AngioDynamics' DIRECT Clinical Study Receives Institutional Review Board Approval for the Treatment of Stage III Pancreatic Cancer

April 17, 2019

LATHAM, N.Y.--(BUSINESS WIRE)--Apr. 17, 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 Company received central Institutional Review Board (IRB) approval to conduct its NanoKnife® Irreversible Electroporation "**D**irect **IREC**ancer **T**reatment" clinical study (DIRECT). The IRB approval closely follows the United States Food and Drug Administration's (FDA) approval of AngioDynamics' investigational device exemption (IDE) application announced on April 1.

Today's approval enables AngioDynamics to accelerate its engagement with local IRBs and marks a significant milestone in the process of making Irreversible Electroporation (IRE) available to patients through the DIRECT clinical study. The Western IRB (WIRB) will serve as AngioDynamics' IRB of record for the DIRECT clinical study.

"AngioDynamics is committed to providing physicians and patients with additional options for the treatment of Stage III pancreatic cancer. The DIRECT IRB approval demonstrates our commitment to initiating this next-generation clinical study as quickly as possible to advance our pursuit of innovative, lifesaving treatments," said Brent Boucher, AngioDynamics Senior Vice President and General Manager of Oncology.

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, allowing participating sites to obtain coverage for procedures performed as well as related routine costs.

The DIRECT clinical study comprises a Randomized Controlled Trial (RCT) at up to 15 sites, as well as a Real-World Evidence (RWE), 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 clinical 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.

The DIRECT clinical study supports a proposed expanded indication for the NanoKnife System in the treatment of Stage III pancreatic cancer.

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.

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Source: AngioDynamics, Inc.

Investor Relations Contact:
AngioDynamics, Inc.
Michael Greiner
518-795-1821
mgreiner@angiodynamics.com

Media Contact:
AngioDynamics, Inc.
Saleem Cheeks
518-795-1174
scheeks@angiodynamics.com