FDA Issues Emergency Use Authorization for Impella RP as Therapy for COVID-19 Patients with Right Heart Failure

June 1, 2020

DANVERS, Mass.--(BUSINESS WIRE)--Jun. 1, 2020-- The United States Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) for Impella RP to include patients suffering from COVID-19 related right heart failure or decompensation, including pulmonary embolism (PE). Abiomed (NASDAQ: ABMD) manufactures Impella RP.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200601005257/en/

Impella RP is now FDA indicated for COVID-19 related complications, including pulmonary embolism. (Photo: Business Wire)

Impella RP is a temporary heart pump that provides circulatory support for patients who develop right side ventricular failure. Five years of pre- and post-market clinical studies support Impella RP's safety and efficacy. In 2017, Impella RP received FDA approval as safe and effective for treating right ventricular failure in the setting of acute myocardial infarction and after cardiac surgery. Biventricular cardiac support can be provided when Impella RP is used in combination with left-side Impella devices.

Since the onset of the COVID-19 pandemic, Impella RP has become a therapeutic choice for clinicians treating certain COVID-19 patients suffering right heart failure. COVID-19 can create a prothrombotic environment in some patients resulting in acute pulmonary embolism which may lead to acute right ventricular failure. For critically ill patients the Impella RP can be rapidly deployed in a matter of minutes using a minimally invasive technique in the cardiac catheterization laboratory or operating room.

In its authorization letter, the FDA writes, "Based on extrapolation of data from the approved indication and reported clinical experience, FDA has concluded that the Impella RP may be effective at providing temporary right ventricular support for the treatment of acute right heart failure or decompensation caused by COVID-19 complications, including PE."

"Acute pulmonary embolism is clearly being recognized as a life-threatening manifestation of COVID-19. Impella RP is an important tool to help cardiologists save lives during this pandemic. As we have demonstrated in our series of patients, early recognition of right ventricular dysfunction and early placement of the Impella RP for patients who are hypotensive can be life-saving," said Amir Kaki, an interventional cardiologist and director of mechanical circulatory support at Ascension St. John Hospital in Detroit.

For example, a 59-year-old Detroit-area woman diagnosed with COVID-19 benefited from Impella RP therapy. Dr. Kaki and his colleague, Dr. Ted Schreiber diagnosed her with an acute pulmonary embolism. After the clot was removed, the patient went into right ventricular failure and became hypotensive.

Drs. Schreiber and Kaki quickly placed an Impella RP and observed what they describe as a "dramatic and immediate" improvement in arterial pressure. Over the next five days, the Impella RP remained in place and the patient was monitored remotely using cloud-based Impella Connect technology. On the fifth day, Impella RP was removed. The patient was later discharged home with her native heart. This case has been highlighted in the American College of Cardiology (ACC) educational programming on COVID-19 and can be reviewed online.

"This patient demonstrated a profound recovery after placement of Impella RP," said Dr. Schreiber, who is chief of cardiology at Ascension St. John Macomb-Oakland Hospital and senior author of a 2018 academic review of pulmonary embolism patients treated with Impella RP. "In the course of 30 seconds, there was a dramatic and immediate hemodynamic response and the patient's blood pressure markedly improved. This case demonstrates the efficacy and robustness of Impella RP in the setting of right ventricular failure."

“We appreciate the work of physicians and healthcare providers to treat these difficult patients and thank the FDA for its emergency use authorization for Impella RP. We are committed to helping our customers improve the outcomes of their patients with our percutaneous heart pumps during these COVID-19 times,” said Michael R. Minogue, Abiomed’s Chairman, President and Chief Executive Officer.

Published academic research presented to the FDA that demonstrates the feasibility of Impella RP to improve right ventricular function in patients with pulmonary embolism includes:

- Zuin, et al., *Europe PMC*, 2019 – This review of the treatment of pulmonary embolism using Impella RP concludes, “reviewed manuscripts demonstrated a significant hemodynamic improvement with a concomitant reduction of the right ventricle afterload in all patients which exhibit a low mortality rate in the short-term period.”
- Elder, et al., *Journal of Interventional Cardiology*, 2018 – This study, reviewing the largest experience of pulmonary embolism patients treated with Impella RP concludes, use of Impella RP in patients with pulmonary embolism and right ventricular failure might improve hemodynamics and facilitate a bridge-to-recovery.
- *Bhatia, et al, Catherization & Cardiovascular Interventions, 2017* – A case review of a 47-year-old man with a massive pulmonary embolism supported with Impella RP for 48 hours. Impella support resulted in immediate increase in mean arterial pressure and decreased vasopressor requirements. The patient was discharged in one week.

The existing FDA PMA labeling for Impella RP and the new EUA for Impella reads as follows:

FDA PMA Indication:

The Impella RP System is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m^2, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

Emergency Use Authorization:

The Impella RP System is authorized to be used by healthcare providers (HCP) in the hospital setting for providing temporary right ventricular support for up to 14 days in critical care patients with a body surface area ≥1.5 m^2, for the treatment of acute right heart failure or decompensation caused by complications related to Coronavirus Disease 2019 (COVID-19), including pulmonary embolism (PE).

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, 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 140,000 patients and more than 650 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.

FDA EUA STATEMENT

The Impella RP has neither been cleared or approved for the indication of providing temporary right ventricular support for up to 14 days in critical care patients with a body surface area ≥1.5 m2, for the treatment of acute right heart failure or decompensation caused by complications related to COVID-19, including PE; The Impella RP has been authorized for the above emergency use by FDA under an EUA; and, The Impella RP has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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.

Abiomed, Impella, Impella 2.5, Impella 5.0, Impella 5.5, Impella LD, Impella CP, Impella RP, SmartAssist and Impella Connect are registered trademarks of Abiomed, Inc., and are registered in the U.S. and certain foreign countries. Impella BTR, Impella ECP, CVAD Study and STEMI DTU Study are pending trademarks of Abiomed, Inc.

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 the scope, scale and duration of the impact of the COVID-19 pandemic, 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 the filings subsequently filed with or furnished to the SEC. 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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Source: Abiomed, Inc.