



**For Immediate Release**

## **Argos Therapeutics Publishes Positive Immune Response, Safety and Manufacturing Data for its Arcelis™ HIV Program in *Clinical Immunology***

**Durham, NC– March 4, 2010** – Argos Therapeutics today announced the publication of a manuscript in the February edition of *Clinical Immunology*, detailing positive immune response, safety and manufacturing data for its AGS-004 immunotherapy for HIV. AGS-004 is a product of the Company's Arcelis™ technology, and is a personalized, RNA-loaded dendritic cell-based immunotherapy that is perfectly matched to each patient's unique HIV viral burden. The manuscript details a clinical study in which AGS-004 was evaluated in type-1 HIV-infected adults who were being treated with antiretroviral therapy (ART). The study demonstrated that AGS-004 is capable of producing a proliferative T cell response to HIV-1 antigens in patients, with full or partial HIV-specific proliferative immune responses occurring in 78% of evaluable subjects.

"While ART improves the morbidity and mortality associated with HIV, it does not improve the immune system's ability to control HIV replication, and it is also associated with significant side effects for patients," said Principal Investigator Jean-Pierre Routy, M.D., from McGill University Health Centre in Montreal. "A new treatment strategy is needed that could potentially limit or delay exposure to ART and its accompanying side effects, and I believe that an immunotherapeutic approach may be able to achieve this, through producing or enhancing the anti-HIV immune responses needed to control viral replication."

Charles Nicolette, Ph.D., Chief Scientific Officer and Vice President of Research and Development of Argos Therapeutics, added, "We are excited about the Arcelis immunotherapy platform because it is so well suited to the pathology of HIV infection; it overcomes the viral variability and the immune suppressive mechanisms that allow the virus to persist chronically and, remarkably, this is achieved without activation of CD4+ T cells, which are known to serve as factories for viral replication. This current study confirms previous proof-of-concept studies that have shown that our approach is able to induce a diverse immune response to HIV in patients."

AGS-004 is produced from autologous, monocyte-derived dendritic cells that are electroporated with RNA encoding for CD40L and for HIV antigens Gag, Nef, Rev, and Vpr, derived from each patient's pre-ART plasma. Data from this study show that four patients demonstrated increases in T cell proliferation specific to the four HIV antigens used in AGS-004, which met the criteria for a full response; three additional subjects demonstrated increases that represented partial responses to AGS-004 therapy. Importantly, HIV viral load was undetectable at baseline and throughout the duration of the study for all subjects.

Reported adverse events were all mild in nature, with no evidence of autoimmunity, and no significant changes in absolute CD4+ and CD8+ cell counts were observed. No subjects discontinued the study due to any adverse event. The study also demonstrated the manufacturing feasibility of AGS-004, which was produced according to current Good Manufacturing Procedures, with AGS-004 being produced within a mean of 6 weeks and yielding 4-12 doses per patient.

“This study demonstrates both the clinical and commercial potential of AGS-004 for HIV therapy,” said Jeff Abbey, President and CEO of Argos. “In addition to the promising immune response data observed, we have also received important data detailing a potentially favorable safety profile, as well as validation for our proprietary immunotherapy manufacturing process. Based on the strong results we have observed so far, we are near completion of a Phase 2a trial of this candidate in HIV, and will initiate a Phase 2b double blind placebo controlled study this year.”

### **About the Study**

The primary endpoint of this study was the change from baseline of the proliferative capacity of CD8+ T cells in response to the four HIV RNA-encoded antigens expressed in AGS-004. The success of the manufacturing process was measured by the ability to produce AGS-004 and provide the first dose to each subject within 12 weeks of initial leukapheresis. The study enrolled adults with HIV-1 infection who had plasma HIV RNA levels of fewer than 200 copies/mL, CD4+ T cell counts of greater than 350 cells/mm<sup>3</sup>, and who had been receiving their first ART regimen for at least 12 weeks prior to enrollment. AGS-004 was successfully generated and administered to 10 subjects, and 9 enrolled subjects were evaluable for the primary endpoint. Patients received monthly injections of AGS-004 in combination with ART.

Development of the Argos HIV program is funded in part with federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. N01-AI-60019, and by CANVAC (HIV-001) and the Canadian Trials Network (CTN) Study No. 229, from whom we have a contract for the development of our HIV program.

The manuscript, titled, “Immunologic activity and safety of autologous HIV RNA-electroporated dendritic cells in HIV-1 infected patients receiving antiretroviral therapy,” was authored by Jean-Pierre Routy, Mohamed-Rachid Boulassel, Bader Yassine-Diab, Charles Nicolette, Don Healey, Renu Jain, Claire Landry, Oleg Yegorov, Irina Tcherepanova, Tamara Monesmith, Lothar Finke, and Rafick-Pierre Sekaly.

### **About the Arcelis™ Technology**

Arcelis is Argos’ proprietary technology for personalizing RNA-loaded dendritic cell immunotherapies for HIV, other infectious diseases, and cancer. This platform is based on optimizing a patient’s own (autologous) dendritic cells to trigger a pathogen- or tumor-specific immune response. To address the challenge of the unique genetic profile of each patient’s disease and the genetic mutations of that disease, Argos loads the autologous dendritic cells with a sample of messenger RNA (“mRNA”) isolated from their disease. Through this process, dendritic cells can potentially prime immune responses to the entire antigenic repertoire, resulting in an immunotherapeutic that is customized to the patient’s specific disease.

### **About Argos Therapeutics, Inc.**

*Argos is an immunotherapy company developing new treatments for cancer, infectious and autoimmune diseases, and transplantation rejection. The Company has generated multiple platform technologies and a diverse pipeline of products based on its expertise in the biology of dendritic cells — the master switch that turns the immune system on or off.*

[www.argostherapeutics.com](http://www.argostherapeutics.com)

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