FDA Confirms Impella RP is Safe and Effective; Only Right-Sided Device with FDA Approval

May 21, 2019

Use of early identification protocol leads to higher survival and native heart recovery, as demonstrated in FDA studies

DANVERS, Mass.--(BUSINESS WIRE)--May 21, 2019-- In a letter sent to healthcare providers today, the U.S. FDA validates that Abiomed's (NASDAQ: ABMD) Impella RP heart pump is safe and effective for treatment of right heart failure. The letter comes after the FDA examined the results from Abiomed's 18-month post-approval study (PAS) of 42 Impella RP patients. The data shows a 64% survival rate and 90% heart recovery for the subgroup of PAS patients who met the enrollment criteria of Impella RP's premarket clinical studies. That survival rate is, as the FDA writes in its letter, "similar to the premarket clinical study survival rate," which was 73%. A control group humanitarian device exemption (HDE) study of a non-Impella surgical device[1] using the same protocol showed a survival rate of 43%.

FDA Data Source	Survival Rates
Post-approval study (n=14)	64% (9/14)
Premarket clinical studies (RR + CAP + HDE PAS) (n=60)	73% (44/60)
PMA control group data (non-Impella surgical device) (n=24)	43% (10/24)

The FDA letter emphasizes the need for early patient selection and determines late identification and treatment of cardiogenic shock as the root cause of differences between the survival rate in the pre-market study and the PAS. The FDA writes, "PAS patients who would not have qualified for the premarket clinical studies were more likely to have been in cardiogenic shock for longer than 48 hours, experienced a cardiac arrest, or suffered a pre-implant hypoxic or ischemic neurologic event before getting the Impella RP system implanted." Healthcare providers are encouraged to use the Impella RP checklist, which the FDA and Abiomed collaborated to develop, to assist with proper patient selection to optimize outcomes.

The FDA has no safety concerns about the Impella RP itself and noted the ongoing collaboration between the agency and Abiomed during this process, including interactive labeling updates around patient selection guidelines and best practices. The 18-month PAS report has been accepted by the FDA and is successfully closed.

Impella RP is the most studied right-sided device and the only percutaneous technology with FDA approval designating it as safe and effective for right heart support. Its exclusive FDA approval is a result of five years of research that included:

- RECOVER RIGHT, an FDA-approved, prospective, multicenter, single-arm study, which commenced after the company received FDA investigational device exemption (IDE) approval in November 2012 and concluded in 2014.
- HDE approval study, which was completed in January 2015
- A Continuous Access Protocol (CAP)
- FDA post-approval study, initiated after PMA approval in September 2017

Abiomed is committed to improving patient outcomes by performing post-market patient surveillance and FDA studies, collecting real-world evidence and developing best practices. Abiomed tracks outcomes on nearly 100% of its U.S. patients through its Impella Quality (IQ) Database, helps improve patient outcomes in real-time through its Impella Connect cloud-based platform, and prospectively conducts FDA clinical studies through its IRB approved cVAD Study.

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® and Impella LD® 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.

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™ heart pump 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.

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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.

[1] Humanitarian Device Exemption (HDE) study of surgical VAD is not powered for comparison but uses the same FDA protocol for right ventricular failure. HDE criteria to meet is safe and probable benefit, compared to safe and effective for PMA approval.

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