FDA Approves Data Streaming from the Impella Console, Setting the Stage for Artificial Intelligence Algorithms to Further Improve Patient Outcomes

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DANVERS, Mass.--(BUSINESS WIRE)--Jul. 16, 2020-- The United States Food and Drug Administration (FDA) has approved one-way digital data streaming during patient support from Abiomed's (NASDAQ: ABMD) Automated Impella Controller (AIC), the external console used with Impella heart pumps. The data streaming capability is facilitated through the Impella Connect interface, a HIPAA-compliant, cloud-based remote monitoring platform that is currently installed at more than 200 hospitals. The approval means console data could be streamed live via Impella Connect to a secure server where artificial intelligence (AI) could provide predictive clinical information to the patient's physician.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200716005318/en/

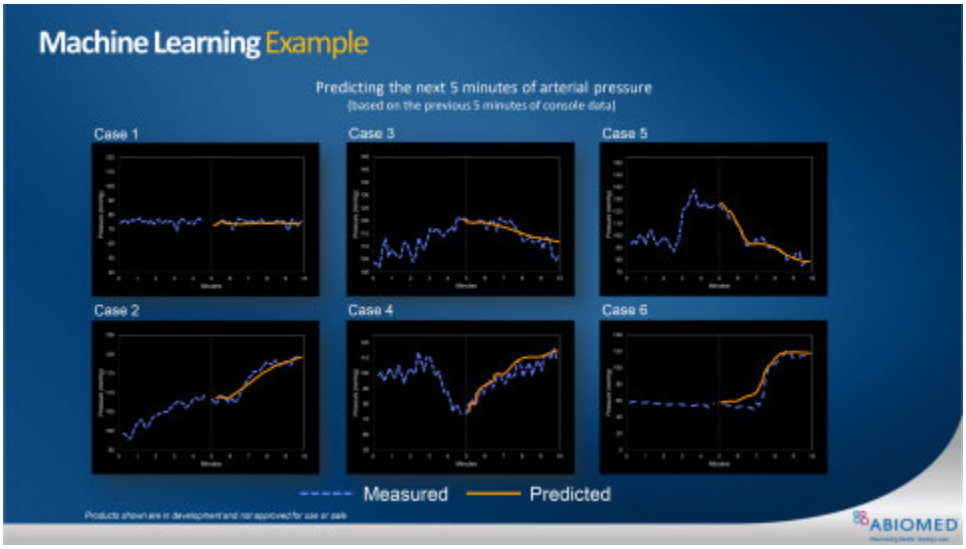

Figure 1 (Photo: Business Wire)

As an example of how this technology might be used in future clinical practice, Abiomed has already trained an AI algorithm to predict the next five minutes of a patient's arterial pressure based only on the prior five minutes of console data. (see Figure 1) Abiomed has also developed AI algorithms to predict other parameters, such as stroke volume, left ventricular pressure and cardiac output. The AI algorithms are not yet cleared or approved for patient use. Once fully developed, they will be submitted for regulatory review.

Predictive analytics are possible by integrating Impella clinical study data with Impella console data from thousands of cases and training artificial intelligence networks on the co-registered data. AI networks could then receive and analyze console data in real-time and send patient-specific predictions to that patient's medical provider. (see Figure 2)

"Artificial intelligence networks, properly trained using large volumes of streaming data, can be powerful tools to aid in clinical decision-making," said Chuck Simonton, MD, Abiomed's chief medical officer. "One day, using artificial intelligence, physicians may be able to confidently predict a patient's future hemodynamics. That would make clinical decision-making more efficient and improve patient outcomes."

Abiomed is also studying artificial intelligence to make more holistic predictions, such as the probability a patient will recover his or her native heart function. This information could help medical providers determine if an alternative course of action is needed.

More information on the future direction of Impella technology, including the application of artificial intelligence, is available in this online presentation.

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. The Impella RP has been authorized for the above emergency use by FDA under an EUA and 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.

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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