

## **Argos Therapeutics Announces Plans for HIV Eradication Study**

Clinical Research Strategy for Immunotherapy Revealed During 7<sup>th</sup> Annual International AIDS Society Conference

**DURHAM, N.C. – July 1, 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, unveiled a new development strategy for AGS-004, a personalized immunotherapy for HIV patients, at the Towards an HIV Cure Symposium on June 29<sup>th</sup> and 30<sup>th</sup>, which precedes the 7<sup>th</sup> Annual International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention in Kuala Lumpur, Malaysia.

"Combination therapies, such as the one we are proposing for AGS-004, will be the crux of HIV eradication research studies moving forward," said Charles Nicolette, Ph.D., Chief Scientific Officer and Vice President of Research and Development for Argos Therapeutics. "AGS-004 is well positioned to be the lead candidate for an eradication study because not only does it not require patients to interrupt their treatment regime, but it also has no added toxicity and therefore can be combined with several other therapies without risking unnecessary side effects. By combining a drug that targets the latent viral load with an immunotherapy custom-made to each individual's diverse viral load, we have the opportunity to possibly eradicate HIV."

"We suspect that an augmented antiviral response will be a useful, if not necessary, component of strategies that may someday clear HIV infection," said David Margolis, M.D., a professor of Medicine, Microbiology and Immunology, Epidemiology, School of Medicine and Director, Program in Translational Clinical Research at the University of North Carolina, Chapel Hill. "The Argos vaccine has the potential advantage that it presents proteins from the patient's own virus to rearm the immune system, and we hope to test this approach very soon."

In Argos Therapeutics' proposed study, AGS-004 will be combined with one or more agents that are capable of activating the latent HIV reservoir thereby making infected cells 'visible' to the immune system. Once the latent HIV has been activated, AGS-004 will be able to identify and kill HIV infected cells, with no added toxicity. The proposed Phase 2 study will aim to treat HIV patients who are currently taking antiretroviral therapy (ART), to evaluate the impact on decreasing or potentially eradicating the infected cells.

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 July 2013 and is expected to be un-blinded in early 2014.

For more information about AGS-004, visit www.ArgosTherapeutics.com.

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. Automated processes allow a single facility to serve all of North America and can be used to treat any cancer or infectious disease with the same manufacturing process and equipment.

## **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 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 late 2013. For more information about Argos Therapeutics, visit www.argostherapeutics.com.

**Source:** Argos Therapeutics

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