FDA Grants Highest Level of Approval to the Next Generation of Impella RP to Treat Right Heart Failure

June 29, 2021

DANVERS, Mass.--(BUSINESS WIRE)--Jun. 29, 2021-- Abiomed's (NASDAQ: ABMD) newest right heart pump, the Impella RP with SmartAssist, has received U.S. Food and Drug Administration (FDA) pre-market approval (PMA) as safe and effective to treat acute right heart failure for up to 14 days.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20210629005367/en/

Impella RP with SmartAssist Receives FDA Pre-Market Approval (Photo: Business Wire)

Impella RP with SmartAssist is the first single-access temporary percutaneous ventricular support device with dual-sensor technology. Impella RP with SmartAssist is an innovative advancement of Impella RP, which was granted a PMA by the FDA in 2017 and has treated thousands of patients globally with right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery. Additionally in June 2020, the FDA issued an emergency use authorization (EUA) for Impella RP as a treatment for patients suffering from COVID-19-related right heart failure or decompensation, including pulmonary embolism (PE).

"Impella RP with SmartAssist further improves an incredibly valuable tool to treat right heart dysfunction," said Robert Salazar, MD, interventional cardiologist, Memorial Hermann Health System Northeast Hospital and Kingwood Medical Center. "The addition of SmartAssist technology to Impella RP is an important advancement to help physicians achieve even better patient outcomes with an improved design and intuitive metrics."

Impella RP with SmartAssist is:

- The first dual-sensor technology heart pump, providing real-time guidance and trends to help with pump management and weaning
- Designed for a simplified setup and insertion
- Enhanced with Impella Connect to enable remote monitoring from any internet-connected device through a secure, HIPAA-compliant website

SmartAssist technology is also available on Impella CP and Impella 5.5 for management of left heart failure and early identification of right heart failure.

Early identification and treatment of patients requiring right heart support is critical because, as demonstrated in Lala et al., 37% of acute myocardial infarction cardiogenic shock (AMICS) patients exhibit right heart dysfunction, which results in a significantly increased risk of mortality. When right heart failure is present, the use of Impella RP within 48 hours of cardiogenic shock onset leads to 73% survival, compared to 14% survival when implanted after 48 hours, according to a FDA PMA post-approval study presented at TCT Connect 2020.

"Early detection of right heart failure and early action is key to improving patient survival rates," said Nishant Patel, MD, cardiothoracic surgeon at Palm Beach Gardens Medical Center. "Data demonstrates that Impella RP dramatically improves survival rates for critically ill patients in need of right heart hemodynamic support. I look forward to improving outcomes further with this new generation of Impella RP."

One patient who benefited from treatment with the first generation of Impella RP is Nancy Wilkins, an active 69-year-old Cincinnati native. In December 2016, Nancy had gone to a routine dentist appointment when she suddenly blacked out at the checkout desk. At the hospital, the medical team discovered she was experiencing a heart attack and rushed her into surgery. When

complications arose during surgery, cardiologists recognized Nancy was going into right heart failure and quickly implanted Impella RP to allow her heart to rest and recover. Click here to learn more about Nancy's story.

The FDA indication for use of Impella RP with SmartAssist is as follows:

The Impella RP with SmartAssist 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.

Impella RP with SmartAssist will be introduced in the United States through a controlled rollout at hospitals that follow cardiogenic shock best practice protocols.

ABOUT IMPELLA HEART PUMPS

The Impella RP® and the Impella RP® with SmartAssist® System are U.S. FDA approved to provide temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m², who develop acute 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.

ABOUT ABIOMED

Based in Danvers, Massachusetts, USA, Abiomed, Inc. is a leading provider of medical devices that provide circulatory support and oxygenation. Our products are designed to enable the heart to rest by improving blood flow and/or provide sufficient oxygenation to those in respiratory failure. For additional information, please visit: www.abiomed.com.

FORWARD-LOOKING STATEMENTS

Any forward-looking statements are subject to risks and uncertainties such as those described in Abiomed's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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Source: Abiomed, Inc.