Impella Featured as an Innovative Technology at U.S. Capitol Event Showcasing Improvements to Women's Health

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DANVERS, Mass.--(BUSINESS WIRE)--Jun. 13, 2019-- Abiomed's (NASDAQ:ABMD) Impella platform is being featured today at a Washington, D.C., event showcasing innovations in medical technology that improve healthcare for women. Abiomed's participation supports its Women's Initiative for Heart Recovery, which provides education and raises awareness of women's cardiovascular diseases and the opportunity for heart recovery. The event, hosted by AdvaMed, brings together members of Congress and their staff at the Rayburn House Office Building on Capitol Hill.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20190613005521/en/

The Impella heart pump helped Iman Dorty's heart recover so she could return home to her family. (Photo: Abiomed, Inc.)

One young woman who benefited from heart recovery with Impella support is Iman Dorty, who is speaking at today's event. When she was 28 and six months into her pregnancy, Iman had a seizure and was rushed to the hospital, where physicians determined an infection was attacking Iman's heart. The medical team induced labor hoping that Iman's heart would regain its strength without the demands of pregnancy, but Iman's heart continued to deteriorate. Physicians then implanted the Impella 5.0 to support the pumping function of her heart. After five days, Impella allowed Iman's heart muscle to rest and recover. The pump was removed, and Iman returned home to her new baby, Liam. Next year, she will celebrate the 10th anniversary of her heart recovery, demonstrating the long-term benefits of heart recovery. When compared to the long-term results of heart transplants, heart recovery is often the ideal option for patients and more cost-effective for the healthcare system[1,2,3,4].

"Because of the dedication of the medical staff who treated me and the support of the Impella heart pump, my heart was able to recover," said Dorty. "Over the last nine years, I've had the great fortune of sharing my story to advocate for heart recovery and educate women about the symptoms of heart disease. But most importantly, I've been able to be a mom and raise my son, Liam."

Cardiovascular disease is the number one killer of women and causes approximately 432,000 deaths annually in American women over the age of 20[5]. Impella therapy can help women who go into cardiogenic shock after developing two types of female-specific cardiovascular diseases: peripartum cardiomyopathy (PPCM) and spontaneous coronary artery dissection (SCAD).

- PPCM is a disease of the heart muscle that occurs during pregnancy or after childbirth and is a leading cause of pregnancy-related deaths in the United States[6]. The disease is often difficult to diagnose as symptoms mimic those of pregnancy. After delivering her daughter Amelia, Jessica Grib developed PPCM and went into cardiogenic shock. Physicians implanted the Impella CP, which allowed her heart to rest and ultimately recover. Today, Jessica's heart function is normal and she's back to her busy routine raising her two children with her husband, Kevin.
- SCAD is a spontaneous tear in the coronary artery that may lead to cardiogenic shock or sudden death. SCAD often occurs in patients who are active and healthy, and 90% of SCAD patients are women. SCAD is the number one cause of heart attacks in young women[7]. The average age is 42[4]. Jara Herron, mother of seven, developed SCAD and went into cardiogenic shock ten days after delivering her daughter. Physicians placed the Impella 2.5 to perfuse her end organs, support her heart and allow it to rest and recover. She returned home to her husband and children and is back to her life as a mom and business-owner.

"Iman, Jessica, Jara, and the thousands of other women who have been treated with Impella, inspire us to make heart recovery the standard of care for women suffering from cardiogenic shock," said Michael R. Minogue, Chairman, President and Chief Executive Officer of Abiomed. "We are committed to enabling heart recovery for these sisters, mothers and daughters so they can return home to enjoy a normal quality of life with their families and friends."

Impella is the most studied mechanical circulatory support device in the history of the FDA and the FDA has concluded, based on clinical studies and a randomized controlled trial, that Impella is safe and effective. Impella is included in 8 clinical guidelines and more than 550 peer-reviewed clinical publications. The Impella Quality (IQ) Database includes real-world data from more than 90,000 Impella cases from more than 1,100 U.S. centers. The cVAD Study, which is an IRB approved, prospective study includes more than 5,000 patients.

As a result, Impella has the highest level of U.S. regulatory approval and is the only FDA-approved, on-label technology for high-risk PCI and AMI cardiogenic shock, including cardiogenic shock derived from cardiomyopathy and right ventricular heart failure.

Learn more about women who have recovered from PPCM and SCAD after hemodynamic support from Impella at www.abiomed.com/patients.

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6. Centers for Disease Control and Prevention, Trends in Pregnancy-Related Deaths: https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pmss.html

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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 re-open blocked coronary arteries. The Impella 2.5, Impella CP, Impella CP with SmartAssist™, Impella 5.0® and Impella LD® 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.

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™ heart pump 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.

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