TCT Connect to Highlight How Impella Enables Improved Outcomes for High-Risk PCI, Cardiogenic Shock and Right Heart Failure Patients

October 8, 2020

DANVERS, Mass.--(BUSINESS WIRE)--Oct. 8, 2020-- The benefits of a more complete revascularization with Impella heart pumps in high-risk percutaneous coronary intervention (PCI) patients and the value of Impella protocol-based treatment for survival and native heart recovery in cardiogenic shock patients will be highlighted at TCT Connect, the 32nd annual scientific symposium of the Cardiovascular Research Foundation. Throughout the virtual conference, October 14-18, leading physicians will present data about the benefits of Impella therapy, while Abiomed (NASDAQ:ABMD) will offer virtual training around access, closure and patient management skills to achieve improved outcomes.

The latest data from the PROTECT III trial has been selected as a TCT Connect 2020 “Best of Abstract” and will be presented by William O’Neill, MD, on Thursday, October 15 at 3:25 p.m. EDT. This presentation will be an update to the PROTECT III data presented at TCT 2019 which demonstrated a reduction in the primary endpoint of death, stroke, myocardial infarction and repeat procedures at 90 days with Impella-supported Protected PCI, compared to the PROTECT II Randomized Controlled Trial (RCT). The PROTECT series of FDA clinical studies, which includes PROTECT I, the PROTECT II RCT and PROTECT III, is the largest-ever FDA study of hemodynamically supported high-risk PCI patients.

Abiomed is hosting two e-satellite symposia where renowned interventionalists will present data and best practices for using Impella technology to improve outcomes in both high-risk PCI and cardiogenic shock.

The first symposium will feature best practices for using percutaneous mechanical circulatory support to enable complete revascularization in complex and sick patients, including COVID-19 patients. It is chaired by Cindy Grines, MD, chief scientific officer of Northside Hospital Cardiovascular Institute in Atlanta and president of the Society for Cardiovascular Angiography and Interventions (SCAI).

The schedule for this symposium is below:

Protected PCI in COVID-19 Era: The Rise in Importance of Complete Revascularization
Saturday, October 17
2:00-3:00 p.m. EDT
Chair: Cindy Grines, MD

Presenters:

- **Protected PCI in COVID-19 Era: The Rise in Importance of Complete Revascularization**
  Cindy Grines, MD
- **Clinical Relevance of Revascularization Extent in Protected PCI: Insight from Italian Studies**
  Francesco Burzotta, MD
- **Contemporary Practices of HR-PCI Using Percutaneous MCS: Results from PROTECT III, The Largest Prospective Multi-Center Single-Arm Study**
  Jeffrey W. Moses, MD
- **Rapid and Safe Adoption of the New Single-Access Technique**
  Duane Pinto, MD

The second symposium will highlight the importance of adopting best practices in AMI cardiogenic shock. It features Giuseppe Tarantini, MD, PhD, director of interventional cardiology at Padua University, and president of the Italian Society of Interventional Cardiology–GISE.

The schedule for this symposium is below:

Achieving >70% AMI Cardiogenic Shock Survival: Best Practices from Around the World
Sunday, October 18
10:00-11:00 a.m. EDT
Chair: William O’Neill , MD

Presenters:

- **Achieving >70% AMI Cardiogenic Shock Survival: Insight from National Cardiogenic Shock Initiative**
  William O’Neill, MD
- **Efficacy and Safety of All Impella Use in Japanese Patients with Drug-Resistant Acute HF: Insight from Japan J-PVAD Study**
  Junya Ako, MD
- **Importance of Timing and Impact of Extensive Revascularization on Long-Term Survival in Cardiogenic Shock: Insights from European Multi-Center Studies**
  Giuseppe Tarantini, MD, PhD
- **Closing Summation, RECOVER III and Intro to RECOVER IV**
  William O’Neill, MD

TCT Connect attendees are also invited to visit Abiomed’s virtual booth, which will open at 7:00 a.m. EDT on October 14 on ProtectedPCI.com, to learn more about the Impella heart pump portfolio and watch training videos on topics such as single access techniques, utilizing the left ventricular waveform, managing Impella positioning, the SmartAssist platform, and cardiogenic shock best practices. In addition, the virtual booth will highlight all the new Impella data being presented during TCT Connect.

In all, Impella will be featured in more than 20 abstracts and presentations at TCT Connect, including topics such as:

- **Intermediate-Term Left Ventricular Function Following Non-Emergent Impella Protected PCI: Restore EF Study**
  Session: Cardiogenic Shock and Hemodynamic Support
  Mitul Patel, MD
  Wednesday, October 14
  8:00 a.m. EDT
- **Early Impella RP Support Improves Outcomes for Acute Right Ventricular Failure Complicated by Cardiogenic shock**
  Session: Cardiogenic Shock and Hemodynamic Support
  Mark Anderson, MD
  Wednesday, October 14
  8:00 a.m. EDT
- **Safety and Efficacy of Percutaneous Mechanical Circulatory Support During High-Risk PCI Using Contemporary Practices: Results from the Largest Single Prospective Real-World Study (PROTECT III)**
  Session: TCT Connect 2020 Best of Abstracts
  William O'Neill, MD
  Thursday, October 15
  3:25 p.m. EDT

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.

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