AngioDynamics Announces First Patient Enrolled in RECOVER-AV Clinical Trial Evaluating AlphaVac F18[85] System for Treatment of Acute Pulmonary Embolism

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Multi-center, multi-national study builds on existing U.S. PE Clearance and CE Mark to assess mechanical thrombectomy treatment and long-term functional outcomes in intermediate-risk PE patients across Europe

LATHAM, N.Y.--(BUSINESS WIRE)--Jun. 23, 2025-- 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 first patient has been enrolled in the RECOVER-AV clinical trial, a prospective, multi-center, multi-national, single-arm study evaluating the AlphaVac Multipurpose Mechanical Aspiration (MMA) F18[85] System in the treatment of acute, intermediate-risk pulmonary embolism (PE).

The study follows the United States Food and Drug Administration (FDA) 510(k) clearance of the AlphaVac F18[85] System for the treatment of PE in the United States in April 2024 and its CE Mark approval in Europe in May 2024. The RECOVER-AV trial is designed to evaluate the safety and efficacy of the AlphaVac F18[85] System in support of its adoption in the Global market, as well as to assess long-term functional outcomes for patients following treatment.

The prevalence of PE in Europe is significant, particularly among hospitalized and older populations. An estimated 435,000 PE events occur annually in the six largest European Union (EU) countries[1].

“The first patient enrollment in the RECOVER-AV trial marks an important step forward as AngioDynamics continues to grow its global clinical presence and commitment to evidence-based care,” said Laura Piccinini, Senior Vice President/General Manager, Cardiovascular and International. “With AlphaVac already 510(k)-cleared in the U.S. and CE-marked in Europe for PE, we’re investing in high-quality data focused on functional recovery and quality of life that will equip clinicians, payers, and patients with even greater confidence in the system’s safe, effective performance and help broaden access to life-saving PE treatment across Europe and the wider global market.”

The trial is enrolling patients with confirmed acute, intermediate-risk PE at up to 20 hospital-based sites in Europe, Canada, and Hong Kong. The primary safety endpoint is the incidence of adverse events by type and seriousness through 12 months. Patients will be followed for 12 months, with functional and quality-of-life outcomes assessed at 30 days and 12 months. Additional investigations, including Cardiac MRI and exercise testing, will provide a more comprehensive assessment of the long-term recovery of patients after mechanical thrombectomy with the AlphaVac MMA F18[85] System.

The RECOVER-AV trial is led by co-Principal Investigators Erik Klok, MD, Professor of Medicine and Vascular Medicine Specialist at Leiden University Medical Center, and Andrew Sharp, MD, Professor of Interventional Cardiology at Mater Misericordiae Hospital and University College Dublin.

“Pulmonary embolism continues to be a leading cause of morbidity and mortality across Europe, underscoring the need for treatment strategies that are both safe and effective,” said Professor Klok. “We’re pleased to collaborate with AngioDynamics to generate evidence that could help shape future standards of care for intermediate-risk PE patients.”

Aleksander Araszkiewicz, MD, PhD, Assistant Professor at Poznan University of Medical Sciences in Poland, completed the first procedure as part of the trial.

“Performing the first case in the RECOVER-AV study marks an important step forward in expanding treatment options for patients with intermediate-risk pulmonary embolism,” said Prof. Araszkiewicz. “The AlphaVac F18 [85] System offers a promising mechanical thrombectomy solution, and I’m encouraged by its ease of use and the immediate clinical results we observed. I look forward to continuing to contribute to this critical research as we work to improve outcomes for PE patients.”

This study builds on the results of the Company’s U.S.-based APEX-AV trial[2], which demonstrated that the AlphaVac F18[85] System is safe and effective for use in intermediate-risk PE patients, with significant improvements in right ventricular function and reduction in clot burden.

The AlphaVac F18[85] System received CE Mark approval in May 2024 for the non-surgical removal of thrombi or emboli from the pulmonary arteries. The System is designed to support frontline treatment of PE and expand options for healthcare providers managing patients with life-threatening venous thromboembolism.

For more information about the RECOVER-AV clinical trial, visit https://www.angiodynamics.com/studies/recover-av/. For important risk information, visit www.angiodynamics.com/about-us/risk-information/.

About the AlphaVac F18[85] System

The AlphaVac F18[85] System is an emergent first-line device that is currently CE marked for the non-surgical removal of thromboemboli from the pulmonary arteries 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. For risk information, visit https://bit.ly/Angio-risk-info.

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.

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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, 2024. AngioDynamics does not assume any obligation to publicly update or revise any forward-looking statements for any reason.

[1] Willich SN, Chuang LH, van Hout B, Gumbs P, Jimenez D, Kroep S, Bauersachs R, Monreal M, Agnelli G, Cohen A. Pulmonary embolism in Europe – Burden of illness in relationship to healthcare resource utilization and return to work. Thromb Res. 2018 Oct;170:181-191.

[2] Ranade M, Foster MT 3rd, Brady PS, Sokol SI, Butty S, Klein A, Maholic R, Safar A, Patel T, Zlotnick D, Gans D, Pollak J, Ferrera D, Stegman B, Basra S, Moriarty J, Keeling B. Novel Mechanical Aspiration Thrombectomy in Patients With Acute Pulmonary Embolism: Results From the Prospective APEX-AV Trial. J Soc Cardiovasc Angiogr Interv. 2024 Dec 27;4(1):102463.

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