Leading HIV Researchers and Argos Therapeutics Highlight Importance of Immunotherapy in HIV Eradication Efforts

DURHAM, N.C. – June 13, 2013 – In conjunction with the U.S. Food and Drug Administration's (FDA) June 14th Public Meeting on HIV Patient-Focused Drug Development and HIV Cure Research, leading HIV researchers and 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 highlighted the role of immunotherapy in potential HIV eradication studies.

"Over the last several decades, HIV drug development has given us the ability to control the viral load of HIV positive patients and ensure that patients do not die of AIDS," 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. "With more and more patients living but requiring lifelong antiretroviral therapy (ART), the next logical step is to find a way to eradicate the disease. Early clinical trials suggest that we may be able to unmask cells that are hiding latent HIV. Combined with the potential of immunotherapy to target and destroy infected cells, eradication may be closer than we ever imagined."

"Our personalized HIV product, AGS-004, is among the most effective immunotherapies in the field at eliminating virally infected cells and therefore an excellent candidate for inclusion in innovative eradication strategies," said Charles Nicolette, Ph.D., Chief Scientific Officer and Vice President of Research and Development for Argos Therapeutics. "The FDA's public meeting on the impact of HIV on daily patient life is an important step in understanding just how much of a burden ART and other HIV treatments are to this patient population. We are formally announcing that our ongoing clinical development of AGS-004 will be directed towards total HIV eradication."

Dr. Nicolette will be detailing Argos' HIV development strategy for AGS-004 at the Towards an HIV Cure Symposium on June 29 and 30 in conjunction with the International AIDS Society in Kuala Lumpur, Malaysia.

About 1.1 million people in the United States are currently living with HIV. Once a patient has been diagnosed with HIV, they are typically prescribed ART consisting of three or more antiretroviral drugs.[1] ART is not a cure for the HIV infection but controls viral replication within a person's body and allows an individual's immune system to strengthen and regain the capacity to fight off infections. However, even patients who are well controlled with ART drugs have a significantly shorter life expectancy than the general population.[2] Additionally, ART drugs do not entirely eliminate chronic inflammation which can lead to co-morbidities such as heart and lung disease, kidney failure, diabetes, high blood pressure, arthritis and memory loss.

"Current treatment options for patients infected with HIV are far from perfect and require patients to take multiple pills at specific times every day for the rest of their lives, often leading to inconsistency in treatment and ultimately an increase in co-morbidities," said Jean-Pierre Routy, M.D., Division of Hematology and Immunodeficiency, Royal Victoria Hospital, McGill University Health Centre. "The goal of an eradication effort utilizing immunotherapy will be to reduce the burden of treatment and maintenance for these patients and ultimately cure them."

The FDA public meeting is intended to obtain patient input on the impact of HIV on daily life, currently available therapies to treat the condition, and patients' views on issues related to HIV cure research. The meeting will take place June 14 from 9:30 a.m. to 5:30 p.m. ET.

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.

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.

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[1] http://www.cdc.gov/hiv/basics/statistics.html
[2] http://www.mayoclinic.com/health/hiv-aids/DS00005/DSECTION=treatments-and-drugs