FDA Issues Emergency Use Authorization for Impella Heart Pumps to Provide Unloading Therapy to COVID-19 Patients

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DANVERS, Mass.--(BUSINESS WIRE)--Aug. 4, 2020-- The United States Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) for left-sided Impella heart pumps to provide left ventricular unloading and support to COVID-19 patients who are undergoing ECMO treatment and develop pulmonary edema or myocarditis. Impella is manufactured by Abiomed (NASDAQ: ABMD).

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200804005379/en/

An Impella heart pump helped Devan Smith, 42, recover from COVID-19. (Photo: Business Wire)

COVID-19 causes widespread inflammation which can result in damage to the lungs and heart. This damage may cause severe left ventricular dysfunction manifesting as pulmonary edema and/or myocarditis. Impella combined with ECMO therapy (known as ECpella™) has become an important tool for physicians treating COVID-19 patients suffering from both heart and lung failure.

Impella is the world's smallest heart pump. It first received FDA clearance in 2008 and FDA PMA approval as safe and effective in 2015. During the last 10 years, Impella has provided left ventricular unloading to approximately 10,000 ECMO patients in cardiogenic shock. The FDA's EUA expands the use of Impella as an ECMO unloading therapy to include COVID-19 patients with pulmonary edema or myocarditis.

"The early clinical evidence continues to accrue in favor of including left ventricular unloading in many patients on ECMO," said Christian Bermudez, MD, surgical director, lung transplantation and ECMO, and professor of surgery at the University of Pennsylvania. "The superior clinical outcomes from the combination of Impella and ECMO are likely the result of reducing the stress on the myocardium and work required of the left ventricle, also reducing secondary lung injury due to pulmonary congestion."

42-year-old Devan Smith, a warehouse worker from Pennsylvania who contracted COVID-19 in May, is an example of a patient who benefited from the unloading effect of Impella. After contracting COVID-19, Devan became severely ill with severe myocarditis, multiorgan failure and respiratory failure. Dr. John Finley, interventional cardiologist at Mercy Catholic Medical Center-Fitzgerald Campus in Darby, Pennsylvania, placed venous arterial (V-A) ECMO to combat the respiratory effects of COVID-19 and placed Impella CP to unload Devan's heart and allow it to rest and recover. After four days of support, Devan's heart showed dramatic improvement and he was weaned off Impella. The next morning, he was taken off ECMO support. After three weeks in the hospital, Devan returned home with his native heart functioning normally. In July, he returned to work.

"I'm so thankful for the physicians, nurses and staff who saved my life," said Smith. "My recovery was made possible by their use of life-saving therapies, like Impella and ECMO, that allowed my body to overcome COVID-19."

"As a community hospital, we are proud to offer patients initiation of advanced mechanical circulatory support treatment options. In this case, ECpella allowed us to support both his circulatory collapse and recurrent life-threatening arrhythmias, as a tertiary center helped treat the virus," said Dr. Finley. "It is remarkable to see the patient return home with completely normal heart function, normal respiratory and renal function. This case is a testament to the capabilities of ECpella in the setting of severe COVID-19 infection and myocardial involvement. Without our advanced treatment offerings of ECpella, this extremely ill patient would not have survived this COVID-19 infection."

This is the second EUA the FDA has granted for Impella during the COVID-19 pandemic. On May 29, 2020, the FDA issued an EUA to expand the use of Impella RP to include patients suffering from COVID-19-related right ventricular complications, including right ventricular dysfunction associated with pulmonary embolism. Combined, the two EUAs authorize the Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist and Impella RP for use in COVID-19 patients. Impella is the only cardiovascular therapeutic device that has received FDA emergency use authorization to treat COVID-19 patients.

Published academic research presented to the FDA that demonstrates the feasibility of ECpella to improve left ventricular function and provide oxygenation to patients includes:

- Pappalardo et al., *European Journal of Heart Failure*, 2017: This study compared ECpella patients with patients treated with ECMO only and found patients in the ECpella group had a significantly lower hospital mortality (47% vs. 80%, p< 0.001) and a higher rate of successful bridging to either recovery or further therapy (68% vs. 28%, p < 0.001) compared with ECMO patients.
- Schrage et al., *Journal of the American College of Cardiology*, 2018: In this study, 106 consecutive patients were treated with Impella in addition to VA-ECMO for cardiogenic shock and 51.9% of all patients were successfully weaned from VA-ECMO support. In the overall cohort, survival at day 30 was 35.8%, which was higher than predicted by the SAVE score (20%) or by the SAPS-II score (6.9%).
- Patel et al., *ASAIO Journal*, 2019: This retrospective study compared mortality outcomes and duration of support, stroke, major bleeding, hemolysis, inotropic score, and cardiac recovery for patients treated for refractory cardiogenic shock with ECMO versus ECpella. ECpella patients were associated with lower mortality rates, lower inotrope use, and comparable safety profiles as compared with ECMO alone.
- Russo et al., *Journal of the American College of Cardiology*, 2019: This meta-analysis examined the efficacy and safety of left ventricular unloading strategies during ECMO in patients with cardiogenic shock and found left ventricular unloading was associated with decreased mortality.

The FDA EUA for Impella left ventricular support systems reads as follows:

Emergency Use Authorization

Emergency Use Authorization (EUA) for emergency use of the Impella Left Ventricular (LV) Support Systems[1] intended for use by healthcare providers (HCP) in the hospital setting for providing temporary LV unloading and support to treat critical care[2] patients with confirmed Coronavirus Disease 2019 (COVID-19) infection who are undergoing extracorporeal membrane oxygenation (ECMO) treatment and who develop pulmonary edema while on veno-arterial (V-A) ECMO support or late cardiac decompensation from myocarditis while on veno-venous (V-V) ECMO support.

1 For purposes of this EUA, the term “Impella LV Support Systems” refers to the Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, and Impella 5.5 with SmartAssist Systems, which are a family of miniaturized percutaneous circulatory support systems for the left ventricle.

2 For purposes of this EUA, “critical care” patients refer to patients in the intensive care unit (ICU) who have confirmed COVID-19 infection.

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 reopen blocked coronary arteries. The Impella 2.5, Impella CP, Impella CP with SmartAssist®, Impella 5.0®, Impella LD®, and Impella 5.5® with SmartAssist® 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. The Impella RP is also authorized for emergency use by healthcare providers (HCPs) 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 m2, for the treatment of acute right heart failure or decompensation caused by complications related to coronavirus disease 2019 (COVID-19), including pulmonary embolism (PE). The Impella RP has not been cleared or approved for the treatment of acute right heart failure or decompensation caused by complications related to COVID-19. Impella Left Ventricular (LV) Support Systems are also authorized for emergency use by HCPs in the hospital setting for providing temporary (≤ 4 days for Impella 2.5, Impella CP, and Impella CP with SmartAssist; and ≤ 14 days for Impella 5.0 and Impella 5.5 with SmartAssist) LV unloading and support to treat critical care patients with confirmed COVID-19 infection who are undergoing ECMO treatment and who develop pulmonary edema while on V-A ECMO support or late cardiac decompensation from myocarditis while on V-V ECMO support. The authorized Impella LV Support Systems have neither been cleared or approved for the authorized indication for use. The Impella RP and Impella LV Support Systems have been authorized for the above emergency use by FDA under an EUA and have 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.

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 SmartAssist 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. 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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