The data submitted to the FDA in support of this expanded PMA indication included an analysis of 229 consecutive patients with mild to moderately reduced ejection fraction from the cVAD Registry study. In this cohort, the majority of patients were turned down for open heart surgery (CABG) due to their surgical risk factors and remaining minority refused surgery. On average, these patients were older, more often female, had more lesions treated, experienced more hypertension and presented with higher ejection fraction than patients in the cVAD registry cohort with ejection fraction less than 35% (n=464). This comparison demonstrated that high risk PCI with Impella support was feasible, safe and achieved favorable outcomes in patients with mild to moderately reduced ejection fraction.

The data collection from the cVAD registry includes Institutional Review Board (IRB) approval, complete data monitoring and Clinical Events Committee adjudication. This clinical data reinforces prior FDA studies demonstrating the safety and effectiveness of Impella support in elective, urgent and emergent patient populations.

“This expanded FDA approval with moderately reduced ejection fraction validates our real-world experience using hemodynamic support in patients turned down for surgery with severe coronary artery disease,” said Ehtisham Mahmud, MD, FACC, FSCAI, Division Chief, Cardiovascular Medicine and Director, Sulpizio Cardiovascular Center, UC San Diego. “These patients who have often been managed medically in the past may have a new option for treatment.”

“Our patients are increasingly more complex, requiring higher levels of operator skill and protocol driven use of hemodynamic support in the cath lab,” said Tony DeMartini, MD, FACC, Interventional Cardiologist, Edward-Elmhurst Health. “These patients often experience improved quality of life and with complete revascularization can have improved ejection fraction following Protected PCI.”

“Abiomed would like to thank the physician community, caregivers, employees and regulators involved in the FDA clinical trials and cVAD post market approval studies,” said Michael R. Minogue, President, Chairman and CEO of Abiomed. “Abiomed takes great satisfaction in knowing that our significant investment in clinical research over the last 12 years has helped thousands of patients, identified best practices and expanded our regulatory indications in both high risk PCI and cardiogenic shock.”

1. Society for Cardiovascular Angiography and Interventions (SCAI), American College of Cardiology (ACC), Heart Failure Society of America (HFSA), Society of Thoracic Surgeons (STS)
device implantation, myocardial infarction, heart transplant, or open-heart surgery. 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.

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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.

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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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