AngioDynamics Completes Patient Enrollment in APEX-AV Study Assessing AlphaVac F18[85] System in Treatment of Pulmonary Embolism

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122 Patients Enrolled in Single-arm IDE Study; 30-Day Follow-up

LATHAM, N.Y.--(BUSINESS WIRE)--Dec. 7, 2023-- 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 the completion of patient enrollment in the Acute Pulmonary Embolism Extraction Trial with the AlphaVac System (APEX-AV). APEX-AV is a clinical study aimed at evaluating the safety and efficacy of the Company's AlphaVac Multipurpose Mechanical Aspiration (MMA) F18 [85] System in the treatment of acute intermediate-risk pulmonary embolism (PE).

PE represents the third-leading cause of cardiovascular mortality in the United States.[1]

"The completion of the APEX-AV Study to assess the performance of the AlphaVac F18 [85] System in reducing thrombus burden and improving right ventricular function is a meaningful step toward expanding treatment options and improving care for patients with pulmonary embolism," said Juan Carlos Serna, AngioDynamics' Senior Vice President of Clinical and Scientific Affairs. "We thank The PERT Consortium™, including our enrolling partners, for its commitment to generating robust clinical evidence to help address the needs of this patient population."

APEX-AV is 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. The primary efficacy endpoint of the APEX-AV Study is the reduction in RV/LV ratio between baseline and 48 hours post-procedure. The primary safety endpoint is the rate of Major Adverse Events (MAEs), including device-related death and major bleeding within the first 48 hours. Patients will be followed for 30 days post-index procedure.

"The completion of the APEX-AV Study represents an important milestone in the catheter-directed therapies CDT space for the treatment of pulmonary embolism. I sincerely thank all the investigators for their commitment and dedication," said 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™.

AngioDynamics initiated the APEX-AV Study in partnership with the widely respected Pulmonary Embolism Response Team (PERT) Consortium™. The study is 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™ and Mona Ranade, MD, Assistant Professor, Interventional Radiology, at the David Geffen School of Medicine at UCLA.

"Data from the APEX-AV study expands the current body of literature on the safety and efficacy of mechanical thrombectomy and broadens the PE treatment options, particularly in this space," said Mona Ranade, MD, Assistant Professor, Interventional Radiology, at the David Geffen School of Medicine at UCLA.

Pulmonary embolism (PE) can be a life-threatening condition that affects around 900,000 people in the United States every year.[2] In most cases, PE is caused by blood clots in the legs, called deep vein thrombosis, that travel to the lungs.[2] Patients with submassive or intermediate-risk PE account for 35% to 55% of hospitalized patients with PE and have a mortality rate of 3 to 14%.[1,3]

Visit https://clinicaltrials.gov/ct2/show/NCT05318092 for more information about the APEX-AV Study.

About the AlphaVac MMA F18[85] System

The AlphaVac MMA F18[85] System is an emergent first-line device that is currently cleared for the removal of thromboemboli from the venous system. 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.

The AlphaVac MMA F18[85] System, when used for treatment of pulmonary embolism, is an investigational device, limited by United States law to investigational use.

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 entity 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] 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.

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

[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.

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