



## **Argos Therapeutics Presents Phase 2a Data for Arcelis™ HIV Program Demonstrating Positive Impact on Viral Diversity and Viral Load**

**Durham, NC – May 17, 2010** – Argos Therapeutics today announced the presentation of data from the Phase 2a trial of AGS-004, demonstrating that the personalized immunotherapy has a positive impact on the genetic diversity of residual HIV virus, and also results in substantially increased time to viral rebound in HIV patients treated with AGS-004 following antiretroviral therapy (ART) interruption. The data were discussed in an oral presentation at the 19th Annual Canadian Conference on HIV/AIDS Research (CAHR), held May 13-16, 2010 in Saskatoon, Saskatchewan. 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.

Argos recently reported interim data from the Phase 2a trial, demonstrating viral load control in the absence of antiretroviral therapy and robust immune responses to a diverse set of HIV antigens. Argos plans to initiate a Phase 2b trial in the first half of 2010. The majority of the costs of the Phase 2b trial will be funded by the National Institutes of Health, as part of a \$21 million contract that Argos was awarded in 2006.

"We observed viral genetic drift post-ART therapy in several patients, and in some patients there was a remarkable decrease in viral diversity post-AGS-004 treatment," said Jean-Pierre Routy, M.D., from McGill University Health Centre in Montreal. "As the virus mutates, it becomes weaker and less able to replicate. The broad immune response generated by AGS-004 may force the virus to mutate and therefore become less robust and diverse, which may explain the positive impact on viral load levels and significant increase in time to viral rebound demonstrated in this study."

"The positive clinical outcomes and viral dynamics presented are consistent with the encouraging interim efficacy data demonstrated in this Phase 2a trial," said Charles Nicolette, Ph.D., Chief Scientific Officer and Vice President of Research and Development of Argos Therapeutics. "The efficacy data, taken with the favorable safety and tolerability profile of AGS-004, provide a solid rationale for continuing to advance this program into a Phase 2b trial, which will begin soon."

AGS-004 utilizes autologous RNA encoding HIV antigens Gag, Vpr, Rev and Nef (GVRN). Genetic evolution of the virus was analyzed through sequencing at least 10 individual clones of each GVRN gene following AGS-004 treatment, and comparing to those isolated from the pre-treatment sample. Prior data presented from the Phase 2a trial demonstrated that, as expected, in some subjects, the post-AGS-004 samples revealed a shift in viral diversity, indicating that the remaining virus did mutate over the course of treatment.

In the current presentation, clinical outcomes were detailed for patients that had reached the primary endpoint (three months without ART). According to the presentation, 17 subjects had completed the

three-month ART interruption. The median time to viral load rebound was four weeks and time to peak viral load was eight weeks. Eighty-two percent of the patients responded to treatment with AGS-004, with a mean reduction in viral load of 1.24 log, compared to pre-ART viral load average. The mean duration of patients' ART interruption was 25.4 weeks. Eight subjects were eligible to continue their treatment interruptions, 14 subjects restarted ART and six subjects had resistance testing completed, with no evidence of drug resistance. Treatment-related adverse events were limited to grade 1 or 2 injection site reactions and flu-like or GI symptoms; no autoimmunity or AIDS-defining events were observed during the study to-date.

The abstract, titled, "AGS-004, an autologous dendritic cell therapy impacts on the evolution of residual HIV virus along with a substantial increase in time to viral rebound, during an STI in the CTN 239 clinical study," was authored by I. Tcherepanova, M.R. Boulassel, A. Carreño, H. Carpenter, M.R. Loutfy, S. Vezina, C. Tremblay, J. Angel, J. Gill, J. Baril, F. Smaill, R. Jain, D. Healey, T. Chew, C. Nicolette and J.P. Routy.

### **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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