First Patient Enrolls in STEMI DTU Randomized Controlled FDA Trial; Study Aims to Further Demonstrate Impella's Safety and Effectiveness

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DANVERS, Mass.--(BUSINESS WIRE)--Dec. 16, 2019-- Abiomed (NASDAQ: ABMD) announces initiation of the ST-Elevation Myocardial Infarction Door-to-Unloading (STEMI DTU) Pivotal Randomized Controlled Trial (RCT), which will explore whether unloading the heart's left ventricle for 30 minutes with an Impella heart pump prior to opening blocked arteries will reduce infarct size after a heart attack and lead to a reduction in future heart failure rates. The first patient in the multi-center trial was enrolled at Spectrum Health in Grand Rapids, Michigan, by Kevin Wolschleger, MD.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20191216005332/en/

The Impella CP heart pump will be used in the STEMI DTU randomized controlled trial, which will study unloading prior to reperfusion as a therapy to reduce heart failure risk. (Photo: Business Wire)

"We are honored to be the first to enroll in this important study which builds on earlier research that shows promise for slowing the growing epidemic of heart failure and improving outcomes for heart attack patients around the world." said Dr. Wolschleger, an interventional cardiologist at Spectrum Health.

"Spectrum Health has one of the longest Impella experiences in the United States, and we are proud and excited to be a part of this pivotal clinical trial that has the promise to bring this paradigm changing therapy to patients," said David Wohns, MD, chief of cardiology at Spectrum Health.

The STEMI DTU RCT is the fourth completed or ongoing randomized controlled trial of Impella, following:

- The successfully completed PROTECT II RCT, which demonstrated Impella is safe and effective compared to the intra-aortic balloon pump (IABP) (*Circulation*, 2012; FDA Press Release, 2015)
- The successfully completed STEM DTU pilot RCT, which demonstrated 30 minutes of unloading prior to reperfusion in STEMI patients is safe and feasible (*Circulation*, 2018)
- The ongoing DanGer Shock RCT of AMI cardiogenic shock patients, which compares patients receiving Impella to conventional therapy (*American Heart Journal*, 2019)

Impella is the most studied mechanical circulatory support device in the history of the FDA. The FDA granted Impella its highest level of regulatory approval based on the PROTECT II randomized controlled trial and multiple other FDA audited prospective trials that demonstrate Impella's safety and efficacy, compared to the intra-aortic balloon pump (IABP). When compared to other mechanical circulatory support devices, Impella has the best overall safety profile for stroke, aortic valve damage, vascular complications, major bleeding and hemolysis.

The STEMI DTU RCT plans to enroll 668 patients undergoing treatment for a STEMI heart attack at up to 60 sites. The study will have two arms. Half the patients will be randomized to receive 30 minutes of left ventricular unloading with the Impella CP heart pump prior to reperfusion. The other half will receive immediate reperfusion, the current global standard of care. The primary endpoint is infarct size as a percent of left ventricular mass, measured at 3-5 days using cardiac MRI.

A study that published in *JAMA Cardiology* in October found deaths from heart failure increased 38 percent between 2011 and 2017. If the STEMI DTU trial successfully concludes, it could annually benefit 200,000 heart attack patients in the United States and more than 4 million patients outside the United States.

"If the STEMI DTU pivotal RCT confirms earlier research, it could lead to a paradigm shift in the way STEMI heart attack patients are treated," said Navin Kapur, MD, the study's co-principal investigator and the executive director of the CardioVascular Center for Research and Innovation (CVCRI) at Tufts Medical Center. "This is the first-ever pivotal trial to examine delayed reperfusion and ventricular unloading as a therapy to slow the growing

epidemic of heart failure and improve the standard of care for these patients. On behalf of the study investigators, we are excited this trial is underway and eagerly anticipate the results."

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®, Impella LD®, and Impella 5.5™ with Smart Assist® 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. Impella is the most studied mechanical circulatory support device in the history of the FDA with more than 10 years of FDA studies, real world clinical data on more than 100,000 patients and more than 550 peer-reviewed publications.

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 Smart Assist® 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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