



AngioDynamics Announces First Patient Enrolled in APEX-AV Study Assessing AlphaVac F18⁸⁵ PE System in Treatment of Pulmonary Embolism

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AngioDynamics, The PERT Consortium™ and Viz.ai partner on APEX Study to facilitate future enrollment to bring innovative treatment to patients with PE

LATHAM, N.Y.--(BUSINESS WIRE)--Oct. 31, 2022-- 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 quality of life for patients, today announced the enrollment of the first patient in the Acute Pulmonary Embolism Extraction Trial with the AlphaVac System (APEX-AV), a clinical study aimed at evaluating the efficacy and safety of the Company's AlphaVac Multipurpose Mechanical Aspiration (MMA) F18⁸⁵ System in the treatment of acute intermediate-risk pulmonary embolism (PE).

APEX-AV is a single-arm Investigational Device Exemption study enrolling patients with confirmed acute, intermediate-risk PE at up to 20 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.

"We are excited to have the first patient enrolled in this important trial as we assess the performance of the AlphaVac F18⁸⁵ System in patients with intermediate-risk pulmonary embolisms," said Juan Carlos Serna, AngioDynamics Senior Vice President of Clinical and Scientific Affairs. "With our partners, we are demonstrating our continued commitment to generating robust clinical evidence with the potential to support our clinical and regulatory strategy to pursue additional indications to treat more patients and advance care."

Pulmonary embolism can be a life-threatening condition and affects approximately 1 in 1,000 people in the U.S. every year¹.

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 President, The PERT Consortium™ and Mona Ranade, MD, Assistant Professor, Interventional Radiology, at the David Geffen School of Medicine at UCLA.

"I would like to congratulate Michael Grushko, MD, Prabhjot Singh MD, and Seth Sokol, MD, at Jacobi Medical Center for enrolling the first patient in the APEX-AV Study. The Study is an important trial in the PE space and will significantly contribute to the growing body of evidence for the treatment of PE. We are looking forward to seeing a larger data set generated with the AlphaVac system," said Keeling.

"We are privileged to have the first patient enrolled in this important PE trial using the AlphaVac F18⁸⁵ System at Jacobi Medical Center. The procedure time was less than 60 minutes, and we were particularly impressed with the design, control, and navigability that the 18Fr cannula provides," said Seth Sokol, MD, Cardiology Specialist, Jacobi Medical Center, and the site Principal Investigator.

To facilitate patient enrollment for its APEX-AV Study, AngioDynamics and The PERT Consortium™, a multi-disciplinary team of physicians and clinicians guiding and influencing pulmonary embolism care, education, and research in institutions across the United States, have partnered with Viz.ai, a leading artificial intelligence powered disease detection, and intelligent care coordination platform. Utilizing access to hospital imaging, Viz.ai's Viz RECRUIT technology identifies trial-eligible patients in real-time, allowing for around-the-clock discovery and notifications to clinical and research teams.

"We are honored to be the partner of choice alongside AngioDynamics and The PERT Consortium™ helping clinical sites participating in the APEX-AV Study identify potential PE patients, assess eligibility at the time of clinical evaluation, and enable real-time recruitment within the health system," said Jayme Strauss, Chief Clinical Officer at Viz.ai. "This partnership furthers our company's mission to increase access to lifesaving treatments."

Viz RECRUIT may facilitate clinical trial enrollment by using artificial intelligence to identify eligible clinical trial candidates and connects the research team to the clinical care team — all in a secure, HIPAA-compliant environment. Viz.ai's cloud-based technology broadens the recruitment funnel in both size and diversity by identifying existing patients at hub and spoke hospitals that are trial-eligible and screening patients as they are evaluated. This capability will allow for more efficient enrollment and streamline workflows and communication at APEX-AV Study sites.

Using artificial intelligence to automatically identify patients during clinical evaluation, Viz RECRUIT may enable real-time recruitment within the health system. Viz RECRUIT's ability to embed clinical research into the care continuum helps speed up enrollment rates which could lead to more timely completion of clinical trials and a faster path to market for life saving therapies.

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

Sources: *[Jankowitz B. et al 2021.SNIS-E-022](#);

About the AlphaVac MMA F18⁸⁵ System

The AlphaVac MMA F18⁸⁵ 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. Risk information: <https://bit.ly/Angio-risk-info>

The AlphaVac MMA F18⁸⁵ System when used for treatment of pulmonary embolism is an investigational device. Limited by United States law to

investigational use.

About Viz.ai

Viz.ai is the pioneer in the use of AI algorithms and machine learning to increase the speed of diagnosis and care, covering more than 200 million lives across 1,200+ hospitals and health systems in the US and Europe. The AI-powered Viz Platform is a disease detection and intelligent care coordination solution that identifies more patients with a particular disease, informs critical decisions at the point of care, optimizes care pathways, and helps improve outcomes. Backed by clinical data, the Viz Platform delivers significant value to patients, providers, and pharmaceutical and medical device companies. For more information visit viz.ai.

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 pulmonary embolism. 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 pulmonary embolism.

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

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

By focusing solely on the entity of pulmonary embolism – 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 quality of life for patients.

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.

¹ Learn About Pulmonary Embolism. [Lung.org](http://www.lung.org). <http://www.lung.org/lung-health-diseases/lung-disease-lookup/pulmonary-embolism/learn-about-pulmonary-embolism>. Published 2020.

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