Argos Therapeutics Receives FDA Approval of Special Protocol Assessment for AGS-003 Phase 3 Trial

International ADAPT Study for the treatment of Metastatic Renal Cell Carcinoma Underway

DURHAM, N.C., July 2, 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, today announced the U.S. Food & Drug Administration (FDA) has approved the Company's revised Special Protocol Assessment (SPA) for its Phase 3 clinical study of AGS-003 for the treatment of metastatic renal cell carcinoma (mRCC). The Autologous Dendritic Cell Immunotherapy (AGS-003) Plus Standard Treatment of Advanced Renal Cell Carcinoma (ADAPT) study has initiated and is expected to begin dosing patients in the second half of 2012, with a primary clinical endpoint of overall survival.

"FDA acceptance of our revised SPA is an important step forward for our continued clinical development of AGS-003 in newly diagnosed mRCC patients," said Jeff Abbey, Chief Executive Officer of Argos Therapeutics. "Based on the highly encouraging long-term survival we observed in our Phase 2 combination study of AGS-003 plus sunitinib, we amended our Phase 3 protocol to focus on a primary endpoint of improving overall survival for patients randomized to receive AGS-003 plus sunitinib versus sunitinib alone. With our revised SPA, the FDA has agreed that the pivotal ADAPT study could support a future BLA submission if the study objectives are met."

In a Phase 2 study, treatment with AGS-003 was associated with encouraging median and long-term survival for newly diagnosed mRCC patients who presented with intermediate or poor risk ("unfavorable" risk) factors. Adding AGS-003 to standard sunitinib doubled overall survival for these patients compared to historical results[1] for unfavorable risk patients treated with sunitinib alone. Importantly, greater than 50 percent of patients in the study survived longer than 30 months after initiating therapy, which is four times the expected rate for sunitinib[2], suggesting a pronounced survival benefit for the combination regimen with no added toxicity.

"The key to AGS-003's encouraging clinical benefit and lack of toxicity is its remarkable specificity for the tumor," stated Charles A. Nicolette, Ph.D., Chief Scientific Officer and Vice President of Research and Development for Argos. "Other immunotherapies use non-mutated self antigens, which are poorly immunogenic and are usually paired with non-specific immune stimulators, or adjuvants. AGS-003 is a fully personalized active immunotherapy that preferentially targets mutated tumor antigens known to drive progression of disease. These mutated antigens are recognized as foreign by T-cells in the body, which allows AGS-003 to direct a potent and highly specific immune response against the tumor, with no collateral damage to healthy tissues."

Dr. Nicolette continued, "In our phase 2 combination study, we demonstrated a statistically significant correlation between the number of anti-tumor T-cells induced and overall survival in mRCC patients receiving AGS-003. This strong correlation validates our mechanism of action

and gives us confidence to advance AGS-003 into the pivotal ADAPT study with a primary objective of improving overall survival."

The ADAPT Phase 3 study is a 2:1 randomized, multicenter, open-label study of AGS-003 in combination with standard targeted therapy, beginning with sunitinib, compared to targeted therapy alone in newly diagnosed mRCC patients. A total of 450 patients will be enrolled at approximately 100 sites in North America and ex-U.S. The study design is similar to the previous Phase 2 combination study, but with key differences that Argos believes will ensure clinical success and that are addressed in the revised SPA. The study's primary endpoint is overall survival (OS). Additional endpoints will include overall response, immune response, progression-free survival (PFS) and safety.

About Special Protocol Assessments (SPA)
A Special Protocol Assessment is a written agreement with the FDA on the details of the design and planned analysis for a clinical trial. It is intended to form the basis for a marketing application and may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of new public health concerns.

About Renal Cell Carcinoma
Renal cell carcinoma is the most common type of kidney cancer accounting for nearly 90% of newly diagnosed cases each year. Overall, 15-20% of kidney cancer patients are diagnosed with the metastasized form of the disease, referred to as mRCC. Taking into account both newly diagnosed mRCC and early stage RCC patients who advance to mRCC, there are an estimated 25,000 cases of mRCC in the U.S. each year. Patients are classified at the time of diagnosis into three disease risk profiles—favorable, intermediate and poor—using objective prognostic risk factors. Prognosis is generally poor for those with newly diagnosed mRCC and one or more risk factors (intermediate and poor risk), where expected survival is only 6 months to less than two years.

About the Arcelis™ Technology

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 injection into the skin to produce the desired patient-specific immune response.

Arcelis technology also overcomes many of the manufacturing and commercialization challenges that have impeded other 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.

[1] Heng et al. International mRCC Consortium Database. November 2011.
[2] Motzer et al. 10th International Kidney Cancer Symposium. October 14, 2011. Poster presentation.

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