AngioDynamics Completes Enrollment for PRESERVE Clinical Study

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Pivotal Study of NanoKnife System for Ablation of Prostate Tissue in an Intermediate-Risk Patient Population

LATHAM, N.Y.--(BUSINESS WIRE)--Aug. 3, 2023--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 quality of life for patients, today announced the completion of enrollment and final treatment in its Pivotal Study of the NanoKnife System for Ablation of Prostate Tissue in an Intermediate-Risk Patient Population (PRESERVE).

The PRESERVE study was initiated by AngioDynamics, Inc. in partnership with the Society of Urologic Oncology Clinical Trials Consortium (SUO-CTC).

"The PRESERVE study demonstrates AngioDynamics' commitment to innovating care delivery," said Juan Carlos Serna, AngioDynamics Senior Vice President of Clinical and Scientific Affairs. "As we mark the completion of enrollment and final treatment in the study, we take another important step towards demonstrating the NanoKnife System's ability to expand treatment options for patients with intermediate-risk prostate cancer and advance our mission to improve patient quality of life. We appreciate the support provided by our PRESERVE study sites and the partnership with the SUO-CTC team in this important effort."

Final patient enrollment in the study was initially announced during AngioDynamics' Fiscal 2023 Fourth Quarter and Full-Year Financial Results conference call on July 12, 2023.

Co-Principal Investigators leading the study are Jonathan Coleman, MD, Urologic Surgeon, Memorial Sloan Kettering Cancer Center, and Arvin George, MD, Urologic Surgeon, University of Michigan. The PRESERVE study will have its primary endpoint analysis at 12 months following treatment.

"As diagnostic tools develop to allow earlier identification and localization of clinically significant forms of prostate cancer, there is a matching need to establish effective forms of treatment that target the disease and preserve patients' quality of life. Evidence is growing to support the use of partial gland ablation for prostate cancer as a reasonable alternative treatment strategy in carefully selected patients. The PRESERVE study, studying the efficacy of irreversible electroporation (IRE) with the NanoKnife System from AngioDynamics in men with intermediate-risk tumors (Gleason Grade 3+4 and 4+3), will help to address further the validity of this therapeutic approach using a treatment, which is well tolerated and easy to apply in prostate tissue," said Co-Principal Investigator Jonathan Coleman, MD, Urologic Surgeon, Memorial Sloan Kettering Cancer Center.

In 2023, the American Cancer Society estimates that there will be about 288,300 new cases of prostate cancer and about 34,700 deaths from the disease in the U.S. It is estimated that 1 out of every 8 men will be diagnosed with prostate cancer during their lifetime, and prostate cancer is more likely to develop in older and non-Hispanic Black men. It is American men's second leading cause of death.¹

The NanoKnife System utilizes Irreversible Electroporation (IRE) technology to effectively destroy targeted tissue, delivering precise treatment margins while preserving vital structures by retaining the structural integrity of the targeted tissue. The delivery of non-thermal energy allows for the preservation of the extra-cellular matrix, facilitating post-ablation histological and functional tissue regeneration. To learn more and view risk information, visit NanoKnife.com.

The PRESERVE study’s primary objectives are determining the NanoKnife System’s ablation effectiveness by measuring the negative in-field biopsy rate at 12 months and determining the NanoKnife System’s procedural and post-procedural safety profile by evaluating adverse event incidence, type and severity through 12 months. The study enrolled and treated 121 patients in 17 facilities across the United States. Learn more about PRESERVE at angiodynamics.com/studies/preserve.

About the NanoKnife System

The NanoKnife System utilizes Irreversible Electroporation (IRE) technology to effectively destroy targeted cells without the use of thermal energy by delivering high-voltage pulses, creating permanent nanopores within the cell membrane. This stimulus induces an apoptotic-like cellular death in the targeted tissue, resulting in a complete ablation of the targeted tissue. Visit nanoknife.com for full product information.

Visit bit.ly/NanoKnifeRiskInfo for risk information. The NanoKnife System has been cleared by the FDA for the surgical ablation of soft tissue. It has not received clearance for the therapy or treatment of any specific disease or condition.

The NanoKnife System, when used for the treatment of prostate cancer, is an investigational device. It is limited by United States law to investigational use.

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 quality of life for patients.

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.

About the Society of Urologic Oncology Clinical Trials Consortium (SUO-CTC)

Created, owned and operated by its members, the Society of Urologic Oncology Clinical Trials Consortium (SUO-CTC) is a clinical research
investigator network of more than 400 members from more than 200 clinical sites in the U.S. and Canada. This national alliance of leading academic and community based uro-oncologists is committed to furthering urology research. The SUO-CTC is a registered 501c3 not-for-profit corporation and has a cooperative relationship with the Society of Urologic Oncology (SUO). For more information, visit suoctc.org.

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 health care 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, 2022. AngioDynamics does not assume any obligation to publicly update or revise any forward-looking statements for any reason.

In the United States, the NanoKnife System has received a 510(k) clearance by the Food and Drug Administration for use in the surgical ablation of soft tissue and is similarly approved for commercialization in Canada, the European Union and Australia. The NanoKnife System has not been cleared for the treatment or therapy of a specific disease or condition.

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Investor Relations:
Stephen Trowbridge
518-795-1408
strowbridge@angiodynamics.com

Media:
Saleem Cheeks
518-795-1174
scheeks@angiodynamics.com

Source: AngioDynamics, Inc.