FDA Grants 510(k) Clearance for Abiomed's Innovative Cardiopulmonary Support Technology

October 26, 2020

DANVERS, Mass.--(BUSINESS WIRE)--Oct. 26, 2020-- The United States Food and Drug Administration (FDA) has granted Abiomed (NASDAQ: ABMD) a 510(k) clearance for an all-in-one, compact cardiopulmonary bypass system called the Abiomed Breethe OXY-1 System™.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20201026005299/en/

The Abiomed Breethe OXY-1 System has received 510(k) clearance from the United States FDA (Photo: Buisness Wire)

The ECMO system provides cardiopulmonary bypass support for patients whose lungs can no longer provide sufficient end organ oxygenation. The 510(k) clearance is to pump, oxygenate, and remove carbon dioxide from blood during cardiopulmonary bypass for up to six hours. The system can help provide oxygenation to patients suffering from cardiogenic shock or respiratory failure such as ARDS, H1N1, SARS, or COVID-19. When used with the Impella heart pump it can unload the heart and oxygenate the body, a combination therapy known as ECpella.

Abiomed's Breethe technology is a novel, easy-to-use cardiopulmonary bypass system that is designed for mobility. The components of the system are designed to reduce the overall equipment footprint, support patient ambulation, and provide an intuitive interface for health care providers to setup and manage. The integrated pump lung unit is engineered with volute spiral technology for uniform blood flow with minimal stagnation and advanced gas exchange technology that allows for full therapy with reduced oxygen requirements.

"As a leader in technology and innovation, the Breethe system is a natural addition to Abiomed's existing product portfolio," said Michael R. Minogue, Abiomed's Chairman, President and Chief Executive Officer. "This ECMO technology will allow us to support new patient populations, such as COVID-19 patients and others who need lung support, and provide combination ECpella therapy to Impella patients who need oxygenation. Furthermore, we will advance the field of native lung recovery and improve patient outcomes by collecting critical research data and developing and teaching best practices."

"Abiomed has a long-established track record of bringing to market improved options to support physicians with innovative technology like Breethe, which is designed to provide advanced respiratory and cardiac support," said Bartley Griffith, MD, the Hales Distinguished Professor of Surgery at University of Maryland, School of Medicine. "Abiomed is committed to advancing heart and lung therapies to help improve patient care and ultimately outcomes."

"The clinical community has long been in need of innovation compared to traditional extracorporeal circulation therapy," said Dr. Zachary Kon, cardiothoracic surgeon at New York University. "The Breethe system is a breakthrough technology because it supports transition from bed to ambulation via system portability. This system has the potential to revolutionize the way we think about extracorporeal life support therapy and can improve patient care."

To help health care providers achieve the best possible outcomes, the Breethe system will be supported 24 hours a day, 7 days a week by Abiomed's experienced field-based, in-hospital clinical team and on-call team from the Clinical Support Center.

This ECMO technology adds to Abiomed's innovative portfolio focused on native heart and lung recovery. For many patients in cardiogenic shock, Abiomed now provides the treatment options of both the catheter-based Impella heart pump, which unloads the left ventricle, perfuses end organs and allows the heart to rest and recover, and Breethe, which provides oxygenation. Impella and Breethe can work together as ECpella to unload the heart and oxygenate the body.

Multiple studies support the association of ECpella therapy to improve outcomes for patients who are suffering from cardiogenic shock and require oxygenation. A study published this month in *Circulation* examined data from 686 consecutive patients at 16 tertiary-care centers from four countries and found ECpella was associated with increased 30-day survival (43% vs 37%; p=0.03). The *European Journal of Heart Failure*, *ASAIO*, and the *Journal of the American College of Cardiology* have published studies that conclude use of ECpella was associated with increased survival rates, as compared to patients who were treated with ECMO only. This benefit is not seen in patients treated with ECMO combined with the intra-aortic balloon pump (IABP). (*see figure 1*) Additionally, the study in the *European Journal of Heart Failure* found higher rates of heart recovery with ECpella use than

with ECMO only (62% vs 36%; p=0.048).

In August, the FDA issued an emergency use authorization (EUA) for all 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.

Abiomed plans to have a controlled launch of the Breethe system at hospitals in the United States, with full U.S. commercial availability expected in calendar year 2021.

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.

ABOUT ABIOMED BREETHE OXY-1 SYSTEM

The Abiomed Breethe OXY-1 System™ is cleared by the U.S. Food and Drug Administration (FDA) to provide extracorporeal circulation. The OXY-1 System pumps, oxygenates and removes carbon dioxide from blood during cardiopulmonary bypass up to six (6) hours in duration.

Under guidance issued by FDA, on April 6, 2020, the Abiomed Breethe OXY-1 System is now permitted to be used temporarily in the U.S. for ECMO therapy greater than six hours. Therefore, it now has a limited indication modification for use longer than six hours in an extracorporeal membrane oxygenation (ECMO) circuit to treat patients who are experiencing acute temporary respiratory or acute cardiopulmonary failure. This limited indication modification for ECMO therapy greater than six hours has not been cleared or approved by FDA and is in effect only for the duration of the public health emergency related to COVID-19 as declared by the U.S. Department of Health and Human Services (HHS).

ABOUT IMPELLA HEART PUMPS

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 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.

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements. 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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Source: Abiomed