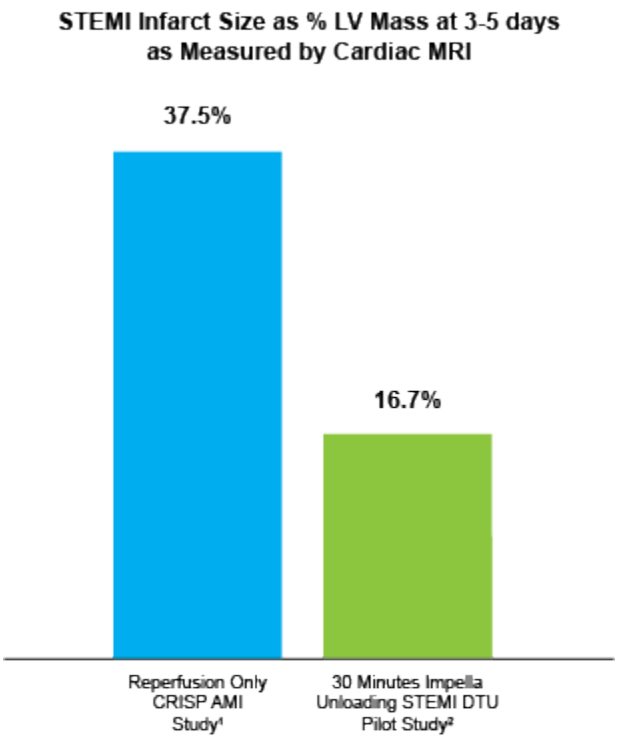
FDA Approves Initiation of STEMI DTU Pivotal Randomized Controlled Trial

May 2, 2019

DANVERS, Mass.--(BUSINESS WIRE)--May 2, 2019-- Abiomed (NASDAQ: ABMD) announces that, on April 26, the FDA approved initiation of the ST-Elevation Myocardial Infarction Door-to-Unloading (STEMI DTU) Pivotal Randomized Controlled Trial. The prospective, multi-center, two-arm trial plans to enroll 668 patients undergoing treatment for a STEMI heart attack. Half the patients will be randomized to receive delayed reperfusion after 30 minutes of left ventricular unloading with the Impella CP. The other half will receive immediate reperfusion, the current standard of care.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20190502005270/en/



The STEMI DTU safety and feasibility trial, when compared to the standard of care (reperfusion only) arm of the CRISP AMI trial demonstrates the potential to reduce infarct size in STEMI. (Graphic: Business Wire)

The trial will test the hypothesis that unloading the left ventricle for 30 minutes prior to reperfusion will reduce myocardial damage from a heart attack and lead to a reduction in future heart failure related events. Myocardial damage can lead to an infarct, and every 5% increase in infarct size is associated with a 20% increase in relative hazard for all-cause mortality or hospitalization for heart failure within one year after a primary PCI[1]. Coronary artery disease is the number one cause of death in the United States. 47% of women and 36% of men over the age of 45 will die within 5 years of their first heart attack[2].

“The STEMI DTU Pivotal Trial has the potential to improve the standard of care, slow the growing epidemic of heart failure and improve outcomes for millions of heart attack patients. This trial is the first of its kind to focus on ventricular unloading as part of a therapeutic approach for heart attacks without cardiogenic shock and could lead to a paradigm shift in the way heart attack patients are treated worldwide,” 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.

Study Summary

Planned Enrollment:

- 668 subjects, enrolled at up to 60 sites
- Additionally, the protocol requires each site to “roll-in” two patients (one in each arm) to test the study protocol before beginning enrollment. The trial allows for an adaptive design, which permits adjustments to the study sample size after an interim analysis.

Expected Timeline:

- Enrollment begins in October 2019 and is expected to end in 3-4 years, 2022-2023
- 6 months after enrollment completion: FDA submission for indication approval, based on primary endpoint and safety data analysis

Endpoints:

- Primary Endpoint - Infarct size as a percent of left ventricular mass, measured at 3-5 days using cardiac MRI
- Key Secondary Effectiveness Endpoint - A composite of the primary endpoint and the following:
  - Cardiogenic shock after 24 hours post enrollment out to 30 days
  - Cardiovascular mortality at 24 months
  - Heart failure requiring hospitalization at 24 months
  - Implantable cardioverter-defibrillator (ICD) and cardiac resynchronization therapy (CRT) placement at 24 months
  - The trial is powered for multiple other secondary endpoints and has numerous exploratory endpoints, such as infarct size to area at risk

Projected Budget:

- $25 million to complete enrollment with an additional two-year follow up to clinical secondary endpoints

Reimbursement:

- Reimbursement for the Impella device is anticipated for patients in the study through CMS category B, as it was during the STEMI DTU safety and feasibility trial

A detailed protocol synopsis is available at this link.

The pivotal trial will build on the promising results of the successful STEMI DTU safety and feasibility trial, which met its goal by demonstrating it is safe and feasible to conduct a study of 30 minutes of unloading with delayed reperfusion. The accompanying chart compares the safety and feasibility trial results to the CRISP AMI trial's standard of care arm (reperfusion only) and demonstrates how 30 minutes of unloading prior to reperfusion has the potential to reduce infarct size in STEMI.

"A successful study will transform the treatment of heart attacks and reduce heart failure for hundreds of thousands of patients each year. As a result, it is important to execute with the highest scientific rigor to ensure a successful study concludes with a Class I recommendation to reach 200,000 U.S. heart attack patients and more than 4 million patients outside the U.S.," said Michael R. Minogue, Chairman, President and CEO of Abiomed.

The pivotal trial will be overseen by a steering committee of five expert cardiologists and clinical trialists. They are: **Dr. Kapur**, **William O'Neill** , MD, medical director of the Center for Structural Heart Disease at Henry Ford Hospital, **Jeffrey Moses**, MD, professor of medicine at Columbia University Medical Center and director of interventional cardiovascular therapeutics at Columbia University Medical Center, **Gregg Stone**, MD, professor of medicine at Columbia University College of Physicians and Surgeons and director of cardiovascular research and education at the Center for Interventional Vascular Therapy at New York-Presbyterian Hospital/Columbia University Medical Center, and **James Udelson**, MD, chief of the division of cardiology at Tufts Medical Center.

The trial is sponsored by Abiomed. Impella heart pumps are not FDA approved for use in STEMI patients without cardiogenic shock.

ABOUT IMPELLA HEART PUMPS

The Impella 2.5 and Impella CP devices are FDA 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 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. 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.

Impella is the most studied mechanical circulatory support device in the history of the FDA and has exclusive PMA approvals for high-risk PCI, as a therapy to allow for native heart recovery after cardiogenic shock derived from AMI or cardiomyopathy, and right ventricular heart failure.

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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.

[1] Stone, et al., Relationship Between Infarct Size and Outcomes Following Primary PCI, *JACC*, 2016

[2] Heart Disease and Stroke Statistics 2019 Update: A Report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee." (*Circulation*. 2019;139(10):56–528).

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