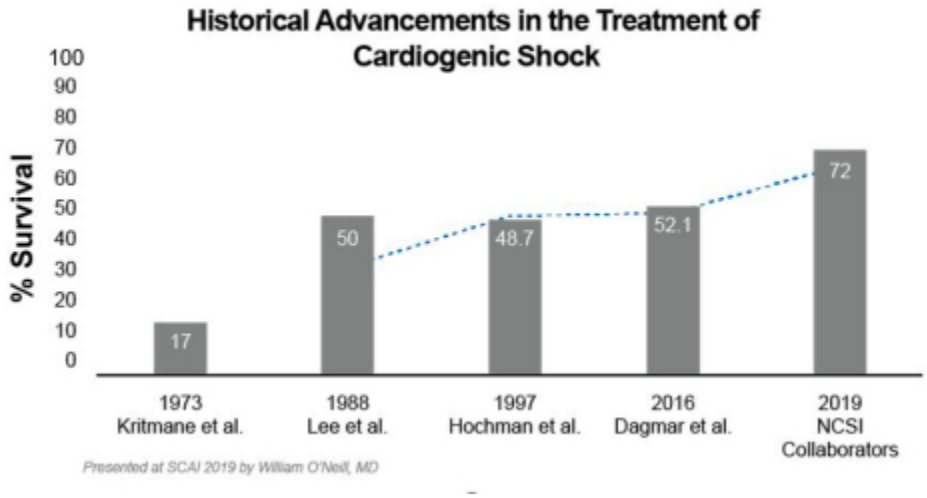
Improves upon AMI cardiogenic shock historical survival of 50%

LAS VEGAS--(BUSINESS WIRE)--May 21, 2019-- Abiomed (NASDAQ:ABMD) announces that new data from the National Cardiogenic Shock Initiative Study (NCSI) on 171 consecutive AMI cardiogenic shock (AMICS) patients from 35 sites demonstrates 72% survival with 98% native heart recovery at discharge. The patients were treated with the NCSI protocol, which includes placing the Impella heart pump before revascularization. The study demonstrates the protocol-based approach to increasing survival rates in cardiogenic shock is reproducible in academic and community hospitals across the United States. Results were presented at the 2019 Society for Cardiovascular Angiography & Interventions (SCAI) Scientific Sessions and simultaneously published in *Catheterization and Cardiovascular Interventions* (CCI).

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20190521005741/en/



National Cardiogenic Shock Initiative (NCSI) with Impella best practices demonstrates 72% survival with 98% native heart recovery at discharge. This improves upon AMI cardiogenic shock historical survival of 50%. (Graphic: Abiomed, Inc.)

The investigators of the physician-led NCSI represent the largest working group studying the effects of mechanical circulatory support in AMICS patients. Their goals are to increase cardiogenic shock survival, which has stagnated for the last 20 years at around 50% and provide unloading therapy to achieve native heart recovery[1]. The NCSI protocol includes best practices of placing Impella pre-PCI, identifying shock early and minimizing the use of inotropes. These best practices were identified retrospectively through Abiomed's Impella Quality (IQ) Database and the U.S. Impella Registry, now called the cVAD Study, and were tested and validated prospectively in the original Detroit CSI study, which demonstrated improved survival and native heart recovery.

The NCSI used patient selection criteria that mimicked prior cardiogenic shock studies[2,3]. Patients included in the study were treated between July 2016 and February 2019.

Patient Characteristics

Demographics	**All (n=171)**
Average age	63 years
Gender – male	77%
AMI cardiogenic shock present on admission	68%
On inotropes or vasopressors prior to or during index procedure	83%
Witnessed out-of-hospital cardiac arrest	20%
In-hospital cardiac arrest	29%
CPR at the time of Impella insertion	10%

"By adopting the NCSI protocol, physicians around the country have standardized the treatment of cardiogenic shock and are improving patient outcomes by using best practices which include early placement of the Impella heart pump," said William O'Neill, MD, medical director of the Center for Structural Heart Disease at Henry Ford Hospital. "Similar to door-to-balloon time, the adoption of these best practices is an evolution in clinical practice that will benefit our sickest patients. Tracking, collecting and applying real-world evidence will allow physicians to continue to increase survival and heart recovery for these patients."

"This new clinical data validates, as prior publications have demonstrated, the importance of best practice protocols to improve survival and native heart recovery for patients with cardiogenic shock," said Michael R. Minogue, Chairman, President and Chief Executive Officer of Abiomed. "Abiomed is committed to investing in innovation, clinical research with prior and future FDA studies, and analyzing real-world evidence through our Impella

Quality (IQ) Database and cVAD Study. We will continue to partner with physicians and hospital teams to create the field of heart recovery."

Since FDA PMA approval, Abiomed has collected data on nearly 100% of U.S. Impella patients in the observational IQ Database. This clinical data, combined with the FDA post-approval studies embedded in Abiomed's prospective 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, reduction of inotropes, early identification of shock, and hemodynamic monitoring with pulmonary artery catheters, have now been validated in multiple publications:

- *Journal of Interventional Cardiology*, 2014: Placement of Impella pre-PCI is associated with more complete revascularization and improved survival to discharge in the setting of AMI cardiogenic shock (65% with Impella placed pre-PCI vs. 41% post-PCI, p=0.023).
- *American Journal of Cardiology*, 2017: Initiation of Impella before PCI and prior to initiation of inotropes or vasopressors is independently associated with improved survival. Survival to discharge was 68%, 46%, 35%, 35%, and 26% for patients requiring 0, 1, 2, 3, and ≥4 inotropes before mechanical circulatory support, respectively (p <0.001), in an analysis of 281 AMI cardiogenic shock patients.
- *Journal of Interventional Cardiology*, 2017: Demonstrates a 48% survival at 30 days when Impella is implanted pre-PCI, compared to a 13% survival when Impella is implanted post-PCI for left main in cardiogenic shock (p=0.004).
- *American Heart Journal*, 2018: Analysis of 15,259 U.S. patients in the IQ Database demonstrated an improvement in survival to explant from 52% to 59% when Impella was placed pre-PCI (p=0.001).
- *National Cardiogenic Shock Initiative Study Late Breaking Clinical Science*, TCT 2018: Data from the first 104 patients utilizing best practices in the National Cardiogenic Shock Initiative (NCSI) Study found 77% survival to discharge with 99% native heart recovery.
- *Circulation*, 2018: Analysis reinforces best practices of reduced use of inotropes and placement of Impella pre-PCI leads to improved survival rates. Survival benefit of Impella pre-PCI revealed trend vs "matched" IABP-Shock: 57.3% vs. 46.7% (p=0.18). Significant survival to discharge benefit with Impella in patients who did not receive inotropes (56.6% vs. 29.4% p<0.01). A subset of patients from this paper was presented at *American College of Cardiology (ACC) 2019 Scientific Sessions* when Andreas Schäfer, MD, presented an abstract that showed improved survival to discharge when Impella is placed pre-PCI of 71% vs. 49% post-PCI (p= 0.0021).
- *Journal of the American College of Cardiology*, 2018: Rab, et al., summarizes data from IQ Database, cVAD Study and NCSI and concluded that best practices are associated with improved survival in AMI cardiogenic shock.
- *Journal of the American College of Cardiology*, 2019: After Inova Heart and Vascular Institute instituted a best practice protocol that includes early use of percutaneous mechanical circulatory support, AMI cardiogenic shock survival at 30 days rose from 44% to 82% (p=0.0001).

1. Impella has exclusive FDA approval as a therapy for cardiogenic shock to allow for native heart recovery.
2. Intra-aortic Balloon Support for Myocardial Infarction with Cardiogenic Shock; Thiele, H, et al., New England Journal of Medicine. 2012 Oct 4; DOI: 10.1056/NEJMoa1208410
3. PCI Strategies in Patients with Acute Myocardial Infarction and Cardiogenic Shock: Results of the Culprit-Shock Trial; Thiele, H. et al., New England Journal of Medicine. 2017 Dec 21; DOI: 10.1056/NEJMoa1710261

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 re-open blocked coronary arteries. The Impella 2.5, Impella CP, Impella CP with SmartAssist™, Impella 5.0® and Impella LD® 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.

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™ heart pump 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.

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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