AngioDynamics Initiates AMBITION BTK RCT and Registry to Advance Treatment for Critical Limb Ischemia

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Trial Evaluates Effectiveness of Innovative Auryon Atherectomy System in Complex Below-the-Knee Cases

LATHAM, N.Y.--(BUSINESS WIRE)--Jan. 30, 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 start of a 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 multicenter, randomized controlled trial (RCT) designed to evaluate the clinical outcomes of the Auryon Atherectomy System in combination with standard balloon angioplasty compared to standard balloon angioplasty alone for the treatment of infrapopliteal lesions in patients with critical limb ischemia. The trial will enroll up to 200 subjects across up to 30 hospital-based sites. Additionally, up to 1,500 subjects treated with the Auryon Atherectomy System at the same sites who do not meet the eligibility criteria of the RCT will be enrolled in a companion Registry.

Lower extremity peripheral artery disease (PAD) affects more than 230 million adults worldwide and is associated with an increased risk of various adverse clinical outcomes.[1] In its most severe form, critical limb ischemia patients are often treated with lower extremity amputation (LEA).[2]

“We are dedicated to expanding innovative treatment options for peripheral artery disease, particularly in challenging cases like below-the-knee lesions,” said Juan Carlos Serna, AngioDynamics Senior Vice President of Scientific and Clinical Affairs. “The AMBITION BTK RCT and Registry represents an important advancement in evaluating the clinical benefits of the Auryon Atherectomy System. Physicians have expressed strong interest in the platform's unique capabilities, and we are eager to demonstrate further its potential to improve outcomes for patients with critical limb ischemia.”

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)[3,4,5,6] and to date, it has been used to treat more than 100,000 patients[7] in the United States and worldwide.

“With the global rise in diabetes, we are seeing a growing number of patients with severe tibial disease,” said AMBITION BTK Co-Principal Investigator Anahita Dua, MD, MS, MBA, FACS, vascular surgeon at Massachusetts General Hospital and an associate professor of Surgery at Harvard Medical School. “In the United States, treatment options for below-the-knee lesions remain limited, often relying primarily on POBA (Percutaneous Old Balloon Angioplasty). These patients frequently present with tibial disease that can extend throughout the entire vessel. An innovative tool like the Auryon laser, which can restore laminar flow, could be a game-changer in their care.”

AMBITION BTK builds upon the positive outcomes of a prior multicenter, prospective trial that evaluated the safety and effectiveness of the Auryon laser atherectomy system in treating BTK lesions in patients with limb ischemia. The earlier study successfully treated 61 complex, calcified lesions across four U.S. centers in 60 patients, achieving strong clinical outcomes with minimal complications. These results demonstrated the System's ability to safely and effectively address challenging BTK cases,[8] leading to the development of the AMBITION BTK RCT and Registry.

“The AMBITION BTK RCT and Registry represents an important advance in the evidence supporting the benefits of laser atherectomy in achieving acute and long-term procedural success,” 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 trial will address an important unmet need for patients with critical limb ischemia and tibial artery disease. The data for the trial will also help better understand the Auryon laser's unique mechanism of action in complex and calcified lesions.”

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.[3,4,5] 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.[3,5,6,9,10]

On February 1, the Company will host its inaugural Cardiovascular Scientific Forum (CVSF). The event will bring together leading physicians and thought leaders in the cardiovascular field to present groundbreaking research, discuss emerging clinical trends, and showcase advancements shaping the future of patient care, including the AMBITION BTK RCT and Registry.

Visit 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.[3,5,9,10] 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.[4,6] The Auryon System’s targeted biological reactions minimize the risk of perforation and preserve the ability to vaporize lesions without thermal ablation.[3,5,9,10] 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.[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.

Safe Harbor

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[1] https://www.ahajournals.org/doi/10.1161/CIR.0000000000001005

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4107174/#:~:text=In%20its%20most%20severe%20form,the%20performing%20of%20major%20LEA

[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] ClinicalTrials.gov. (2023*). Evaluation of the safety and efficacy of the Auryon Atherectomy System for the treatment of below-the-knee arteries in patients with chronic limb-threatening ischemia (NCT05284240)*. U.S. National Library of Medicine. https://clinicaltrials.gov/study/NCT05284240?term=NCT05284240&rank=1

[9] 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

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

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