AngioDynamics Announces CE Mark Approval in Europe for the Auryon System

September 3, 2024

Regulatory approval enables entry of Auryon Atherectomy System in European market

LATHAM, N.Y.--(BUSINESS WIRE)--Sep. 3, 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 Auryon Atherectomy System, an innovative technology for the treatment of Peripheral Artery Disease (PAD), including Critical Limb Ischemia (CLI) and In-Stent Restenosis (ISR)[1,2,3].

The Auryon Atherectomy System uses revolutionary solid-state laser technology to treat PAD lesions and occlusions effectively. Auryon is the first laser atherectomy system to efficiently treat lesions of any type, length, or location (above and below the knee)[1,2,3], with minimal impact on vessel walls.

"The CE Mark approval of the Auryon System is a significant milestone that underscores our commitment to bringing safe and effective solutions to healthcare professionals treating peripheral artery disease," said Laura Piccinini, AngioDynamics Senior Vice President and General Manager of Endovascular Therapies and International. "This approval validates the clinical value of the Auryon System and allows us to expand our presence in Europe, as the prevalence of PAD continues to grow across the region[4]. We are committed to supporting physicians with innovative technologies that empower them to deliver the best possible care when treating some of the most challenging cases of this disease."

The Auryon Atherectomy System, which received FDA 510(k) clearance in 2020, has treated over 50,000 patients in the United States[5]. The recent CE Mark approval now provides patients with PAD in the European Union access to the Auryon System's advanced laser platform. This approval also expands the Company's reach to a global PAD market valued at $1.1 billion[5].

The technology underlying the Auryon Atherectomy System has been shown in clinical studies to be effective in treating lesions ranging from soft plaque to severely calcified[1,2,3]. The System uses a 355nm wavelength laser platform, enabling the use of short UV laser pulses with targeted biological reactions that are effective in treating PAD while minimizing the risk of perforation and preserving the ability to vaporize lesions without thermal ablation[1,3,8,9].

The Auryon Atherectomy System features aspiration and off-set capability in certain catheter sizes, allowing clinicians to address the risk of embolization and to treat all lesion types[1], while answering a need for non-surgical intervention options for PAD, including ISR, and CLI.

Nicolas Shammas, MD, and the Midwest Cardiovascular Research Foundation have published a prospective, multi-center, single-arm investigation examining the use of the Auryon laser system in patients with below-the-knee critical limb ischemia (CLI). The study demonstrated that the Auryon laser system effectively reduced residual stenosis to ≤30% in the majority of patients post-treatment, without any cases of target lesion revascularization[6].

The recently published PATHFINDER registry further supports these findings, showing no flow-limiting dissections and significant improvement in Ankle-Brachial Index (ABI), Rutherford classification, and Walking Impairment Questionnaires at both 6 and 12 months in a real-world clinical setting[7].

These results add to a growing body of evidence indicating that the Auryon laser system is a safe and effective treatment option for a wide range of complex patients with PAD.

For important risk information, visit www.auryon-system.com/risk-information.

About the Auryon Atherectomy System

The Auryon Atherectomy System uses innovative technology to deliver powerful treatment of arterial occlusions. The Auryon Atherectomy System is the first laser atherectomy system to efficiently treat any lesion type, any lesion length, at any lesion location, with minimal impact on vessel walls[1,3,8,9]. The Auryon Atherectomy System uses solid-state laser technology for the treatment of PAD and is CE Marked with an indication for treatment, including atherectomy, of infrainguinal stenoses and occlusions, including ISR[10,11]. The Auryon System's targeted biological reactions minimize the risk of perforation and preserve the ability to vaporize lesions without thermal ablation[1,3,8,9]. The Auryon System uses a 355nm wavelength laser platform which enables the use of longer wavelengths and shorter pulses to produce a groundbreaking delivery of short UV laser pulses[8]. For more information, please visit www.Auryon-PAD.com.

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

[1] Rundback J, Chandra P, Brodmann M, Weinstock B, Sedillo G, Cawich I, et al. *Novel laser-based catheter for peripheral atherectomy: 6-month results from the Eximo Medical B-Laser IDE study*. Catheter Cardiovasc Interv. 2019;1-8.

[2] Auryon System Indications for Use

[3] Shammas NW, Chandra P, Brodmann M, Weinstock B, Sedillo G, Cawich I, et al. *Acute and 30-day safety and effectiveness evaluation of Eximo Medical’s B-Laser , a novel atherectomy device, in subjects affected with infrainguinal peripheral arterial disease: Results of the EXPAD-03 trial* . Cardiovas Revasc Med. 2020;21(1):86-92

[4] Horváth, L., Németh, N., Fehér, G., Kívés, Z., Endrei, D., & Boncz, I. (2023). *Epidemiology of peripheral artery disease: Narrative review*. Life, 13(6), 1257. https://pubmed.ncbi.nlm.nih.gov/35888129/

[5] AngioDynamics’ Canaccord Genuity 44th Annual Growth Conference https://investors.angiodynamics.com/static-files/922d9caa-1088-4e4a-ba23-2f1486aa8817. Published 2024.

[6] Shammas NW, Yates T, Sastry A, Ricotta J, Beasley R, Swee W, Torey JT, Shammas GA, Jones-Miller S, Corbet M. *Prospective, Multi-center, Single-Arm Study of the Auryon Laser System for Treatment of Below-the-Knee Arteries in Patients With Chronic Limb-Threatening Ischemia: 30-Day Results of the Auryon BTK*. Am J Cardiol. 2024 May 15;219:1-8.

[7] Das TS, Shammas NW, Yoho JA, Martinez-Clark P, Ramaiah V, Leon LR, Pacanowski JP, Tai Z, Ali V, Arslan B, Rundback J. *Solid state, pulsed-wave 355 nm UV laser atherectomy debulking in the treatment of infrainguinal peripheral arterial disease: The Pathfinder Registry*. Catheter Cardiovasc Interv. 2024 May;103(6):949-962.

[8] Herzog A, Bogdan S, Glikson M, Ishaaya AA, Love C. *Selective tissue ablation using laser radiation at 355 nm in lead extraction by a hybrid catheter; a preliminary report*. Lasers Surg Med. 2016;48(3):281-287

[9] Vogel A, Venugopalan V. *Mechanisms of pulsed laser ablation of biological tissues*. Chem Rev. 2003;103(2):577-644

[10] Auryon System Indications for Use

[11] Built-in aspiration available only with the 2.0- and 2.35-mm catheters.

View source version on businesswire.com: https://www.businesswire.com/news/home/20240903360421/en/

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

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

Source: AngioDynamics, Inc.