AngioDynamics Receives 510(k) Clearance for AlphaVac F18[85] System in Treatment of PE

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New Indication for Treatment of Pulmonary Embolism Enhances Device Utility in Critical Medical Scenarios

LATHAM, N.Y.--(BUSINESS WIRE)--Apr. 4, 2024-- AngioDynamics, Inc. (NASDAQ: ANGO), a leading and transformative medical technology company focused on restoring healthy blood flow in the body's vascular system, expanding cancer treatment options and improving patient quality of life, today announced that the United States Food and Drug Administration (FDA) has cleared the AlphaVac F18[85] System for the treatment of pulmonary embolism (PE), enhancing its utility in critical medical scenarios such as PE.

PE affects around 900,000 people in the United States every year and is the third leading cause of cardiovascular mortality in the nation.[1,2] Patients with sub-massive or intermediate-risk PE account for 35% to 55% of hospitalized patients with PE and have a mortality rate of 3% to 14%.[2,3]

The expanded FDA indication allows for the utilization of the AlphaVac F18[85] System for the treatment of PE, which broadens the applicability of the AlphaVac F18[85] System in the non-surgical removal of thrombi or emboli from the venous vasculature. The indication expands treatment options for patients with PE, reducing thrombus burden and improving right ventricular function.

"FDA clearance marks a significant advancement in patient care and safety. This milestone underscores our commitment to merging physician-centric design with patient outcome-driven solutions," said Juan Carlos Serna, AngioDynamics Senior Vice President of Scientific and Clinical Affairs. "In addition to meeting our primary endpoints, the trial also showed a meaningful, favorable reduction in clot burden, ultimately improving patient outcomes."

In December 2023, AngioDynamics announced the completion of patient enrollment in its Acute Pulmonary Embolism Extraction Trial with the AlphaVac System (APEX-AV) study, a single-arm Investigational Device Exemption study that enrolled 122 patients with confirmed acute, intermediate-risk PE across 25 hospital-based sites in the United States to assess the AlphaVac F18[85] System for the treatment of PE.

The APEX-AV study was initiated in partnership with the widely respected Pulmonary Embolism Response Team (PERT) Consortium™ and led by co-Principal Investigators William Brent Keeling, MD, Associate Professor of Surgery, Department of Surgery, at the Emory University School of Medicine, and Immediate Past President, The PERT Consortium™ andMona Ranade, MD, Assistant Professor, Interventional Radiology, at the David Geffen School of Medicine at UCLA.

"The addition of the AlphaVac System in the mechanical thrombectomy world is a critical step forward in the treatment of PE patients," said Dr. Keeling. "The rapid patient enrollment and the excellent safety and efficacy outcomes from the APEX-AV study validate the need for such technologies to be part of the PE treatment algorithm."

The primary efficacy endpoint of the APEX-AV Study was the reduction in RV/LV ratio between baseline and 48 hours post-procedure. The primary safety endpoint was the rate of Major Adverse Events (MAEs), including events such as major bleeding and serious device-related clinical deterioration, pulmonary vascular injury, and cardiac injury, within the first 48 hours. Patients were followed for 30 days post-index procedure.

"The 510(k) clearance of the AlphaVac System represents an important milestone towards the treatment of PE," said Mona Ranade, MD, Assistant Professor, Interventional Radiology, at the David Geffen School of Medicine at UCLA. "The data from the APEX-AV study showed a significant improvement in the RV function and a rapid resolution of clot burden in the pulmonary arteries."

The APEX-AV Study showed a mean decrease in the RV/LV ratio from baseline to 48 hours post-procedure of 0.45 (significantly greater than the pre-defined performance goal of 0.12 ($p < 0.001$)) and a MAEs rate of 4.1% (significantly lower than the pre-defined performance goal of 25% ($p < 0.001$)). The study also showed a 35.5% mean reduction in clot burden from baseline to 48 hours post-procedure.[4]

"Catheter-based therapies are becoming a major tool in the PE space," said John M. Moriarty, MD, President-elect, The PERT Consortium™, Professor, Interventional Radiology, UCLA. "With a handle that can limit blood loss and a true large bore cannula with a 33 Fr funnel, I expect the AlphaVac System to play a crucial role in the treatment of PE."

About the AlphaVac F18[85] System

The AlphaVac F18[85] System is an emergent first-line device that is currently cleared for the removal of thromboemboli from the venous system and for the treatment of PE. The System includes an ergonomic handle, an 18F cannula with an 85-degree angle, an obturator, and a waste bag assembly. The APEX-AV Study was designed to provide safety and efficacy data for a clearance specific to PE. For risk information, visit https://bit.ly/Angio-risk-info.

About The PERT Consortium™

The purpose of The PERT Consortium™ is to serve the general public by undertaking activities to advance the status of PE care and promote research in the treatment of PE. Specifically, the Consortium's purpose is to:

Promote the adoption of the PERT model in healthcare institutions across the United States to ensure the prompt diagnosis and treatment of PE.

Expand the current body of scientific literature on the diagnosis and treatment of PE through the funding of scientific endeavors.

Educate the general public and healthcare professionals regarding PE diagnosis, treatment and care.

By focusing solely on the entirety of PE – its etiology, pathophysiology, prevention, management approach, outcomes of specific treatments and follow-up pathways – it is the intention of the Consortium to increase awareness of treatment options available to patients with PE, to reduce its incidence worldwide, to improve health outcomes and to positively influence the impact of this terrible disease.

About AngioDynamics, Inc.

AngioDynamics is a leading and transformative medical technology company focused on restoring healthy blood flow in the body's vascular system, expanding cancer treatment options and improving patient quality of life.

The Company's innovative technologies and devices are chosen by talented physicians in fast-growing healthcare markets to treat unmet patient needs. For more information, visit www.angiodynamics.com.

Safe Harbor

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements regarding AngioDynamics' expected future financial position, results of operations, cash flows, business strategy, budgets, projected costs, capital expenditures, products, competitive positions, growth opportunities, plans and objectives of management for future operations, as well as statements that include the words such as "expects," "reaffirms," "intends," "anticipates," "plans," "believes," "seeks," "estimates," "projects," "optimistic," or variations of such words and similar expressions, are forward-looking statements. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. Investors are cautioned that actual events or results may differ materially from AngioDynamics' expectations, expressed or implied. Factors that may affect the actual results achieved by AngioDynamics include, without limitation, the scale and scope of the COVID-19 global pandemic, the ability of AngioDynamics to develop its existing and new products, technological advances and patents attained by competitors, infringement of AngioDynamics' technology or assertions that AngioDynamics' technology infringes the technology of third parties, the ability of AngioDynamics to effectively compete against competitors that have substantially greater resources, future actions by the FDA or other regulatory agencies, domestic and foreign healthcare reforms and government regulations, results of pending or future clinical trials, overall economic conditions (including inflation, labor shortages and supply chain challenges including the cost and availability of raw materials), the results of on-going litigation, challenges with respect to third-party distributors or joint venture partners or collaborators, the results of sales efforts, the effects of product recalls and product liability claims, changes in key personnel, the ability of AngioDynamics to execute on strategic initiatives, the effects of economic, credit and capital market conditions, general market conditions, market acceptance, foreign currency exchange rate fluctuations, the effects on pricing from group purchasing organizations and competition, the ability of AngioDynamics to obtain regulatory clearances or approval of its products, or to integrate acquired businesses, as well as the risk factors listed from time to time in AngioDynamics' SEC filings, including but not limited to its Annual Report on Form 10-K for the year ended May 31, 2023. AngioDynamics does not assume any obligation to publicly update or revise any forward-looking statements for any reason.

[1] Learn About Pulmonary Embolism. Lung.org. http://www.lung.org/lung-health-diseases/lung-disease-lookup/pulmonary-embolism/learn-about-pulmonary-embolism. Published 2023.

[2] Giri J, Sista AK, Weinberg I, et al. Interventional Therapies for Acute Pulmonary Embolism: Current Status and Principles for The Development Of Novel Evidence: A Scientific Statement From The American Heart Association. Circulation 2019;140(20)e774-e801.

[3] Machanahalli Balakrishna A, Reddi V, Belford PM, Alvarez M, Jaber WA, Zhao DX, Vallabhajosyula S. Intermediate-Risk Pulmonary Embolism: A Review of Contemporary Diagnosis, Risk Stratification and Management. Medicina (Kaunas). 2022 Aug 30;58(9):1186.

[4] Data on file.

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Investors:
Stephen Trowbridge
Executive Vice President & CFO
518-795-1408
strowbridge@angiodynamics.com

Media:
Saleem Cheeks
Vice President, Communications
518-795-1174
scheeks@angiodynamics.com

Source: AngioDynamics, Inc.