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Argos Reports Immunogenicity Results of AGS-004 in HIV Program

DURHAM, N.C., July 26, 2017 (GLOBE NEWSWIRE) -- Argos Therapeutics Inc. (NASDAQ:ARGS), an immuno-oncology company focused on the development and commercialization of individualized immunotherapies based on the Arcelis® precision immunotherapy technology platform, today announced immunogenicity data from a study of AGS-004 dendritic cell therapy in patients treated during acute HIV infection. These data were recently published in the Journal of AIDS Research and Human Retroviruses.

The immunogenicity data was generated in a single arm, open label study in six patients with acute HIV infection conducted at the University of North Carolina and Duke University. AGS-004, an autologous cell therapy manufactured using the Arcelis® precision immunotherapy technology platform, was produced on an individual basis for each patient. To manufacture AGS-004, dendritic cells that were obtained through a leukapheresis were co-electroporated with in vitro transcribed RNA encoding autologous HIV antigens derived from viremic plasma of patients taken before commencement of anti-retroviral therapy (ART) and CD40L, which induces secretion of IL-12, a cytokine necessary to generate a CD8+ memory T-cell response.

In this study, AGS-004 was administered monthly to subjects with acute HIV infection suppressed by ART. AGS-004 was added to ART, and ART treatment was suspended after the immune response reached a predefined threshold. ART was then re-initiated based upon an evaluation of certain indicators of viral rebound. An assessment was made of HIV specific memory T-cell responses by multi-color flow cytometry following 3 — 4 doses of AGS-004.

The study achieved its primary endpoint, with all six patients demonstrating a positive immune response, defined as a greater than 2-fold increase from baseline in the number of multi-functional HIV-1 specific effector / memory T-cells. Because of this positive immune response, all six patients were able to have ART interrupted, with rebound viremia occurring at a median of 29 days, following which ART was resumed. Additionally, the magnitude of the immune response was positively correlated with longer time to viral rebound following interruption of ART. Viral rebound after ART interruption is widely attributed to latently infected cells known as the "viral reservoir" which is ineffectively targeted by immunotherapy alone. Consistent with prior clinical studies, AGS-004 was found to be well-tolerated, with no serious adverse events reported.

The favorable results of this study provide support for Argos' ongoing HIV eradication study in which AGS-004 is being administered in combination with vorinostat, a latency-reversing drug. This study is being conducted at the University of North Carolina, with planned enrollment of up to 12 patients and with initial data expected in early 2018. Funding for the development of AGS-004 for the treatment of HIV is being provided by the National Institutes of Health and the Collaboratory of Research for AIDS Eradication.

"We are encouraged by the results of this study, in which AGS-004 generated a targeted immune response against the HIV virus," noted Charles Nicolette, PhD, Chief Scientific Officer of Argos. "This is an important first step in our goal of not only combating active HIV infection, but also of eliminating the HIV viral reservoir, which has not yet been achieved with any currently available agent or combination therapy. We are hopeful that our strategy of stimulating cells that are latently infected with the HIV virus with the latency-reversing agent vorinostat will enable AGS-004-stimulated memory / effector T-cells to identify and eliminate these latently infected cells, thus potentially eliminating the HIV viral reservoir."

About Argos Therapeutics

Argos Therapeutics is an immuno-oncology company focused on the development and commercialization of individualized immunotherapies for the treatment of cancer and infectious diseases using its Arcelis® technology platform. Argos' most advanced product candidate, Rocapuldencel-T, is being evaluated in the pivotal ADAPT Phase 3 clinical trial for the treatment of metastatic renal cell carcinoma (mRCC). In addition, Rocapuldencel-T is being studied in a Phase 2 investigator-initiated clinical trial as neoadjuvant therapy for renal cell carcinoma (RCC). Argos is also developing a separate Arcelis®-based product candidate, AGS-004, for the treatment of human immunodeficiency virus (HIV), which is currently being evaluated in combination with vorinostat, a latency-reversing drug, in an investigator-initiated Phase 2 clinical trial aimed at HIV eradication in adult patients. Funding for the development of AGS-004 has been provided by the National Institutes of Health, the National Institute of Allergy and Infectious Diseases, and the Collaboratory of Research for AIDS Eradication.

Forward-Looking Statements

Any statements in this press release about Argos' future expectations, plans and prospects, including statements about the AGS-004 trial in patients with acute HIV infections, including the immunogenicity results, and the HIV eradication study, clinical development of Argos' product candidates and future expectations and plans and prospects for Argos and other statements containing the words "believes," "anticipates," "estimates," "expects," "intends," "plans," "predicts," "projects," "targets," "may," "potential," "will," "would," "could," "should," "continue," 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 such forward-looking statements as a result of various important factors, including whether Argos' cash resources will be sufficient to fund its continuing operations for the period anticipated; whether preliminary or interim clinical data will be indicative of the final data from a clinical trial; 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; whether the results of such trials will warrant submission for approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether Argos' product candidates will receive approval from regulatory agencies on a timely basis or at all; whether, if product candidates obtain approval, they will be successfully distributed and marketed; whether Argos can successfully establish commercial manufacturing operations on a timely basis or at all; and other factors discussed in the "Risk Factors" section of Argos' Form 10-Q for the quarter ended March 31, 2017, which is on file with the SEC, and in other filings Argos makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent Argos' views as of the date hereof. 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 the date hereof.

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