AngioDynamics Announces First Patient Enrolled in PATHFINDER I Registry Examining Long-Term Effectiveness and Safety of Auryon Atherectomy System

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LATHAM, N.Y.--(BUSINESS WIRE)--Aug. 17, 2020-- AngioDynamics, Inc. (NASDAQ: ANGO), a leading provider of innovative, minimally invasive medical devices for vascular access, peripheral vascular disease, and oncology, today announced the enrollment of the first patient in the PATHFINDER I: Post-Market Registry (PATHFINDER I-Registry, EX-PAD-05).

The PATHFINDER I Registry is a pilot study to evaluate the safety and efficacy of the Auryon Atherectomy System in the real-world treatment of de novo, re-stenotic, and in-stent restenosis (ISR) lesions in infrainguinal arteries of patients with Peripheral Artery Diseases (PAD).

“We believe that the solid-state laser technology utilized in the Auryon System is the future of atherectomy treatment,” said Jim Clemmer, President and Chief Executive Officer of AngioDynamics, Inc. “Providers are showing an eagerness to enroll patients in the study and treat patients with our game-changing technology. Their strong support of the PATHFINDER I Registry, along with the enrollment of our first patient, represents a meaningful step toward achieving our shared goal of advancing the standard of care for patients with PAD and related conditions.”

PAD is typically caused by the buildup of fatty plaque (known as atherosclerosis) in the arteries that carry blood to the extremities, and it affects over 200 million people around the globe, including 8.5 million people in the United States[1]. The prevalence of PAD for men and women increases with age and other factors, such as high blood pressure, smoking, diabetes, and high cholesterol[2]. Left untreated, PAD can progress to cause life-threatening conditions, such as coronary artery disease and cerebrovascular disease[2].

Jason Yoho, M.D., of the Heart and Vascular Institute of Texas enrolled the first PATHFINDER I Registry patient, a 61-year old woman with a past medical history of atrial fibrillation, hypertension, hyperlipidemia, and prior myocardial infarction. She was initially evaluated for severe claudication at rest and was classified as Rutherford 5 (ischemic ulceration not exceeding ulcers of the digits of the foot). A diagnostic angiography of her right leg revealed severely calcified and diseased anterior and posterior tibial arteries. She was treated with the Auryon Atherectomy System.

“Thanks to the successful Auryon laser atherectomy procedure, which was performed in conjunction with balloon angioplasty, there is now excellent, rapid flow restored into the pedal arch. In this case of severely calcified and tortuous anatomy, other devices likely would not have been as successful,” said Dr. Yoho. “Having a passion for CLI and limb salvage, my staff and I are eager to advance the body of knowledge around the Auryon Atherectomy System through the PATHFINDER I Registry. I am excited that AngioDynamics is dedicated to improving upon existing atherectomy technology and increasing the quality of care in the peripheral space. It is critical that we aggressively seek out and support promising new technologies, such as the Auryon System, so that we can provide patients with the best outcomes possible.”

The Auryon System is a proprietary solid state laser technology platform that is FDA-indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions, including ISR, which is the gradual re-narrowing of the artery after a blockage has been previously treated with a stent. The Auryon System uses a 355nm wavelength laser platform which enables the use of longer wavelengths and shorter pulses to produce the groundbreaking delivery of short UV laser pulses. The Auryon system’s targeted biological reactions address the risk of perforation and preserve the ability to vaporize lesions without thermal damage.

Ten healthcare delivery sites in the United States are expected to participate in the PATHFINDER I Registry, each of which is equipped with an Auryon System. Sites are located in Texas, Iowa, Arizona, New Jersey, and Florida. AngioDynamics expects a total of 100 eligible PAD patients to participate in the PATHFINDER I Registry, which will track outcomes for patients for 24 months after treatment with the Auryon System.

The PATHFINDER I Registry is structured as a prospective, non-randomized, single arm, multicenter observational study that will evaluate the performance of the Auryon System during procedures and measure clinical outcomes, both intermediate and long-term. Initial findings from the pilot registry study will inform and help shape a subsequent larger registry that is expected to include approximately 1,000 patients.

Visit www.clinicaltrials.gov/ct2/show/NCT04229563 for more information about the PATHFINDER I Registry. For more information about the AURYON Atherectomy System, visit www.angiodynamics.com/products/66/Auryon/. For important risk information, visit www.angiodynamics.com/about-us/risk-information/

About AngioDynamics, Inc.

AngioDynamics, Inc. is a leading provider of innovative, minimally invasive medical devices used by professional healthcare providers for vascular access, peripheral vascular disease, and oncology. AngioDynamics’ diverse product lines include market-leading ablation systems, vascular access products, angiographic products and accessories, drainage products, thrombolytic products and venous products. For more information, visit www.angiodynamics.com.

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[1] American Heart Association - PAD Resources. www.heart.org. https://www.heart.org/en/health-topics/peripheral-artery-disease/pad-resources. Published 2019. Accessed July 27, 2020.

[2] Özguler İ, Üstunel L, Uysal A. The relationship between acute arterial occlusions and the stage of peripheral arterial disease according to the Fontaine Classification. *The Turkish Journal of Geriatrics*. 2018;22(2):214-221. doi:10.31086/tjgeri.2019.95

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Investor Relations Contact:

AngioDynamics, Inc.
Stephen Trowbridge

518-795-1408
strowbridge@angiodynamics.com

Media Contact:

AngioDynamics, Inc.
Saleem Cheeks
518-795-1174
scheeks@angiodynamics.com

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