



## **JAIDS Study by Argos Therapeutics Evaluates Impact of Personalized Immunotherapy in HIV-Infected Patients**

**DURHAM, N.C. – September 16, 2013** – Argos Therapeutics Inc., a biopharmaceutical company focused on the development and commercialization of fully personalized immunotherapies for the treatment of cancer and infectious diseases using its Arcelis™ technology platform, today announced the publication of key findings on its dendritic cell-based immunotherapy, AGS-004 in the treatment of HIV-infected patients receiving antiretroviral therapy (ART). The study confirmed that antiviral cytotoxic T-cell immunity can be induced in HIV infected patients without being accompanied by generalized systemic immune activation.

The study, which was published ahead-of-print for the upcoming October issue of *JAIDS: Journal of Acquired Immune Deficiency Syndromes*, is a follow-up to a previously reported study of 10 patients that showed the combination of ART with AGS-004 induced HIV-specific CD8 T-cell responses in the majority of them. The current study assessed additional AGS-004-induced immune changes, specifically B- and T-cell subsets and the level of immune activation in the patients.

“Chronic low-level inflammation in ART treated patients is associated with increased incidence of non-HIV related comorbidities, multi-organ pathologies resembling pre-mature aging and early death,” said Charles Nicolette, Ph.D., Chief Scientific Officer and Vice President of Research and Development of Argos Therapeutics. “The results of the current study are important because they confirm that AGS-004-induced anti-HIV immune responses without contributing to undesirable systemic immune activation.”

The published results show that the personalized HIV immunotherapy did not induce changes in the proportion of CD4 and CD8 T-cell subsets, including Treg, and no elevation in systemic T cell immune activation was observed. While an increase in proliferating naïve B cells was noted, no change in memory B cell frequencies or circulating immunoglobulins was observed.

To create AGS-004, ribonucleic acid (RNA) is isolated from HIV particles obtained from patients, and dendritic cells are generated from a single leukapheresis procedure. Selected RNAs are then used to “program” the dendritic cells with the patient-specific payload to trigger an immune response against the patient’s HIV infected cells. These patient-specific, antigen-loaded dendritic cells are formulated into a ready-to-use, intradermal injection.

Argos is currently conducting a randomized, double-blind, Phase 2b study testing the efficacy and safety of AGS-004 on host control of HIV replication during analytical treatment interruption for HIV-1 positive patients who have a stable ART regimen for more than three months prior to screening. The trial is expected to be fully enrolled by the end of June 2013 and is expected to be un-blinded in early 2014.

For more information about AGS-004, visit [www.ArgosTherapeutics.com](http://www.ArgosTherapeutics.com).

For the full text of the study published ahead-of-print in *JAIDS*, visit [goo.gl/eT0ze8](http://goo.gl/eT0ze8).

### **About the Arcelis™ Technology Platform**

Arcelis is a fully personalized, active immunotherapy technology that captures all antigens, including mutated and variant antigens that are specific to each patient’s disease. It has been shown to

overcome immunosuppression by producing a durable memory T-cell response without adjuvants that are associated with toxicity. The technology can be leveraged to manufacture personalized therapies for any cancer or infectious disease.

The Arcelis process integrates readily into many current treatment paradigms, using only a small tumor or blood sample and the patient's own dendritic cells, which are derived and optimized following a single leukapheresis procedure. The proprietary process uses RNA isolated from the patient sample to program the dendritic cells to target the entire disease-antigen repertoire. The activated, antigen-loaded dendritic cells are then formulated into the patient's plasma and administered as an intradermal injection to produce the desired patient-specific immune response.

Arcelis technology also overcomes many of the manufacturing and commercialization challenges that have impeded other personalized cancer immunotherapies. A single manufacturing facility can serve all of North America and automated processes have been developed for cost-effective and scalable commercial manufacturing.

### **About Argos Therapeutics**

Argos Therapeutics is a biopharmaceutical company focused on the development and commercialization of fully personalized immunotherapies for the treatment of cancer and infectious diseases using its Arcelis™ technology platform. Argos' most advanced product candidate, AGS-003, has initiated a pivotal Phase 3 study for the treatment of mRCC, and the Company plans to have data from its Phase 2b study of AGS-004 for the treatment of HIV in the first half of 2014. For more information about Argos Therapeutics, visit [www.argostherapeutics.com](http://www.argostherapeutics.com).

**Source:** Argos Therapeutics

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