AngioDynamics Announces CE Mark Approval in Europe for AlphaVac F18[85] System

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Regulatory approval enables entry of AlphaVac Mechanical Thrombectomy System in European market

LATHAM, N.Y.--(BUSINESS WIRE)--May 21, 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 European CE Mark approval of the AlphaVac F18[85] System for the non-surgical removal of thrombi or emboli from the pulmonary arteries and for the treatment of pulmonary embolism (PE).

"The CE Mark represents a major step forward in enhancing patient care and safety for endovascular therapies in the EU, a market with a higher prevalence of PE when compared to the United States," said Laura Piccinini, AngioDynamics Senior Vice President/General Manager, Endovascular Therapies and International. "This designation allows us to broaden our reach and provide innovative solutions to more healthcare professionals treating patients diagnosed with PE – on an increasingly global scale."

An estimated 435,000 PE events occur each year in the six largest European Union (EU) countries.[1] Compared to the United States, the prevalence of PE is higher for those patients admitted to the emergency department in Europe, and European patients also had higher acuity and worse outcomes.[2]

The CE Mark for the AlphaVac F18[85] System expands treatment options for healthcare professionals in the EU by offering a tool that helps reduce thrombus burden and improve right ventricular function in patients with PE.

In December 2023, AngioDynamics announced the completion of patient enrollment in its United States-based 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 to assess the AlphaVac F18[85] System for the treatment of PE.

The APEX-AV trial 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 Major Adverse Event (MAE) 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[3] and a mean procedure time of 37.2 minutes.[3]

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. The APEX-AV Study was designed to provide safety and efficacy data specific to PE. 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.

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] 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] Germini F., Zarabi S., Eventov M., Turcotte M., Li M., de Wit K. Pulmonary embolism prevalence among emergency department cohorts: A systematic review and meta-analysis by country of study. Journal of Thrombosis and Haemostasis. 2022 Dec; 19(1):173-185
[3] Data on file.

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