Argos Therapeutics' Arcelis™ HIV Immunotherapy Shows Feasibility to Generate Fully Functional Dendrtic Cells from Viremic Patients

-Argos to Start Phase 1 Trial in Preventing or Delaying Initiation of Antiretroviral Therapy (ART) in ART-Naïve Patients-
--Data Presented Orally and in a Poster at HIV DART™ 2010 Conference--

DURHAM, N.C. – Dec. 9, 2010 – Argos Therapeutics announced today that its Arcelis HIV immunotherapy, AGS-004, showed feasibility in *in vitro* models to generate fully functional dendritic cells (DC) from viremic patients. Argos plans to start a Phase 1 trial of AGS-004 to test the prevention or delay in the initiation of antiretroviral therapy (ART) in ART-naïve patients. Data were presented orally and in a poster at the HIV DART™ 2010 Conference in Los Cabos, Mexico.

"Clinical development of AGS-004 in ART-naïve patients may demonstrate efficacy in delaying ART therapy," said Charles Nicolette, Ph.D., chief scientific officer and vice president of research and development of Argos. "The Phase 1 study will also evaluate whether the immunotherapy will restore the central and effector memory CD8+ T cell phenotype as demonstrated in earlier studies using product generated from leukapheresis of ART-suppressed individuals."

In a Phase 2 study, AGS-004 in combination with analytical treatment interruption was shown to delay viral rebound kinetics and significantly lower mean viral loads. These effects occurred in the absence of activation of CD4+ T cells. Immunologic activity was assessed by changes in proliferative capacity of HIV-specific CD8+ T cells and confirmed that AGS-004 was immunogenic in the majority of subjects. The predominant CD8+ central and effector memory T-cell responses induced by AGS-004 were shown to be IL-12 dependent and were comparable with profiles displayed by HIV-infected individuals defined as long-term non-progressors (CD8+, CD28+ and CD45RA-). In the study, the DCs were manufactured from monocytes collected by leukapheresis obtained from ART-suppressed individuals, and RNA was derived from their pre-ART plasma samples. This procedure was necessary because DCs generated from viremic leukapheresis were defective in IL-12 production that was shown to be caused by the viral protein R protein.

The new DC differentiation protocol uses IFNγ, TNFα, and PGE_2 followed by electroporation with four RNA-encoded antigens together with RNA encoding CD40L. After further incubation for four hours, the cells were cryopreserved in single-dose aliquots. Products were analyzed for yield, viability, immunophenotype and cytokine production. The DC differentiation and maturation protocol for AGS-004 manufactured from treatment naïve viremic patients resulted in matured DCs secreting IL-12 and was indistinguishable from products generated from ART-suppressed or healthy subjects.

About the Arcelis™ Technology

Arcelis is Argos' proprietary technology for personalizing RNA-loaded dendritic cell immunotherapies for cancer, HIV and other infectious diseases. This platform is based on optimizing a patient's own (autologous) dendritic cells to trigger a tumor- or pathogen-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 the patient's 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

Contacts:

David Schull or Andreas Marathovouniotis
Russo Partners LLC
(212) 845-4271 or (212) 845-4235
david.schull@russopartnersllc.com or andreas.marathis@russopartnersllc.com

Jeff Abbey
Argos Therapeutics
(919) 287-6308
jabbey@argostherapeutics.com

# # #