Largest Study of Hemodynamically Supported High-Risk PCI Patients Finds More Complete Revascularization with Impella Leads to Improved Outcomes

October 15, 2020

DANVERS, Mass.--(BUSINESS WIRE)--Oct. 15, 2020-- Abiomed (NASDAQ: ABMD) announces new PROTECT III study data that demonstrates reduced rates of MACCE (composite of death, stroke, myocardial infarction and repeat procedures) when Impella is used to achieve a more complete revascularization in a single setting for high-risk percutaneous coronary intervention (PCI) patients. PROTECT III is an ongoing, prospective, single-arm FDA post-approval study for the PMA approval of Impella 2.5 and Impella CP in high-risk PCI. The PROTECT III interim analysis findings are being presented by William O'Neill, MD, medical director of the Center for Structural Heart Disease at Henry Ford Hospital, at TCT Connect, the 32nd annual scientific symposium of the Cardiovascular Research Foundation, as a part of the "Best of Abstracts" session at 3:24 p.m. EDT today.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20201015005176/en/

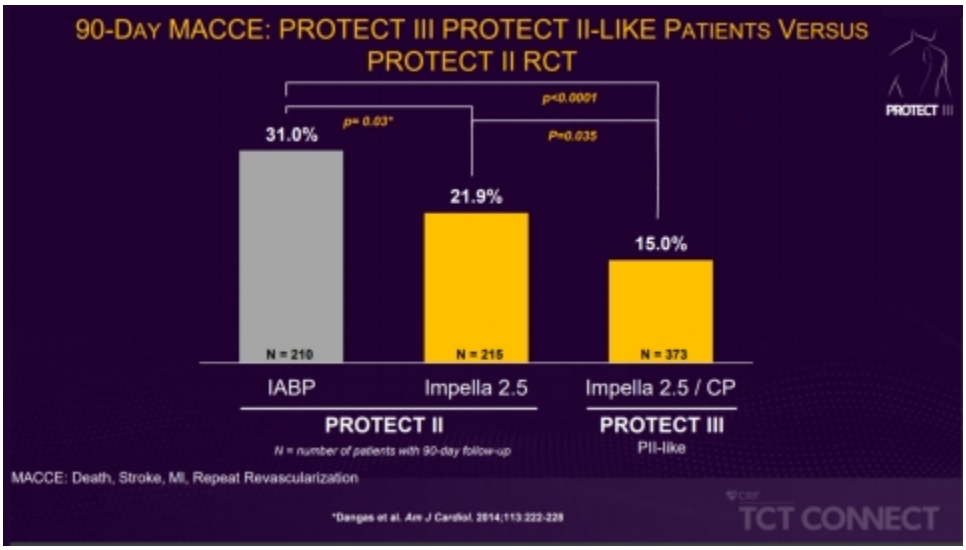

Figure 1 (Graphic: Business Wire)

PROTECT III builds on the PROTECT II Randomized Controlled Trial (RCT) which found, when compared to intra-aortic balloon pump (IABP), Impella use led to a 29% reduction in MACCE at 90 days. The study authors analyzed patients in PROTECT III who would have qualified for PROTECT II, known as "PII-like" patients, and compared them to PROTECT II patients. PII-like patients in PROTECT III had improved 90-day MACCE rates, compared to PROTECT II patients (15% vs. 21.9%, p=0.035). (*see figure 1*)

The study also found PII-like patients in PROTECT III were older, sicker and more complex, with more comorbidities, more vessels treated and more rotational atherectomy, yet they had improved in-hospital safety with:

- Significantly fewer bleeding complications (1.8% vs. 12.5%, p<0.001)
- Similar low vascular complications (1.0% vs. 1.4%, p=0.659)
- Similar low instances of stroke (0.40% vs. 0.46%, p=0.913)

The PROTECT series of FDA clinical studies, which includes PROTECT I, the PROTECT II RCT and PROTECT III, is the largest-ever FDA study of hemodynamically supported high-risk PCI patients. This PROTECT III interim analysis included 1,143 patients undergoing elective non-emergent PCI with Impella at 45 sites between March 2017 and September 2019.

"This data is an important continuation of knowledge in high-risk PCI. Looking back at PROTECT II data, we understood the safety and efficacy of Impella," said Jeffrey W. Moses, MD, a PROTECT III lead investigator and director of interventional cardiovascular therapeutics and professor of medicine at Columbia University Medical Center. "But now, with PROTECT III showing fewer adverse events, we understand how to apply best practices and the result is better patient outcomes."

"This novel, contemporary data from PROTECT III clearly demonstrates how the evolution and adoption of Impella best practices can lead to an improvement in safety and MACCE and it provides important information as we prepare for the upcoming PROTECT IV Randomized Controlled Trial of Impella in high-risk PCI," said Dr. O'Neill.

PROTECT III is part of a growing body of evidence supporting the benefits of a more complete revascularization in high-risk PCI, which leads to better patient outcomes. The Restore EF study, presented yesterday at TCT Connect, demonstrates the use of contemporary best practices with Impella in high-risk PCI significantly improves left ventricular ejection fraction (LVEF), heart failure symptoms, and anginal symptoms at 90-day follow up in a wide variety of hospitals settings including rural, urban, community and academic centers. PROTECT III also strengthens the overall body of evidence about Impella safety, which is detailed in figure 2.

The PROTECT III post-approval study will inform best practice protocols for the upcoming prospective, two-arm PROTECT IV RCT, which will leverage and validate key learnings from the cVAD Study, Impella Quality (IQ) Database and real-world data collected since the completion of the PROTECT II RCT. PROTECT IV will compare complete revascularization PCI with Impella to complete revascularization PCI without any planned hemodynamic support.

The PROTECT series of studies are sponsored by Abiomed as part of its commitment to improving clinical outcomes.

To share best practices in high-risk PCI, Abiomed is hosting a symposium at TCT Connect on Saturday, October 17, at 2:00 p.m. EDT, titled *Protected PCI in COVID-19 Era: The Rise in Importance of Complete Revascularization*. The symposium is chaired by Cindy Grines, MD, chief scientific officer

of Northside Hospital Cardiovascular Institute in Atlanta and president of the Society for Cardiovascular Angiography and Interventions (SCAI). It will feature best practices for using percutaneous mechanical circulatory support to enable complete revascularization in high-risk patients.

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 reopen blocked coronary arteries. 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 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. 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.

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 SmartAssist 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. Abiomed, Impella, Impella 2.5, Impella 5.0, Impella 5.5, Impella LD, Impella CP, Impella RP, SmartAssist and Impella Connect are registered trademarks of Abiomed, Inc., and are registered in the U.S. and certain foreign countries. Impella BTR, Impella ECP, CVAD Study and STEMI DTU Study are pending trademarks of Abiomed, Inc.

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 the scope, scale and duration of the impact of the COVID-19 pandemic, 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 the filings subsequently filed with or furnished to the SEC. 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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Source: Abiomed