AngioDynamics Receives FDA IDE Approval for RELIEF Feasibility Study Evaluating NanoKnife IRE Platform as Minimally Invasive Treatment for Benign Prostatic Hyperplasia (BPH)

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Prospective Feasibility Study to Examine IRE as a Tissue-Sparing, Minimally Invasive Option for Men with BPH-Related Lower Urinary Tract Symptoms

LATHAM, N.Y.--(BUSINESS WIRE)--Jun. 17, 2026-- 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 that the U.S. Food and Drug Administration (FDA) has approved the Company's Investigational Device Exemption (IDE) application to initiate the RELIEF study. RELIEF is a feasibility study evaluating irreversible electroporation (IRE), the non-thermal ablation technology delivered by the Company's NanoKnife System, for the treatment of lower urinary tract symptoms (LUTS) in men with benign prostatic hyperplasia (BPH).

BPH is among the most prevalent urologic conditions affecting men in the United States, with an estimated 15 million men exhibiting symptoms and more than 300,000 surgical procedures performed annually.[1,2] BPH can cause lower urinary tract symptoms, including urinary frequency, urgency, weak stream, and incomplete bladder emptying, that impair daily function and quality of life.

Current treatment options range from pharmacologic therapy to surgical interventions such as transurethral resection of the prostate (TURP) and newer minimally invasive procedures, underscoring the need for additional approaches that balance effectiveness with preservation of sexual and urinary function.

"The NanoKnife System has an established role in the treatment of men with intermediate-risk prostate disease. Physicians have consistently reported meaningful improvements in urinary symptoms following IRE with the NanoKnife System, a signal we believe warrants further clinical evaluation," said Juan Carlos Serna, AngioDynamics Senior Vice President, Scientific and Clinical Affairs. "The RELIEF study will generate the initial safety and effectiveness data needed to advance IRE as a tissue-sparing solution for the millions of men living with BPH."

The NanoKnife System is cleared for the surgical ablation of prostate tissue. In prior clinical experience with IRE in the prostate, physicians observed meaningful improvements in urinary symptoms associated with BPH in patients treated for intermediate-risk prostate disease, an observation that provided clinical rationale for the RELIEF study.[3]

The RELIEF study is a prospective, single-arm clinical study that will enroll 40 subjects at up to five clinical sites in the United States. Patients, at six months post-treatment, will be evaluated for the primary endpoints and will also be followed for a total of five years for secondary endpoints. The primary effectiveness endpoint is the mean change in International Prostate Symptom Score (IPSS) from baseline to six months post-procedure. The primary safety endpoint is the incidence and severity of device-related adverse events during that period.

The study is led by co-Principal Investigator Felix Cheung, MD, Urologic Surgeon, Memorial Sloan Kettering Cancer Center. RELIEF will evaluate the preliminary safety and effectiveness of IRE delivered via the NanoKnife System for the relief of BPH-related symptoms. The results will establish the evidence foundation for future clinical development of IRE as a minimally invasive treatment option for BPH.

"The RELIEF study was designed with scientific rigor at its core. The study incorporates validated, well-established endpoints such as IPSS, uroflowmetry, and quality-of-life measures, alongside careful monitoring of sexual function and long-term durability through five years of follow-up," said Felix Cheung, MD, Urologic Surgeon, Memorial Sloan Kettering Cancer Center. "This thoughtful, methodical approach will generate the high-quality evidence needed to determine whether IRE can offer men with BPH/LUTS a non-resecting alternative with meaningful functional preservation."

In the RELIEF study, electrodes are placed transperineally into predefined treatment zones of the prostate under transrectal ultrasound guidance and general anesthesia. Treatment planning targets the transition zone bilaterally while preserving critical structures, including the neurovascular bundles, external sphincter, and urethra. The NanoKnife System delivers short pulses of electrical energy to create permanent nanopores in cell membranes, resulting in precise, non-thermal ablation of prostate tissue.

For more information about the RELIEF study, visit: https://clinicaltrials.gov/study/NCT07640776.

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 angiodynamics.com.

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.[4] 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 soft tissue and tumors of the pancreas, kidney, liver, or prostate, including intermediate risk prostate cancer.

The NanoKnife System has not received clearance for the therapy or treatment of any specific disease or condition.

The NanoKnife System when used for the treatment of benign prostate hyperplasia is an investigational device. Limited by United States law to investigational use.

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, 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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