FDA Approves Impella 5.0 and Impella LD Extended Duration of Use to 14 Days for Cardiogenic Shock Derived from AMI or Cardiomyopathy

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DANVERS, Mass.--(BUSINESS WIRE)--May 13, 2019-- Abiomed (NASDAQ:ABMD) announces the U.S. FDA has approved the expansion of the Impella 5.0 and Impella LD PMA labeling for the treatment of cardiogenic shock. The expansion extends the duration of support for each pump from 6 days to 14 days. The Impella 5.0 and the Impella LD are forward flow heart pumps that deliver up to 5 L/min, stabilizing a patient's hemodynamics, unloading the left ventricle, and perfusing the end organs, allowing for the potential of native heart recovery or return to heart function baseline. The Impella 5.0 is implanted through the femoral or axillary artery and the Impella LD is implanted directly into the aorta. Both allow patients to walk around the unit while on support.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20190513005623/en/

Erin Hanussak, then 33 years old, suffered from myocarditis and went into cardiogenic shock. She benefited from Impella CP and Impella 5.0 support. (Photo: Abiomed, Inc.)

Impella heart pumps have FDA PMA approval to treat heart attack patients in cardiogenic shock, and for shock associated with peripartum cardiomyopathy or myocarditis, and have the unique ability to enable the heart to rest and recover, allowing patients to return home with their own heart. The expanded indication allows for the opportunity to provide longer duration of support for critically ill patients and a longer period of assessment of heart recovery.

One patient who benefited from Impella 5.0 support is Erin Hanussak, then 33 years old, who suffered from myocarditis and went into cardiogenic shock. Her ejection fraction was 15%. Under the care of Jacob Abraham, MD, a Heart Failure Cardiologist at Providence St. Vincent Medical Center and Medical Director of its Center for Advanced Heart Disease, physicians implanted the Impella CP heart pump. Although Erin's condition improved, the team determined that her heart needed additional support. Surgeons inserted the Impella 5.0 into her axillary artery, which allowed Erin to begin physical therapy and walk the hospital corridors with hospital staff. Her kidneys began to improve and after 12 days, the Impella 5.0 was explanted. Erin returned home to her family with her native heart and is back to her busy life as a mom.

"Early recognition, escalation and a heart team approach are crucial for patients in cardiogenic shock," said Dr. Abraham. "The Impella 5.0 and Impella LD's ability to provide greater hemodynamic support and unload the left ventricle make them ideal tools for patients like Erin who need longer duration support and will benefit from ambulation."

The FDA's original PMA approval indicating Impella as safe and effective for the treatment of cardiogenic shock was granted in 2016. This approval was based on an analysis of 415 patients from the FDA study RECOVER 1 and the U.S. Impella registry, and an Impella literature review of 692 patients in 17 clinical studies. Additionally, more than 24,000 Impella patients supported by Impella devices were reviewed in a safety analysis.

The Impella heart pump platform 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.

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.

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.

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