NEWS RELEASE

Multi-Center, Multi-Society Study of Impella-supported Patients with Cardiogenic Shock due to Myocarditis in Japan Achieves 30-day Survival of 77%

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BOSTON--(BUSINESS WIRE)-- **Abiomed** (ABMD) announces the result of a three-year, investigator-led study of all Impella-supported patients treated at 109 hospitals in Japan shows a 30-day survival rate of 77% for patients with cardiogenic shock due to myocarditis. This study is an update to a 2020 interim analysis and was announced at the **2022 Transcatheter Cardiovascular Therapeutics (TCT) conference** in Boston.

The Impella 5.5 with SmartAssist heart pump delivers full cardiac support, allowing the heart to rest and enabling the heart to achieve its natural pumping function without additional support. This heart pump is designed for long-duration support, enables patient mobility and optimizes recovery by using real-time intelligence. (Graphic: Business Wire)

The analysis examined 143 consecutive patients with cardiogenic shock due to myocarditis who received Impella support or Impella plus VA ECMO support, known as ECpella. These patients are included in the **J-PVAD registry**, a registry conducted by 10 Japanese professional societies, including the Japanese Circulation Society (JCS). The results demonstrated a 77% survival at 30 days for these patients. A previous analysis of myocarditis patients who only received VA ECMO support found 48% survival at 30 days (**Journal of Heart and Lung Transplantation**, 2021).

“These findings further demonstrate the potential of increasing native heart recovery in myocarditis patients through the use of Impella, which is an important consideration given the limited number of heart transplants,” said lead investigator Koichi Toda, MD, a cardiovascular surgeon at the department of cardiovascular surgery at Osaka University Graduate School of Medicine.

Myocarditis is the inflammation of the heart muscle often caused by a viral infection. This inflammation may affect the heart's electrical system and cause the muscle to enlarge, which has the potential to weaken the heart and force it to work harder to circulate blood and oxygen to the rest of the body. Ultimately, this could lead to heart failure.

According to a **U.S. Centers for Disease Control and Prevention** (CDC) report, rates of myocarditis have increased since the start of the COVID-19 pandemic to approximately 146 cases per 100,000 people, up from <10 cases per 100,000 people. The same report also showed that patients with COVID-19 had close to 16 times the risk for developing myocarditis compared to patients who did not have COVID-19.

"Myocarditis is a growing epidemic in the COVID-19 era. It is exciting to see data from this study demonstrates the potential for Impella support to improve patient outcomes in this very sick patient population," said Masahiro Ono, MD, a cardiovascular surgeon at Methodist Healthcare in San Antonio, Texas.

In Aug. 2020, the **U.S. FDA 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.

In January 2022, 31-year-old Bobby Goines, a husband, father of three and sales representative from Conway, AR, was diagnosed with myocarditis due to COVID-19 and was in cardiogenic shock. At CHI St. Vincent, Dr. Thurston Bauer implanted Impella 5.5 with SmartAssist to support Bobby's heart and allow it to rest. After eight days of support, during which Bobby was able to walk around the unit and his condition improved, Impella was weaned and removed. Bobby returned home with normal heart function and is now back to work and enjoying time with his family. You can learn more about Bobby's heart recovery story **here**.

ABOUT IMPELLA HEART PUMPS

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.

ABOUT ABIOMED

Based in Danvers, Massachusetts, USA, Abiomed (ABMD) is a leading provider of medical technology that provides 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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