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Argos Announces First Dosing of HIV Patient with AGS-004 Derived from the Latent Viral Reservoir

New Manufacturing Process Utilizes Latent Viral RNA Antigens

DURHAM, N.C., Sept. 06, 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 reported that for the first time a patient in the ongoing Phase 2 HIV eradication trial at the University of North Carolina (UNC) has been dosed with AGS-004 dendritic cell therapy manufactured utilizing RNA antigens from the patient's latent viral reservoir. To the Company's knowledge, this is also the first time an HIV patient has received a therapy utilizing RNA antigens from the patient's latent viral reservoir in a clinical trial conducted in the United States.

The latent viral reservoir consists of infected immune cells in which the HIV virus is dormant and therefore hidden from attack by the immune system. Largely because of the latent viral reservoir, currently available agents for the treatment of HIV, while able to limit the proliferation of the HIV virus, have not been successful in eradicating the virus and thus curing HIV. Argos is supporting an investigator-initiated clinical trial combining AGS-004 with the latency-reversing agent, vorinostat, under the direction of David Margolis, MD, Professor of Medicine, Division of Infectious Diseases, and Director of the HIV Cure Center at the University of North Carolina. The trial is designed to test the hypothesis that boosting antiviral immunity with AGS-004, an active immunotherapy that stimulates T cells to attack HIV-infected cells, combined with a latency reversing drug to expose the virus in latently infected cells to the immune system, may enable eradication of the virus.

Four participants currently enrolled in the trial have received AGS-004 manufactured using RNA antigens derived from infectious plasma collected from the patient prior to the initiation of antiretroviral therapy (ART). The most recently enrolled patient is receiving, and all future patients will receive, AGS-004 manufactured with RNA antigens amplified directly from the patient's own latent viral reservoir, which do not need to be collected prior to the initiation of ART. Because of the high rate of mutation of the HIV virus, the isolation of specific viral antigens from each patient's own viral reservoir may facilitate a more focused immune system attack.

"We believe that the new manufacturing process may allow AGS-004 to generate immune responses that are much better matched to the viral variants that will emerge during latency reversal with vorinostat treatment and, therefore, maximize the opportunity for viral clearance," noted Charles Nicolette, Chief Scientific Officer of Argos. "In addition, this approach eliminates the requirement for eligible patients to have archived infectious plasma prior to the initiation of anti-retroviral therapy, greatly expanding the eligible patient population."

In the ongoing Phase 2 eradication trial, AGS-004 has continued to be well tolerated to date, consistent with prior experience, including the Phase 1/2 trial for which immunogenicity data was recently reported.

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.

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 Phase 2 HIV eradication trial and the use of RNA antigens from a patient's latent viral reservoir, 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 June 30, 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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