Abiomed Appoints New Chief Medical Officer Charles Simonton, M.D.

June 15, 2020

DANVERS, Mass.--(BUSINESS WIRE)--Jun. 15, 2020-- Abiomed (Nasdaq: ABMD), maker of the Impella heart pump, announced today it has appointed Charles (Chuck) Simonton, M.D., as vice president and chief medical officer.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200615005190/en/

Abiomed Appoints New Chief Medical Officer Charles Simonton, M.D. (Photo: Business Wire)

Dr. Simonton is renowned for his leadership in product development and large-scale clinical trials. He was most recently at Abbott Vascular where he served as chief medical officer and divisional vice president of Global Medical Affairs since 2008. At Abbott Vascular, he led the programs that resulted in the United States Food and Drug Administration's (FDA) approval of carotid stents, MitraClip and Absorb BVS, in addition to the EXCEL and COAPT trials. Prior to Abbott, Dr. Simonton spent almost 30 years as an interventional cardiologist working with complex cardiac and vascular patients. He started at Duke University Medical Center then moved to the Sanger Clinic in Charlotte, North Carolina, where he created his own research team to study patient outcomes following the use of new cardiac technologies. Dr. Simonton founded the Carolinas Cardiovascular Research Foundation at the Carolinas Heart Institute, which is now part of Atrium Health.

He received his medical degree from Harvard Medical School and did his internship, residency and chief residency in the Department of Internal Medicine at the University of California, San Francisco, and his cardiology fellowship at Duke University.

Dr. Simonton's appointment comes as Abiomed accelerates its clinical research, including multiple FDA randomized control trials (RCTs) such as the STEMI-DTU RCT, the PROTECT IV RCT, and the RECOVER IV RCT. Dr. Simonton will also play an integral role as Abiomed launches new, innovative products and incorporates artificial intelligence.

"I am excited to be a part of Abiomed's dedicated team focused on developing innovative medical devices. Over the years, I have become very familiar with the benefits of Impella and its ability to unload the heart and have seen how it is transforming the standard of care. I am impressed with Abiomed's talent, culture, and mission and I am thrilled to be joining the company," said Dr. Simonton.

Dr. Seth Bilazarian, who has been vice president and chief medical officer of Abiomed since 2015, will assume medical leadership of Abiomed's physician education and training programs as vice president, medical education and training, as Abiomed grows its online education offering with CAMP PCI and creates cutting-edge virtual proctoring programs. Dr. Bilazarian has been instrumental in guiding and executing medical professional education and training at Abiomed. His new role, which will report to Dr. Simonton, will expand upon those responsibilities and further differentiate Abiomed as an industry leader.

"The addition of Dr. Chuck Simonton makes our world-class medical office even stronger," said Michael R. Minogue, Abiomed's Chairman, President, and Chief Executive Officer. "Chuck's impressive record of accomplishments and expertise will complement Seth's leadership in advancing our education and training programs and help Abiomed rise to the next level for our patients and physicians."

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 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. The Impella RP is also authorized for emergency use by healthcare providers (HCP) 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 neither been cleared nor approved for the treatment of acute right heart failure or decompensation caused by complications related to COVID-19. The Impella RP has been authorized for the above emergency use by FDA under an EUA and has 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 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 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