

DURHAM, N.C., Aug. 10, 2015 (GLOBE NEWSWIRE) -- Argos Therapeutics Inc. (Nasdaq: [ARGS](#)) ("Argos"), an immuno-oncology company focused on the development and commercialization of fully individualized immunotherapies for the treatment of cancer based on the Arcelis® technology platform, today announced the initiation of a single-center pilot clinical trial of AGS-003 as a neoadjuvant immunotherapy in patients with localized renal cell carcinoma. The study is being conducted at Roswell Park Cancer Institute (RPCI) in Buffalo, New York, and is designed to enroll a maximum of ten patients who will be treated with AGS-003 before nephrectomy in order to assess immune system response and tumor effects.

"There is tremendous potential for approaches that use the body's own defense mechanisms to treat cancer, and we are dedicated to advancing promising approaches in this rapidly expanding area of cancer research," said [Thomas Schwaab, MD, PhD](#), chief of strategy, business development & outreach, associate professor in the departments of urology and immunology and urology clinic director at Roswell Park Cancer Institute and principal investigator for the AGS-003 pilot study. "AGS-003 has shown strong potential in trials targeting metastatic renal cell carcinoma, and we look forward to advancing research to determine whether this therapy can help the body build an effective immune response to kill tumor cells in patients with localized disease. The goal is to develop a treatment that will interrupt the cancer's progression before it has a chance to spread to additional organs."

AGS-003 is an autologous dendritic-cell-based immunotherapy designed to induce a memory T-cell response specific to each patient's unique tumor antigens. It is produced using a small sample from a patient's own tumor and dendritic cells derived from a leukapheresis procedure. In an open-label phase 2 study, treatment with AGS-003 plus sunitinib yielded a median overall survival of more than 30 months in newly diagnosed, unfavorable-risk metastatic renal cell carcinoma patients. Argos is evaluating AGS-003 in the pivotal phase 3 ADAPT trial in combination with standard targeted therapy for the treatment of metastatic renal cell carcinoma. The ADAPT trial is fully enrolled; interim data analyses are expected next year, with final data expected in the first part of 2017.

The pilot study is in patients with localized renal cell carcinoma, who must be eligible to undergo a partial or radical nephrectomy. Patients will receive five weekly doses of AGS-003 prior to surgery and will remain in the study for approximately six months.

"With this pilot study, for the first time we will be able to assess the effects of AGS-003 in

patients with kidney cancer that has not spread to nearby lymph nodes or other parts of the body," said Charles Nicolette, chief scientific officer and vice president of research and development at Argos Therapeutics. "It is also an important opportunity to manufacture AGS-003 using a needle biopsy procedure for tumor collection prior to surgery and to directly study immune changes within the primary tumor before and after administration of AGS-003."

To learn more about the clinical research study, call 1-877-ASK-RPCI (1-877-275-7724) or send an e-mail to ASKRPCI@roswellpark.org .

Dr. Schwaab was also recently named to Argos' inaugural Scientific Advisory Board and receives compensation from Argos for this service.

About Roswell Park

The mission of Roswell Park Cancer Institute (RPCI) is to understand, prevent and cure cancer. Founded in 1898, RPCI is one of the first cancer centers in the country to be named a National Cancer Institute-designated comprehensive cancer center and remains the only facility with this designation in Upstate New York. The Institute is a member of the prestigious National Comprehensive Cancer Network, an alliance of the nation's leading cancer centers; maintains affiliate sites; and is a partner in national and international collaborative programs. For more information, visit www.roswellpark.org , call 1-877-ASK-RPCI (1-877-275-7724) or email askrpci@roswellpark.org

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About the Arcelis® Technology Platform

Arcelis® is a fully personalized immunotherapy technology that captures mutated and variant antigens that are specific to each patient's disease. It is designed to overcome immunosuppression by producing a durable memory T-cell response without adjuvants that may be associated with toxicity. The technology is potentially applicable to a wide range of

different cancers, and is designed to overcome many of the manufacturing and commercialization challenges that have impeded other personalized cancer immunotherapies. The Arcelis® process uses only a small tumor or blood sample and the patient's own dendritic cells, which are optimized from cells collected by a single leukapheresis procedure. The proprietary process uses RNA isolated from the patient's disease sample to program dendritic cells to target disease specific antigens. The activated, antigen-loaded dendritic cells are then formulated into the patient's plasma and administered via intradermal injection.

About Argos Therapeutics

Argos Therapeutics is an immuno-oncology company focused on the development and commercialization of fully personalized immunotherapies for the treatment of cancer using its Arcelis® technology platform. Argos' most advanced product candidate, AGS-003, is being evaluated in the pivotal ADAPT phase 3 clinical trial for the treatment of metastatic renal cell carcinoma (mRCC). The Company is also developing a separate Arcelis®-based product candidate, AGS-004, for the treatment of HIV, currently being evaluated in a phase 2 clinical trial aimed at HIV eradication in adult patients. For more information about Argos Therapeutics, visit www.argostherapeutics.com.

Forward Looking Statements

Any statements in this press release about Argos' future expectations, plans and prospects, including statements about Argos and other statements containing the words "believes," "anticipates," "plans," "expects," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including whether Argos' cash resources will be sufficient to fund our continuing operations for the period anticipated; whether results obtained in clinical trials will be indicative of results obtained in future clinical trials; whether Argos' product candidates will advance through the clinical trial process on a timely basis and receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether, if product candidates obtain approval, they will be successfully distributed and marketed; and other factors discussed in the "Risk Factors" section of Argos' Annual Report on Form 10-K for the year ended December 31, 2014 which is on file with the SEC. In addition, the forward-looking statements included in this press release represent Argos' views as of August 10, 2015. Argos anticipates that subsequent events and developments will cause Argos' views to change. However, while Argos may elect to update these forward-looking statements at some point in the future, Argos specifically disclaims any obligation to do so. These forward-looking

statements should not be relied upon as representing Argos' views as of any date subsequent to August 10, 2015.

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