AngioDynamics Enrolls First Patient in AMBITION BTK Trial Advancing Treatment for Critical Limb Ischemia

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Trial Investigates Use of Auryon Atherectomy System in Cases with Challenging Below-the-Knee Blockages

LATHAM, N.Y.--(BUSINESS WIRE)--Jul. 28, 2025-- AngioDynamics, Inc. (NASDAQ: ANGO), a 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 enrollment of the first patient in the Randomized Study of the **A**uryon Atherecto**m**y System Used in Combination with Standard **B**alloon Angi**o**plasty Versus S**t**andard Balloon Angioplasty Alone Treating **I**nfrapopliteal Lesi**on**s in Subjects with Critical Limb Ischemia **B**elow-**t**he-**K**nee (AMBITION BTK).

AMBITION BTK is a prospective, multicenter, randomized controlled trial (RCT) designed to investigate the clinical safety and effectiveness of the Auryon Atherectomy System combined with standard balloon angioplasty, compared to balloon angioplasty alone, in treating infrapopliteal lesions in patients with Critical Limb Ischemia (CLI). The primary endpoint will be evaluated using a win-ratio approach, comparing the two treatment groups based on the following components in a hierarchical manner at 12 months: freedom from major amputation, freedom from clinically driven target lesion revascularization (CD-TLR), and primary patency.

The RCT will include up to 224 patients at up to 30 sites. In parallel, a companion registry will enroll up to 1,500 additional patients who are ineligible for the RCT and are treated with the Auryon System above or below the knee.

“The enrollment of the first patient in the AMBITION BTK trial is a significant milestone in our commitment to advancing clinical evidence for the treatment of below-the-knee peripheral artery disease (PAD),” said Laura Piccinini, Senior Vice President/General Manager, Cardiovascular & International, AngioDynamics. “There is a pressing need for new treatment strategies to help patients suffering from chronic limb ischemia, and we are proud to partner with clinicians to evaluate the Auryon System in this important setting.”

The overall risk of limb loss in CLI is estimated at 20–25% at one year if left untreated, reflecting a large impact on quality of life and healthcare costs.[1] Incidence of infrapopliteal disease in patients with CLI, particularly in the diabetic population, is estimated to be >70%.[2]

“Treatment options for below-the-knee lesions are still limited and often depend heavily on balloon angioplasty,” said AMBITION BTK Co-Principal Investigator Ehrin Armstrong, FACC, FSCAI, FSVM, MD, MSc, Interventional Cardiologist and Vascular Disease, Director of Clinical Research, Advanced Heart and Vein Center. “The Auryon laser can restore laminar flow and therefore has the potential to improve outcomes in this challenging patient population significantly.”

The first patient in the trial was treated by Anahita Dua, MD, MS, MBA, FACS, a vascular surgeon at Massachusetts General Hospital and associate professor of Surgery at Harvard Medical School, and Co-Principal Investigator of AMBITION BTK.

“I’m excited to perform the first patient case in the AMBITION BTK study. Patients with below-the-knee disease often face limited treatment options and poor long-term outcomes,” said Dr. Dua. “Across the world, there has been a significant increase in patients with below-the-knee (BTK) disease, which is, unfortunately, resulting in an amputation epidemic. Having new tools and techniques to restore blood flow to the foot, allowing wounds to heal, and patients to preserve both their limbs and lives, is critically important and the focus of this trial. This trial will allow us to collect high-quality, real-world data using a robust research design, helping us truly evaluate the impact of laser technology in BTK disease.”

The Auryon laser can be used to treat all infrainguinal lesion types, including above-the-knee (ATK), BTK, and In-Stent Restenosis (ISR)[3,4,5,6] and, to date, it has been used to treat more than 100,000 patients in the United States and worldwide.[7]

Visit https://www.angiodynamics.com/studies/ambition-btk/ and https://clinicaltrials.gov/study/NCT06777901 for more information about the AMBITION BTK RCT and Registry.

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.[3,5,8,9] 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.[4,6] The Auryon System’s targeted biological reactions minimize the risk of perforation and preserve the ability to vaporize lesions without thermal ablation.[3,5,8,9] 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.[4] 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.

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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, tariffs, 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, 2025. AngioDynamics does not assume any obligation to publicly update or revise any forward-looking statements for any reason.

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[1] https://pmc.ncbi.nlm.nih.gov/articles/PMC10531516/

[2] https://www.jacc.org/doi/10.1016/j.jcin.2023.11.040

[3] 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-LaserTM IDE study. Catheter Cardiovasc Interv. 2019;1-8.

[4] Auryon System Indications for Use

[5] 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-LaserTM, 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

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

[7] AngioDynamics’ J.P. Morgan Healthcare Conference Presentation https://investors.angiodynamics.com/static-files/f7e7b49f-744d-4169-9a66-95a78d2f1525. Published 2025.

[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

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