AngioDynamics Receives FDA Approval to Initiate Pilot Study for the Use of NanoKnife® to Treat Prostate Cancer

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LATHAM, N.Y.--(BUSINESS WIRE)--May 22, 2019-- AngioDynamics, Inc. (NASDAQ: ANGO), a leading provider of innovative, minimally invasive medical devices for vascular access, peripheral vascular disease, and oncology, today announced that the United States Food and Drug Administration (FDA) approved the Company's investigational device exemption (IDE) application for its NanoKnife ® Irreversible Electroporation pilot study for the ablation of prostate cancer tissue in low-risk patients.

The prospective, non-randomized pilot study includes six subjects at up to three clinical sites. The pilot study is intended to inform the design of a pivotal clinical study in the United States to support the approval of a future Premarket Approval Application (PMA).

"On the heels of our first patient enrollment in our Stage III pancreatic cancer IDE, we are excited to receive approval to conduct a separate pilot IDE for the treatment of prostate cancer," said Brent Boucher, AngioDynamics Senior Vice President and General Manager of Oncology. "This pilot study represents the next step in our comprehensive approach to establish NanoKnife® as a platform technology to treat numerous cancers and conditions."

Prostate cancer is the second leading cause of cancer death in American men[1]. Approximately one man out of every nine will be diagnosed with prostate cancer during his lifetime[1]. Traditional treatment options have focused on standard whole-gland therapies, such as active surveillance, radical prostatectomy, and external beam radiation[2]. However, over the last decade, focal therapy has been evaluated as an alternative for select patients diagnosed with localized prostate cancer in order to minimize treatment-related toxicity[2].

The NanoKnife® System is a unique, minimally invasive technique that has been used to successfully treat focal prostate lesions through irreversible electroporation.

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, fluid management systems, vascular access products, angiographic products and accessories, drainage products, thrombolytic products and venous products. For more information, visit www.angiodynamics.com.

About the NanoKnife System

The NanoKnife System has received 510(k) clearance from the Food and Drug Administration for the surgical ablation of soft tissue. The NanoKnife System utilizes low energy direct current electrical pulses to permanently open pores in target cell membranes. These permanent pores, or nano-scale defects, in the cell membranes result in cell death. The treated tissue is then removed by the body's natural processes over a matter of weeks, mimicking natural cell death. Unlike other ablation technologies, the NanoKnife System does not achieve tissue ablation using thermal energy.

The NanoKnife System consists of two major components: a Low Energy Direct Current, or LEDC Generator and needle-like electrode probes. Up to six electrode probes can be placed into or around the targeted soft tissue. Once the probes are in place, the user enters the appropriate parameters for voltage, number of pulses, interval between pulses, and the pulse length into the generator user interface. The generator then delivers a series of short electric pulses between each electrode probe. The energy delivery is hyperechoic and can be monitored under real-time ultrasound.

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," "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 from AngioDynamics' expectations. Factors that may affect the actual results achieved by AngioDynamics include, without limitation, 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 fourth 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, the results of on-going litigation, challenges with respect to fourth-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 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, 2018. 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.

[1] Key Statistics for Prostate Cancer. https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html. Accessed May 21, 2019.

[2] Giannarini, G., Gandaglia, G., Montorsi, F., & Briganti, A. (2014). Will Focal Therapy Remain Only an Attractive Illusion for the Primary Treatment of Prostate Cancer? *Journal of Clinical Oncology*, 1299-1301

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