



Argos Therapeutic Arcelis™ Immunotherapy AGS-003 in Combination With Sunitinib Shows Statistically Significant Correlation of Immune System Response to Overall Survival in Phase 2 Study in Patients with Advanced Renal Cell Carcinoma (RCC)

-High Resolution Immune Monitoring Analysis Shows AGS-003 in Combination With Sunitinib Overcomes Immuno-Suppressive Environment of RCC and Induces Tumor-Specific Multi-Functional Memory Cytotoxic T Lymphocytes (CTL) in Phase 2 Study-

DURHAM, N.C. – Jan. 31, 2012 – Argos Therapeutics Inc., today announced that it presented a high resolution immune monitoring analysis of AGS-003-006, a Phase 2 study of its Arcelis™ immunotherapy, AGS-003, in combination with sunitinib in patients with advanced renal cell carcinoma (RCC). The results showed a statistically significant correlation between anti-tumor memory T cell responses and overall survival. AGS-003 in combination with sunitinib overcame the immuno-suppressive environment of RCC and induced a tumor-specific multi-functional memory CTL response. The results were presented orally at the Global Technology Community's (GTC) 4th Immunotherapeutics and Immunomonitoring Conference in San Diego.

"We believe that the high resolution immune monitoring analysis of the Phase 2 study of AGS-003 and sunitinib represents the first time that pattern recognition algorithms originally developed for gene microarray datasets have been applied to an immunologic dataset to identify immune correlates to clinical outcome," said Charles Nicolette, Ph.D., Argos' chief scientific officer and vice president of research and development. "The multiparametric flow cytometry data from the study that we analyzed demonstrated that the combination of AGS-003 and sunitinib induced tumor-specific multi-functional memory CTL that were statistically significant correlates to overall survival in the study, thereby supporting the intended mechanism of action of AGS-003."

AGS-003-006 was an open label Phase 2 trial of AGS-003 in combination with sunitinib in patients with newly diagnosed, unfavorable-risk, metastatic clear cell RCC. AGS-003 was designed to stimulate the proliferation and multi-functionality of CTLs targeted directly to the autologous RCC tumor antigens. In analyzing the data from the trial we sought to detect immune correlates by using multi-parametric flow cytometry to identify 16 unique RCC antigen reactive CTL subsets based on the expression of the surface markers CD28, CD45RA, CD27 and CCR7, present in blood draws collected prior to treatment with AGS-003 or sunitinib and after administration of five doses of AGS-003 in combination with sunitinib. Furthermore, each CTL subset was partitioned to an additional 64 functional subsets based on the expression of three cytokines (IFN- γ , TNF- α , IL-2), lytic function (Granzyme b, CD107 expression) and proliferation. Correlates of CTL subsets with subjects' clinical lab characteristics were analyzed using an adaption of a binary tree-structured vector quantization (BTSVQ) approach used to cluster and visualize

microarray data. The BTSVQ approach implements a two-way unsupervised clustering that allows each subject's clinical lab assessments, progression-free survival (PFS) and overall survival (OS) to be mapped back to immune responses to identify unique clustering patterns with clinical value. The data analysis identified one subset of CTL, with the CD8+CD28+CD45RA- memory CTL phenotype that trended with longer disease free intervals and was a statistically significant correlate to overall survival.

About the Arcelis™ Technology

Arcelis is Argos' proprietary technology for personalizing RNA-loaded dendritic cell immunotherapies. 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 fully personalized for each patient's disease.

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 based on its Arcelis™ technology platform. Using biological components from each patient, Arcelis-based immunotherapies employ the patient's dendritic cells to activate an immune response specific to the patient's disease. Argos' most advanced product candidates include AGS-003 for the treatment of metastatic renal cell carcinoma, or mRCC, and AGS-004 for the treatment of HIV.

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