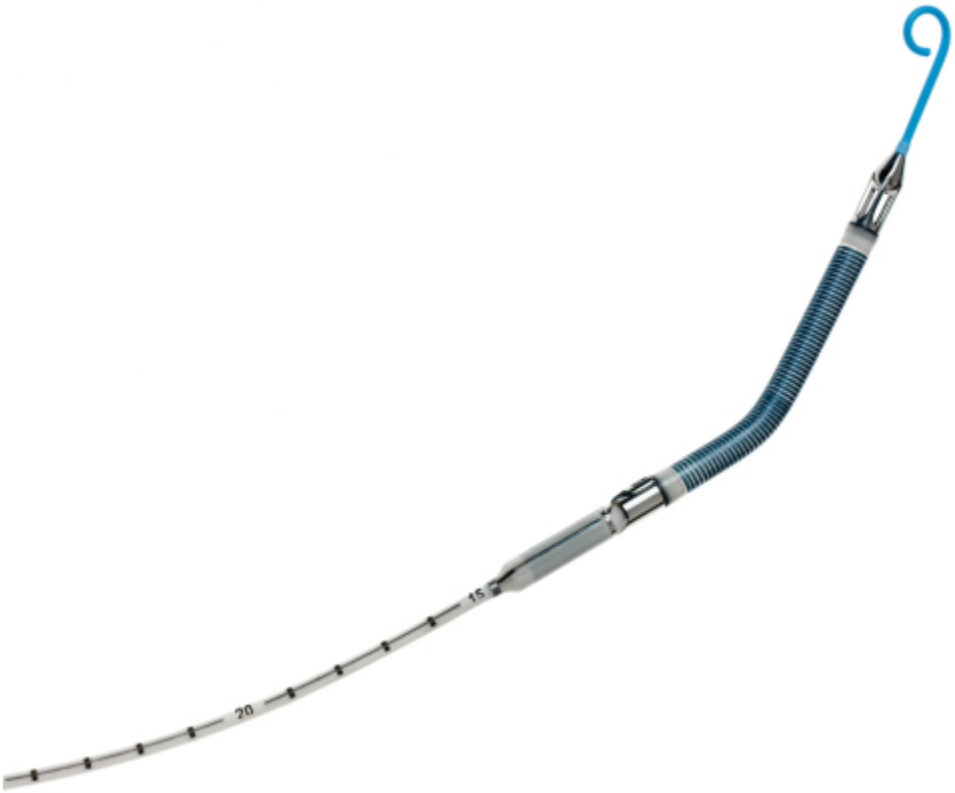
Abiomed Announces 1,000th Patient Treated with Impella in Japan

October 7, 2019

TOKYO--(BUSINESS WIRE)--Oct. 7, 2019-- Abiomed (NASDAQ: ABMD), a leading provider of breakthrough heart support technologies, announces the 1,000th patient has been treated with the Impella heart pump in Japan. The Impella 2.5 and Impella 5.0 heart pumps are approved for the treatment of drug-resistant acute heart failure and are the first and only percutaneous temporary ventricular support devices Pharmaceuticals and Medical Devices Agency (PMDA) approved in Japan. Impella is a minimally invasive therapy that takes over the pumping function of the heart, pumping blood around the body while the heart rests and recovers.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20191007005168/en/



The Impella 5.0 is a forward flow heart pump that delivers up to 5 L/min, stabilizing a patient's hemodynamics, unloading the left ventricle and perfusing the end organs, allowing for the potential of native heart recovery or return to heart function baseline. (Photo: Business Wire)

The first patient in Japan was successfully treated in October 2017 with the Impella 5.0 heart pump at Osaka University Hospital under the leadership of Professor Yoshiki Sawa, M.D., Ph.D. of the Department of Cardiovascular Surgery, Osaka University's Graduate School of Medicine. Since then, more than 100 hospitals across Japan can now provide Impella support to patients and 138 hospitals have been approved by the government and the Circulatory Support Committee.

Of the first 1,000 Japanese cases, procedural outcomes data is available on the first 580 cases[1]. The data demonstrates improvements in AMI cardiogenic shock and myocarditis survival rates during the procedure, compared to traditional therapies:

AMI Cardiogenic Shock:

- With Impella only (n=109):
  - 87% survival to Impella explant with 97% heart recovery[2]
- With Impella + percutaneous cardiopulmonary support (PCPS) (n=89):
  - 54% survival at explant and 75% heart recovery[2]
- With PCPS only:
  - 21% survival to discharge, according to the DPC Database[3] and 31% survival to 30 days according to the JCS Shock Registry[4]

Myocarditis:

- With Impella only and with Impella + percutaneous cardiopulmonary support (PCPS) (n=62):
    - 83% survival to Impella explant

- With PCPS only:
    - 43% survival to discharge according to the DPC Database[3] and 52% survival according to the Sawamura CHANGE PUMP Study[5]

The protocols used to introduce Impella in Japan were developed based on best practices learned from the experience treating patients in Europe and the United States, including the National Cardiogenic Shock Initiative, the Impella Quality (IQ) Database and the cVAD Study.

According to Professor Sawa, "Since the first case was implemented in October 2017, the number of patients treated with Impella heart pump has been increasing steadily. In Japan, many cardiologists understand the effectiveness of Impella as an unprecedented new option for heart treatment and they are actively working to introduce Impella in their hospitals. As a result, two years after the first case, the number of sites which can provide Impella treatment to the patient has reached more than 100 nationwide with better clinical outcomes[6]. I expect that the goal of Impella therapy can not only contribute to saving lives, but to heart recovery for more patients."

"In the past two years we have accumulated clinical results safely with rigorous training and education on best practice protocols, which allowed us to achieve optimal results," said Eizo Nishimura, president of Abiomed Japan K.K. "Impella is a new option to increase survival and heart recovery rate and turn circulatory support into 'therapy.' I would like to thank all the healthcare professionals for their efforts to deliver this innovative technology to more than 1,000 patients. We will continue our effort to make contributions to develop the field of heart recovery, enabling many patients to recover their heart function and return to their normal lives."

1) Interim tracking data provided by Abiomed Japan as of March 2019
2) Percentage of survival values at Impella removal without the transfer to the circulatory assist device such as IAPB, PCPS and VAD
3) Aso, Critical Care. 2016. 20:80
4) Ueki, PE-767. JCS2016 Poster Session
5) Sawamura, Circ J 2018; 82:699-707
6) O'Neill, AHJ 2018; 202:33-38

ABOUT IMPELLA 2.5 and 5.0 HEART PUMP IN JAPAN

The Impella 2.5® and Impella 5.0® heart pumps received Pharmaceuticals and Medical Devices Agency (PMDA) approval from the Japanese Ministry of Health, Labor & Welfare (MHLW) in September 2016 and received reimbursement, effective September 2017.

In Japan, the Impella heart pump is used for the following indication: In the treatment of drug-resistant acute heart failure attributable to causes such as cardiogenic shock, a catheter is inserted percutaneously/transvascularly without chest-opening surgery, and blood is aspirated via the tip of a catheter inserted/placed into the left ventricle and pumped out via the outlet port located in the ascending aorta, thereby assisting with antegrade blood circulation in the body. It aims to improve hemodynamics and the recovery of the heart muscles through prompt assistance of antegrade blood flow in a minimally invasive manner while reducing burden on the heart muscles, allowing for prompt recovery of cardiac function.

ABOUT IMPELLA HEART PUMPS IN THE UNITED STATES AND EUROPE

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 re-open blocked coronary arteries. The Impella 2.5, Impella CP, Impella CP with SmartAssist®, Impella 5.0®, Impella LD®, and Impella 5.5™ with Smart Assist® 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. Impella is the most studied mechanical circulatory support device in the history of the FDA with real world clinical data on more than 100,000 patients and more than 550 peer-reviewed publications.

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 Smart Assist® 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.

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 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 Quarterly Report on Form 10-Q. 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20191007005168/en/

Source: Abiomed, Inc.

Tom Langford
Director, Communications & Public Relations
978-882-8408
tlangford@abiomed.com

Ingrid Goldberg Ward
Director, Investor Relations
978-646-1590
igoldberg@abiomed.com

Itsuki Shinohara (Abiomed Japan)
Manager, Public Relations
81-3-4588-537
ishinohara@abiomed.com