



AngioDynamics Announces First Patient Enrolled in NanoKnife® DIRECT Clinical Study for the Treatment of Stage III Pancreatic Cancer

May 13, 2019

LATHAM, N.Y.--(BUSINESS WIRE)--May 13, 2019-- AngioDynamics, Inc. (NASDAQ: ANGO), a leading provider of innovative, minimally invasive medical devices for vascular access, peripheral vascular disease, and oncology, today announced enrollment of the first patient in its NanoKnife® Irreversible Electroporation (IRE) "Data IRE Cancer Treatment" clinical study (DIRECT).

The DIRECT Study supports a proposed expanded indication for the NanoKnife System in the treatment of Stage III pancreatic cancer. The first patient enrollment closely follows the United States Food and Drug Administration's (FDA) April 1, 2019 approval of AngioDynamics' investigational device exemption (IDE) application.

"The enrollment of our first patient soon after receiving FDA approval is a strong signal that clinicians are eager to evaluate treatment alternatives that improve the dismal prognosis for Stage III pancreatic cancer patients," said Brent Boucher, AngioDynamics Senior Vice President and General Manager of Oncology. "We look forward to confirming that our proprietary NanoKnife technology offers a compelling alternative to the current standard of care and believe that this study will provide a pivotal dataset for claims and reimbursement purposes."

AngioDynamics' DIRECT clinical study features 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, which allows participating sites to obtain coverage for procedures performed in addition to any related routine costs.

"We are pleased to be the first enrolling site. The DIRECT Study represents an important milestone in the standardization of care for patients with Stage III pancreatic cancer. Our goal is to generate important data that should standardize and optimize the use of IRE in the treatment of locally advanced pancreatic cancer, significantly improving outcomes for patients with this late-stage diagnosis," said Dr. Robert C.G. Martin, Co-Principal Investigator of the DIRECT Study and Surgical Oncologist at the University of Louisville.

The DIRECT Study comprises a Randomized Controlled Trial at up to 15 sites, as well as a Real-World Evidence, next-generation registry 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.

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

There are approximately 57,000 new cases and 46,000 estimated deaths from pancreatic cancer in the United States annually¹. Total deaths due to pancreatic cancer are projected to increase dramatically to become the second leading cause of cancer-related deaths before 2030². 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 diagnosis³. Approximately 35 to 40 percent of patients will present with Stage III and 45 to 55 percent with metastatic disease³. 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 years³. 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 percent³.

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.

¹American 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>

³American 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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