AngioDynamics Receives FDA Clearance for The NanoKnife® System for Prostate Tissue Ablation

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LATHAM, N.Y.--(BUSINESS WIRE)--Dec. 9, 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 it received U.S. Food and Drug Administration (FDA) 510(k) clearance for the NanoKnife System for prostate tissue ablation.

The Company received clearance for the NanoKnife System for prostate tissue ablation following the completion of the pivotal PRESERVE clinical study and submission of results to the FDA in September. The study evaluated the safety and effectiveness of the system for ablating prostate tissue in patients with intermediate-risk prostate cancer (PCa). Conducted in collaboration with the Society of Urologic Oncology Clinical Trials Consortium (SUO-CTC), PRESERVE enrolled 121 patients across 17 clinical sites.

"We are incredibly proud to receive FDA clearance for the NanoKnife System's use in prostate tissue," said Jim Clemmer, President and Chief Executive Officer of AngioDynamics. "This milestone is the first step in recognizing our vision to become the standard, function-preserving treatment for men with prostate tumors. The NanoKnife System minimizes the life-altering complications often associated with traditional treatments by selectively targeting prostate tissue while preserving critical functions. As we expand our global footprint and increase access to our technology, we are launching comprehensive education and awareness campaigns to empower physicians with hands-on training and clinical support while engaging patients through innovative outreach initiatives."

Mr. Clemmer added, "These efforts are designed to accelerate the adoption of the NanoKnife System, redefine the standard of care for prostate health, and deliver treatment outcomes that patients and physicians need. AngioDynamics is committed to driving meaningful impact through this revolutionary technology, providing new hope to patients and improved quality of life."

The PRESERVE clinical study met its primary effectiveness endpoint demonstrating the performance of the NanoKnife System for the ablation of prostate tissue in patients with intermediate-risk PCa. At 12-months post-procedure, 84.0% of men were free from in-field, clinically significant disease. In addition, the study demonstrated strong quality of life outcomes with short-term urinary continence being preserved (96.6% at baseline, 95.4% at 12-months) and the ability to maintain erections sufficient for intercourse only decreasing 9% compared to baseline (80.7% to 71.7%).[1]

The study's results validated the robust safety and clinical efficacy profile of the NanoKnife System, reinforcing findings from more than 32 clinical studies performed around the world involving over 2,600 patients.[1]

Prostate cancer is the second most common cancer in men worldwide, with approximately 1.5 million new cases diagnosed annually.[2] Many of these patients seek alternatives to radical procedures that can lead to significant, long-term urological side effects.[3] The NanoKnife System is the first and only non-thermal, radiation-free, ablation technology designed to treat prostate tissue by using IRE technology, offering patients a minimally invasive option for prostate treatment.

The NanoKnife System delivers an innovative alternative to conventional radical surgery or radiotherapy, which often results in significant dysfunction in urinary continence and erectile potency.[4] With its non-thermal approach, the system is engineered to preserve vital structures inside and outside the prostate, offering patients improved outcomes, reduced recovery times, and enhanced quality of life.[5]

For important risk information, visit https://www.angiodynamics.com/about-us/risk-information/#inano

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.[6] Visit nanoknife.com for full product information.

United States: The NanoKnife System with six outputs is indicated for surgical ablation of soft tissue, including prostate tissue.

Canada: The NanoKnife System is a medical device for cell membrane electroporation. Electroporation is a phenomenon that occurs in cell membranes as cells are exposed to an electrical field of sufficiently high intensity. The electric field acts as a physical stimulus, bringing about alterations in cell membranes that result in increased permeability.

European Union: The NanoKnife System is indicated for the ablation of prostate tissue in patients with intermediate risk prostate cancer.

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, 2024. AngioDynamics does not assume any obligation to publicly update or revise any forward-looking statements for any reason.

[1] Data on file.

[2] https://www.wcrf.org/cancer-trends/prostate-cancer-statistics/

[3] Cheng JY. The Prostate Cancer Intervention Versus Observation Trial (PIVOT) in Perspective. *J Clin Med Res*. 2013;5(4):266-268. doi:10.4021/jocmr1395w

Lomas DJ, Ziegelmann MJ, Elliott DS. How informed is our consent? Patient awareness of radiation and radical prostatectomy complications. *Turk J Urol*. 2018;45(3):191-195. Published 2018 Dec 20. doi:10.5152/tud.2018.81522

[4] Faiella E, Santucci D, D'Amone G, et al. Focal minimally invasive treatment in localized prostate cancer: comprehensive review of different possible strategies. *Cancers (Basel)*. 2024;16(4):765. doi:10.3390/cancers16040765

Donovan JL, Hamdy FC, Lane JA, et al. Patient-reported outcomes 12 years after localized prostate cancer treatment. *NEJM Evid*. 2023;2(4):EVIDoa2300018. doi:10.1056/EVIDoa2300018

[5] Faiella E, Santucci D, D'Amone G, et al. Focal minimally invasive treatment in localized prostate cancer: comprehensive review of different possible strategies. *Cancers (Basel)*. 2024;16(4):765. doi:10.3390/cancers16040765

Scheltema MJ, Geboers B, Blazevski A, et al. Median 5-year outcomes of primary focal irreversible electroporation for localised prostate cancer. *BJU Int*. 2023;131 Suppl 4:6-13. doi:10.1111/bju.15946

Resnick MJ, Koyama T, Fan KH, et al. Long-term functional outcomes after treatment for localized prostate cancer. *N Engl J Med*. 2013;368(5):436-445. doi:10.1056/NEJMoa1209978

Golberg A, Yarmush ML. Nonthermal irreversible electroporation: fundamentals, applications, and challenges. *IEEE Trans Biomed Eng*. 2013;60(3):707-714. doi:10.1109/TBME.2013.2238672

[6] Lee EW, Thai S, Kee ST. Irreversible electroporation: a novel image-guided cancer therapy. *Gut Liver*. 2010;4 Suppl 1(Suppl 1):S99-S104. doi:10.5009/gnl.2010.4.S1.S99

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