Argos Therapeutics Announces New Data Demonstrating Prolonged Overall Survival in a Phase 2 Study of its Arcelis™ Immunotherapy AGS-003 in Combination with Sunitinib in Patients with Metastatic Renal Cell Carcinoma (mRCC)

-Results Support Planned, Randomized Phase 3 ADAPT Study-

DURHAM, N.C. – Feb. 4, 2012 – Argos Therapeutics Inc. today announced that updated results from an open label Phase 2 study of its Arcelis™ immunotherapy, AGS-003, in combination with sunitinib in patients with unfavorable risk, metastatic renal cell carcinoma (mRCC), had demonstrated prolonged survival. Based upon these results, the company is planning to initiate the international Phase 3 ADAPT study. Data from the open-label Phase 2 study were presented in a poster and oral session at the 2012 ASCO Genitourinary Cancers Symposium in San Francisco.

"We observed encouraging clinical and immunologic responses which correlated with prolonged survival," said Robert Figlin M.D., director of the Division of Hematology/Oncology at the Cedars-Sinai Samuel Oschin Comprehensive Cancer Institute and presenter of the new findings. "In this study, AGS-003 in combination with sunitinib was associated with a median overall survival longer than has been reported for sunitinib alone in unfavorable risk, metastatic RCC patients. These encouraging results support the planned Phase 3 ADAPT study, which is designed to compare the addition of AGS-003 to sunitinib versus sunitinib alone in patients with newly diagnosed, metastatic RCC."

Twenty-one patients with newly diagnosed, metastatic clear cell RCC were enrolled in this Phase 2 study. Following nephrectomy or metastasectomy to harvest tumor mRNA, autologous monocytes were collected by leukapheresis, in order to produce RNA-loaded dendritic cells specific to each patient's disease. Treatment consisted of six-week cycles of sunitinib, four weeks on and two weeks off, plus AGS-003, which was administered as an intradermal injection every three weeks for five doses, and then every 12 weeks until progression in combination with sunitinib. Immune responses were evaluated at baseline and following five doses of AGS-003 using multiparametric flow cytometry, to assess the induction of anti-tumor, $CD28^+$ memory T cell responses. Results indicate that multiple partial responses were observed with this combination regimen, while 11 of 15 (73%) patients with serial immune assessments demonstrated increases in their $CD28^+$ memory T cells. These immune responses correlated directly with prolonged survival in this study. Overall, the median progression-free survival was 11.2 months and estimated Kaplan-Meier median overall survival was 29.3 months in this study, based upon follow-up through January 2012. In addition, AGS-003 was well tolerated in combination with sunitinib, with no immunotherapy related serious adverse events observed.

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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