First 1,000 Patients Treated with Impella 5.5 with SmartAssist, a Heart Pump Designed for Surgeons

November 5, 2020

DANVERS, Mass.--(BUSINESS WIRE)--Nov. 5, 2020-- Abiomed (NASDAQ: ABMD) announces 1,000 patients have been treated with the Impella 5.5 with SmartAssist heart pump in the first year after the U.S. Food and Drug Administration (FDA) granted Impella 5.5 with SmartAssist its highest level of approval for safety and efficacy.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20201105005280/en/

The Impella 5.5 with SmartAssist heart pump helped Keith Brown, 64, recover from a heart attack. (Photo: Business Wire)

In October 2019, the first U.S. patients were successfully treated by cardiac surgeons at Cleveland Clinic, Hackensack Meridian Health and Cedars-Sinai Medical Center. Since then, more than 120 hospitals in the U.S. and Europe have implanted the temporary heart pump.

The first 1,000 patients were treated primarily for cardiomyopathy, AMI cardiogenic shock, and post-cardiotomy cardiogenic shock, with an average duration of support of 14 days. (*see figure 1*) Uses of Impella 5.5 with SmartAssist include:

- Escalating a patient's care to a higher level of cardiac support
- Providing bi-ventricular support, when used in combination with Impella RP
- Unloading the left ventricle of patients on ECMO, a combination therapy known as ECpella

In July, a study published in the *American Society for Artificial Internal Organs (ASAIO) Journal* found 84% survival to explant for Impella 5.5 with SmartAssist patients in cardiogenic shock and other challenging cardiac conditions. 76% of those patients achieved native heart recovery.

In August, the FDA granted Impella 5.5 with SmartAssist, and other left-side Impella heart pumps, an emergency use authorization (EUA) to treat certain patients with COVID-19 related complications who are undergoing ECMO treatment.

In October, the 2020 expert consensus from EACTS, ELSO, STS and AATS named Impella as a Class IIb recommendation as the primary or concomitant treatment option for post-cardiotomy cardiogenic shock with severe isolated left ventricular dysfunction. Impella is now recommended in 10 society clinical guidelines and consensus statements.

"We, as heart failure cardiologists and cardiac surgeons, are understanding the effectiveness of Impella 5.5 with SmartAssist as an unprecedented new option for cardiogenic shock patients as a bridge to recovery or bridge to next therapy," said Shelley Hall, MD, chief, transplant cardiology, MCS and heart failure at Baylor Scott and White Dallas. "This fully unloading device allows us to treat hemodynamically challenged patients faster and easier with improved outcomes. The Impella 5.5 with SmartAssist is contributing to saving lives and giving these critically ill patients a chance at survival."

One such patient is 64-year-old Keith Brown. After Keith collapsed and went into cardiac arrest, initial treatment methods weren't effective. That's when Michael Kwan, MD, and Masahiro Ono, MD, from Methodist Hospital in San Antonio, escalated Keith's care and implanted Impella 5.5 with SmartAssist to provide maximum support and optimize the opportunity for Keith's heart to recover.

Keith's condition immediately began to improve, and he was able to walk around the hospital while on Impella support. The SmartAssist technology helped the physicians with patient management and assisted in weaning Keith off Impella after four days on support. Keith fully recovered and went home with his native heart. Today, Keith cares for his elderly father, enjoys time with his two children, and looks forward to traveling more with his wife.

"The Impella 5.5 with SmartAssist is a promising option for heart failure patients in cardiogenic shock," said Mani Daneshmand, MD, director of heart & lung transplantation and mechanical circulatory support at Emory University Hospital. "A forward flow, minimally invasive heart pump gives surgeons an important new tool. With this heart pump, we have seen exceptional outcomes for our patients."

"This heart pump is markedly improving the standard of care and enabling the management of higher risk cardiac surgery patients with a reduced left ventricular ejection fraction. It is incredible to have the opportunity to bring this advanced technology to our patients and see the improved outcomes firsthand," said Raymond Lee, MD, a cardiothoracic surgeon at Providence Health in Santa Monica, California.

Impella 5.5 with SmartAssist delivers peak flows of greater than 6 liters per minute. Benefits of the Impella 5.5 with SmartAssist include:

- **Impella Connect**, providing cloud-based remote monitoring in the COVID-19 era
- **Ease of insertion**, via the axillary artery or anterior aorta
- **Designed for long-duration support**, with patient ambulation, ceramic bearings and no pigtail
- **Forward flow with maximum unloading**, to provide end organ and coronary perfusion and allow the heart to rest
- **Enables heart recovery**, as a minimally invasive, weanable VAD
- **Ease of patient management**, can be intelligently positioned, weaned and managed with SmartAssist

It is available in the U.S. and Europe for hospitals with established heart recovery protocols.

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.

ABOUT IMPELLA HEART PUMPS

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 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.

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.

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.

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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