Argos Therapeutics Enrolls Initial Patients in Pivotal Phase 3 ADAPT Study

AGS-003, first fully personalized, dendritic-based immunotherapy being evaluated in combination with targeted therapy for mRCC

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DURHAM, N.C. – January 14, 2012 – 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, announced that the first patients have been enrolled in the ADAPT Phase 3 clinical study for AGS-003, its most advanced product candidate. AGS-003 is an investigational, fully personalized, dendritic-cell based immunotherapy. The ADAPT study is designed to examine the potential for AGS-003 plus standard targeted drug therapy to extend overall survival versus standard therapy alone in newly diagnosed patients with unfavorable risk metastatic renal cell carcinoma (mRCC).

The ADAPT study is a randomized, multicenter, open-label clinical trial expected to enroll 450 patients in approximately 120 sites, mostly in North America, under an approved Special Protocol Assessment by the Food and Drug Administration. Secondary endpoints include progression-free survival, safety, overall response and immune response. By the end of first quarter 2013, the company expects to have nearly 70 active sites, primarily in the U.S., while the remaining North American and global sites are expected to be activated by summer of 2013.

Robert Figlin, MD, FACP, primary investigator for the ADAPT study and director of the Division of Hematology/Oncology at Cedars-Sinai, said, “The commencement of the ADAPT study is a very exciting milestone for the kidney cancer community, which already has great enthusiasm for the evolving field of immunotherapy. With this Phase 3 trial, we are setting out to prove the merits of a unique dendritic-cell based personalized immunotherapy and its ability to re-educate the immune system to recognize and kill cancer. One important aspect is the fact that we are adding AGS-003 to what is already considered the backbone of today’s best available care, in an attempt to improve treatment outcomes for patients with an aggressive form of the disease.”

In a previous Phase 2 study, treatment with AGS-003 plus sunitinib was associated with encouraging median and long-term survival with no added toxicity in newly diagnosed, unfavorable risk mRCC patients. Compared to historical results with sunitinib alone, the combination was associated with median overall survival nearly double that expected in unfavorable risk mRCC patients.[1,2] More than 50 percent of patients in the Phase 2 study survived longer than 30 months, which is nearly four times the expected long-term survival rate for sunitinib in similar risk patients.[3] Furthermore, results demonstrated a statistically significant correlation between the number of anti-tumor, memory T-cells induced and overall survival, directly supporting the intended AGS-003 mechanism of action.[4] Updated Phase 2 survival and immunologic data will be presented during the 2013 ASCO Genitourinary Cancers Symposium.

Jeff Abbey, Chief Executive Officer of Argos Therapeutics, said, “The initiation of enrollment in the Phase 3 ADAPT study is a major milestone in the clinical development of AGS-003, our first Arcelis technology product candidate. We intend to prove that our fully personalized approach to immunotherapy, uniquely designed to target the entire disease-antigen repertoire, can overcome immunosuppression and extend overall survival for those suffering with metastatic RCC. We are fortunate to be working with many of the country’s top cancer centers and to have widespread support from national advocacy organizations such as the Kidney Cancer Association and the Society of Urologic Oncology Clinical Trials Consortium.”

To create AGS-003, ribonucleic acid (RNA) is isolated from a small tumor sample obtained from standard tumor removal surgery (nephrectomy), and the patient’s dendritic cells are taken during a single leukapheresis procedure. The tumor RNA is used to “program” the dendritic cells with the entire disease-antigen repertoire to trigger an immune response against the patient’s specific cancer. These antigen-loaded dendritic cells are formulated into a ready-to-use, intradermal injection.

To be considered for the ADAPT study patients must be 18 or older, newly diagnosed with clear cell mRCC and identified at diagnosis as unfavorable risk with 1-4 baseline risk factors, based on the recently validated Heng risk factor model.[1] Patients must be candidates for standard tumor removal surgery and treatment with standard targeted drug therapy, starting with sunitinib.

Patients participating in the ADAPT study randomized to the combination arm will receive one standard 6-week cycle of sunitinib prior to treatment initiation with AGS-003. The study aims to deliver at least eight doses of AGS-003 over the initial 12 months, in combination with standard targeted therapy, followed by booster doses every three months for those continuing to benefit after the first year of treatment. All AGS-003 therapy for the trial will be manufactured at a single facility in North America.

For more information about AGS-003 and the ADAPT study, visit www.ADAPTkidneycancer.com, or follow us on Twitter @ADAPTkdnycancer.

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 the second half of 2013. Argos also recently completed a successful Phase 1a study of AGS-009 in patients with lupus. For more information about Argos Therapeutics, visit www.argostherapeutics.com.

Source: Argos Therapeutics
*****Autologous Dendritic Cell Immunotherapy (AGS-003) Plus Standard Treatment of Advanced Renal Cell Carcinoma

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[1] Heng et al. J Clin Oncol. 2011:29 (suppl; abstr 4560).
[2] Heng et al. International mRCC Consortium Database. November 2011.
[3] Motzer et al. 10th International Kidney Cancer Symposium. October 14, 2011. Poster presentation.
[4] Figlin et al. J Clin Oncol. 2012;30 (suppl 5; abstr 348).