AngioDynamics Receives FDA Approval to Initiate NanoKnife® DIRECT Clinical Study for the Treatment of Stage III Pancreatic Cancer

April 1, 2019

LATHAM, N.Y.--(BUSINESS WIRE)--Apr. 1, 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 "**D**irect **IREC**ancer **T**reatment" clinical study (DIRECT).

The DIRECT Study supports a proposed expanded indication for the NanoKnife System in the treatment of Stage III pancreatic cancer. In January 2018, the FDA granted the Company's NanoKnife System a Breakthrough Device Designation under the 21st Century Cures Act.

"The DIRECT study design demonstrates our commitment to provide an option that addresses a pressing unmet need for patients with Stage III pancreatic cancer," said Jim Clemmer, President and Chief Executive Officer of AngioDynamics. "We are confident that our comprehensive approach, crafted through a constructive dialogue with the FDA, will generate meaningful data for clinicians, patients, payors and other stakeholders who are equally committed to fighting this disease, and we are dedicated to the idea that the standard of care for this deadly disease can—and should —improve."

The NanoKnife System is a next-generation ablative technology that physicians have identified as an innovative treatment for pancreatic cancer, as evidenced by 42 publications documenting more than 800 patients that have been treated for Stage III pancreatic cancer with NanoKnife technology between 2012 to 2019.

The NanoKnife System received 510(k) clearance from the FDA for the surgical ablation of soft tissue in 2008. Unlike other ablative technologies, the NanoKnife System utilizes low-energy, direct-current electrical pulses to permanently open pores in target cell membranes and does not rely on thermal effects. These permanent defects in the cell membranes result in cell death. The treated tissue is then removed by the body's natural processes in a matter of weeks, mimicking natural cell death.

AngioDynamics' DIRECT study will feature a comprehensive data collection strategy that will provide meaningful clinical information to healthcare professionals, support a regulatory indication for the treatment of Stage III pancreatic cancer, and facilitate reimbursement for hospitals and treating physicians. The next-generation study is classified as a Category B IDE by the FDA, allowing participating sites to obtain coverage for procedures performed as well as related routine costs.

The DIRECT study comprises a Randomized Controlled Trial (RCT) at up to 15 sites and a real-world evidence, next-generation registry (RWE) at up to 30 sites, each with a NanoKnife System treatment arm and a control arm. AngioDynamics expects each NanoKnife arm to consist of approximately 250 patients with an equal number of control patients. The primary endpoint of the study is overall survival.

The RCT component of the DIRECT study will illustrate the promise of the NanoKnife System by isolating variables in a controlled setting. Recognizing that results from a hyper-controlled setting do not always translate to clinical practice, the study also includes a RWE component to provide clinicians, patients, and payors with data generated in a real-world setting.

As part of the DIRECT clinical study, AngioDynamics is launching AngioDIRECT.com to facilitate the enrollment of participants. The online platform will provide patients and their families with information about pancreatic cancer and details about the study. It will also feature a physician locator to help prospective participants and referring healthcare professionals identify clinical study locations.

"Existing evidence that has accumulated over the last 10 years has shown that Irreversible Electroporation is an effective adjunctive treatment for patients with locally advanced pancreatic cancer," said Dr. Robert C.G. Martin, Co-Principal Investigator of the DIRECT Study and Surgical Oncologist at the University of Louisville. "We anticipate that this trial will demonstrate how the NanoKnife System can be utilized to enhance the quality of life for patients with Stage III pancreatic cancer."

"I've had promising experience utilizing Irreversible Electroporation as a treatment option for pancreatic cancer patients," said Dr. Govindarajan Narayanan, Co-Principal Investigator of the DIRECT Study and Chief of Interventional Oncology at the Miami Cancer Institute. "We expect that the results of this trial will lead to a widely available alternative treatment option for advanced pancreatic cancer patients."

There are approximately 57,000 new cases and 46,000 estimated deaths from pancreatic cancer in the United States annually[1]. Total deaths due to pancreas cancer are projected to increase dramatically to become the second leading cause of cancer-related deaths before 2030[2]. The mortality rate is high due to the aggressive nature of the disease and lack of early warning signs, and less than 20 percent of patients are candidates for surgical resection at time of diagnosis[1,3]. Approximately 35 to 40 percent of patients will present with Stage III and 45 to 55 percent with metastatic disease[1]. Regardless of the stage of pancreatic cancer, it is one of the least survivable cancers, and survival rates have not improved substantially for more than forty years[1]. For all stages combined, the five-year relative survival rate is 8 percent and, for those with advanced disease at the time of diagnosis, the five-year survival rate remains at 3 percent[1].

There are limited treatment options for Stage III and IV disease, with chemotherapy and/or radiotherapy considered the standard of care[3]. There have been advancements in both techniques, but this has come at the cost of greater toxicity[3], limiting the number of patients that are candidates for treatment.

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 Ablation 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 in a matter of weeks, mimicking natural cell death. Unlike other ablation technologies, the NanoKnife Ablation System does not achieve tissue ablation using thermal energy.

The NanoKnife Ablation System consists of two major components: a Low Energy Direct Current, or LEDC Generator and needle-like electrode probes. Up to six (6) 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]American Cancer Society. (2019). *Cancer Facts & Figures*. Retrieved March 14th, 2019, from https://www.cancer.org/cancer/pancreatic-cancer/about/key-statistics.html

[2] Projecting Cancer Incidence and Deaths to 2030: The Unexpected Burden of Thyroid, Liver, and Pancreas Cancers in the United States. Lola Rahib, Benjamin D. Smith, Rhonda Aizenberg, Allison B. Rosenzweig, Julie M. Fleshman and Lynn M. Matrisian DOI: 10.1158/0008-5472.CAN-14-0155 https://www.ncbi.nlm.nih.gov/pubmed/24840647

[3]American Society of Clinical Oncology. (2019). *Pancreatic Cancer: Statistics*. Retrieved March 14th, 2019, from https://www.cancer.net/cancer-types/pancreatic-cancer/statistics

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