



Argos Therapeutics Presents Data Showing Memory T Cell Expansion After Administration of Fully Personalized Immunotherapy Correlates with Overall Survival Benefit in Patients with Metastatic Renal Cell Carcinoma

Analysis of Phase 2 data evaluating induced memory T cell immunity following treatment with AGS-003 in combination with sunitinib presented at the 2013 Annual Meeting of the Society for Immunotherapy of Cancer (SITC).

Durham, NC- November 11, 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, presented an analysis of data from its Phase 2 clinical trial showing that treatment with AGS-003, the company's lead product candidate, in combination with sunitinib, induced memory T cell responses in metastatic renal cell cancer (mRCC) patients that correlated with statistical significance to overall survival (OS). The poster, entitled "Multi-Functional Cytotoxic T Cell Expansion Correlates with Overall Survival after Administration of Autologous Dendritic Cell Immunotherapy in Renal Cell Cancer Patients," was presented on November 9 at the 28th Annual Meeting of the Society for Immunotherapy of Cancer in National Harbor, Maryland.

AGS-003, an investigational fully personalized immunotherapy, is designed to elicit an immune response by inducing CD8+CD28+ memory T cells that are known to correlate with improved clinical outcomes. In the Phase 2 trial, the Company monitored the immune responses in 14 evaluable intermediate and poor risk mRCC patients using multi-color flow cytometry. The data were analyzed for correlations between immune responses and survival using an adaptation of the bioinformatics pattern recognition algorithm, Binary Tree-Structured Vector Quantization (BTSVQ). Patients in the trial received treatment in standard six-week cycles of sunitinib plus AGS-003 every three weeks for five doses and then every 12 weeks until progression. BTSVQ identified unique cytotoxic T cell (CTL) signatures displaying broad markers of immune function (MIFs) that were statistically significant predictors of survival duration as well as mono-functional late-stage effector T cells that inversely correlated with patient survival.

"We believe that these additional findings from our Phase 2 trial support the *in vivo* mechanism of action of AGS-003," said Charles Nicolette, Argos' chief scientific officer and vice president of research and development, adding, "we also believe this is the first demonstration in a clinical trial that the magnitude of an adaptive immune response following immunotherapy correlates with prolonged survival."

The Phase 2 clinical trial of AGS-003 in combination with sunitinib enrolled 21 intermediate and poor risk mRCC patients who had a time from diagnosis to initiation of systemic therapeutic treatment of less than one year. Fourteen of these patients were evaluable for immune responses, and median overall survival for these 14 patients was 39.5 months.

Earlier this year, Argos initiated a pivotal Phase 3 clinical trial for AGS-003 (“ADAPT”). The randomized, multicenter, open-label ADAPT clinical trial is designed to examine the potential for AGS-003 plus standard targeted drug therapy to extend OS versus standard therapy alone in newly diagnosed mRCC patients. Argos is using BTSVQ to analyze multi-color flow cytometry data in the ADAPT trial, which will enroll a total of 450 patients in approximately 130 global sites.

About the Arcelis™ Technology Platform

Arcelis is a fully personalized immunotherapy technology that captures mutated and variant antigens that are specific to each patient’s disease. It is designed to overcome immunosuppression by producing a durable memory T cell response without adjuvants that may be associated with toxicity. The technology is potentially applicable to a wide range of different cancers and infectious diseases and is designed to overcome many of the manufacturing and commercialization challenges that have impeded other personalized immunotherapies. The Arcelis process uses only a small tumor or blood sample and the patient’s own dendritic cells, which are collected and optimized following a single leukapheresis procedure. The proprietary process uses RNA isolated from the patient’s disease sample to program dendritic cells to target disease antigens. The activated, antigen-loaded dendritic cells are then formulated into the patient’s plasma and administered via intradermal injection.

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 pivotal Phase 3 study for the treatment of mRCC, and the Company recently completed enrollment of its Phase 2b study of AGS-004 for the treatment of HIV. For more information about Argos Therapeutics, visit www.argostherapeutics.com.

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