AngioDynamics Announces FDA 510(k) Clearance of Auryon XL Radial Access Catheter to Treat Peripheral Arterial Disease

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225-cm Catheter Length Expands Access Points in Atherectomy Procedures to Help Reduce Access Site Complications and Accelerate Patient Recovery

LATHAM, N.Y.--(BUSINESS WIRE)--Jan. 23, 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 that the United States Food and Drug Administration (FDA) has cleared the Auryon XL Catheter, a 225-cm radial access catheter, for use with the Auryon Atherectomy System in the treatment of Peripheral Arterial Disease (PAD).

According to the American Heart Association, PAD affects 8.5 million Americans and 200 million people worldwide each year[1]. Studies have shown that radial access is associated with a significantly lower risk of major bleeding and access site complications when compared to femoral access[2,3] in the treatment of patients.

"Since its launch in September 2020, the Auryon Atherectomy System, with its innovative solid-state laser technology, has fundamentally changed patient treatment for PAD and quickly become an essential tool for providers and patients," said Kimberly Nelson, Senior Director of Auryon Global Marketing at AngioDynamics, Inc. "Our entry into the Radial-to-Peripheral (R2P) space with Auryon XL is an important part of our focus on advancing the quality of care delivery and it demonstrates our commitment to meeting the unmet needs of patients and atherectomy providers."

The Auryon XL Catheter, available in 0.9 mm and 1.5 mm diameters, expands treatment access points in atherectomy procedures for PAD. Use of a general radial access catheter may reduce incidents of major bleeding, when compared to femoral access, by more than 70%[3]. Additionally, it may eliminate the need for the use of femoral closure devices and allow for the treatment of bilateral disease in a single session, supporting improved patient mobility, earlier discharge and faster patient recovery times.

"Radial access is more than an entry point; it's a transformative expressway to enhanced patient outcomes," said Ankur Lodha, M.D., interventional cardiologist at Cardiovascular Institute of the South located in Lafayette, Louisiana. "With an innovative design and its ease-of-use, the Auryon XL Catheter brings significant advancements to radial procedures as the first non-orbital atherectomy device – setting a new standard for laser atherectomy technology."

Following FDA 510(k) clearance, AngioDynamics initiated a limited market release of the Auryon XL Catheter in the United States in January 2024 and expects to enter full market release in February 2024.

The Auryon laser can be used to treat all infrainguinal lesion types, including above-the-knee (ATK), below-the-knee (BTK) and In-Stent Restenosis (ISR)[5,6,8,11], and to date, it has been used to treat more than 50,000 patients[7] in the United States.

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[5,6,8]. 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[5,8-10].

For important risk information, visit www.angiodynamics.com/about-us/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[5,8-10]. The Auryon Atherectomy System uses solid-state laser technology for the treatment of PAD and is FDA cleared with an indication for treatment, including atherectomy, of infrainguinal stenoses and occlusions, including ISR[6,11]. The Auryon System's targeted biological reactions minimize the risk of perforation and preserve the ability to vaporize lesions without thermal ablation[5,8-10]. 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[6]. For more information, please visit www.Auryon-PAD.com.

About Cardiovascular Institute of the South

Founded by Dr. Craig Walker in 1983, Cardiovascular Institute of the South (CIS) is a world-leader in preventing, detecting and treating cardiovascular and peripheral vascular disease. CIS offers a comprehensive heart and vascular program with expert physicians trained in many specialties, including internal medicine, nuclear cardiology, electrophysiology, lipid management, coronary artery disease, peripheral vascular disease, structural heart and valve disease, venous disease and interventional procedures. CIS has earned international acclaim as a pioneer of research, development and education, as well as an innovator in the treatment of peripheral vascular disease. With a dedicated team of more than 1,075 team members, CIS provides comprehensive cardiovascular care at 21 locations across Louisiana and Mississippi, with 11 telemedicine programs. CIS has also been recognized by Modern Healthcare as a Best Place to Work in Healthcare for four years in a row. CIS remains at the forefront of technology, providing the highest-quality, compassionate care. This mission has guided the institute for 40 years of excellence.

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.

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

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