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Treatment With AGS-003 and Sunitinib Associated With Doubling of Expected Survival in Patients With Unfavorable Risk Metastatic Renal Cell Carcinoma (mRCC)

Results presented on May 30, 2014 at the ASCO Annual Meeting, show that intermediate risk mRCC patients had a median overall survival of 57.1 months, with 23 percent surviving for more than five years to date, including two patients in long-term remission following continued AGS-003 dosing.

Argos to also present progress update on the pivotal ADAPT Phase 3 clinical trial for AGS-003 in poster presentation at ASCO on June 2, 2014.

DURHAM, N.C., June 2, 2014 (GLOBE NEWSWIRE) -- Argos Therapeutics, Inc. (Nasdaq:ARGS), 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 updated results from a completed phase 2 study highlighting the long-term survival observed in patients treated with sunitinib combined with AGS-003, the company's investigational fully personalized immunotherapy for cancer. Results were presented in a poster presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting on Friday, May 30, 2014.

According to the results of the study titled "*Long-term survival in unfavorable-risk mRCC patients treated with a combination of autologous immunotherapy (AGS-003) plus sunitinib,"* presented by lead author Asim Amin, MD, PhD, treatment with AGS-003 in combination with sunitinib in an unfavorable risk mRCC patient population, resulted in median progression free survival (PFS) of 11.2 months and median overall survival (OS)of 30.2 months. Based upon recently published findings from the International mRCC Database Consortium, similar risk mRCC patients with a time from diagnosis to treatment of less than one year risk factor (DxTx < 1yr) have an expected median PFS of 5.7 months and median OS of 14.7 months. In addition, 33 percent of patients survived for greater than 4.5 years and 23% for more than five years, with two patients remaining in long-term remission for longer than five years following continued dosing with AGS-003. Adverse events (AEs) associated with the use of AGS-003 were minor with no grade 3 or 4 AEs and no evidence of autoimmunity.

"In this study of unselected, unfavorable risk metastatic RCC patients, the combination of a personalized immunotherapy with targeted therapy resulted in encouraging median and long-term survival, without added toxicity. The long-term survival we observed suggests this combination has the potential to modulate the immune response that may translate into a durable clinically meaningful outcome," said Dr. Amin.

AGS-003 is a fully personalized immunotherapy comprised of autologous tumor RNA-loaded dendritic cells. To create AGS-003, ribonucleic acid (RNA) is isolated from a small tumor sample taken from the patient in a standard tumor removal procedure s dendritic cells are obtained from a single leukapheresis procedure. The tumor RNA is used to program optimized dendritic cells with the entire disease-antigen repertoire from the patient's tumor to trigger an immune s specific cancer. The antigen-loaded dendritic cells are then formulated into an intradermal injection for administration to the patient.

"AGS-003 is designed to overcome tumor-induced immunosuppression and elicit a durable T-cell response. In this study, the correlation between the AGS-003 induced T-cell response and prolonged survival suggests the combination of AGS-003 plus sunitinib has the potential to produce durable immunologic responses and extend expected survival. The ongoing pivotal phase 3 ADAPT trial has been designed to confirm these findings," said Robert A. Figlin, MD, FACP, co-author of the poster presentation.

"These results showing the potential for AGS-003 to double the expected PFS, OS and extend long-term survival in unfavorable risk mRCC, provide strong support for the ongoing, pivotal ADAPT phase 3 trial. Our goal at Argos is to bring this promising, fully personalized immunotherapy to mRCC patients as quickly as possible to address persistent unmet needs in current standard of care," said Jeff Abbey, CEO and president of Argos Therapeutics.

On Monday, June 2, 2014, Argos will also present an update on progress in the ongoing ADAPT Phase 3 clinical trial for AGS-003 in a separate poster presentation at ASCO. The poster, entitled *"Enrollment insights in the synchronous mRCC population: An update from the ongoing ADAPT Phase 3 study experience"*, will be presented by Robert A. Figlin, MD, FACP, from 1:15 PM - 5:00 PM; abstract #TPS4599, poster board #162A.

The ADAPT study is a randomized international Phase 3 trial comparing standard targeted therapy plus AGS-003 to standard therapy alone in the treatment of mRCC. More than 120 sites in North America and select other countries have been activated

and > 400 patients have been consented for the tumor collection phase of the study.

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, is being evaluated in the pivotal ADAPT Phase 3 clinical trial for the treatment of metastatic renal cell carcinoma (mRCC). The company also plans to report data from its Phase 2b trial of AGS-004 for the treatment of HIV in mid-2014. For more information about Argos Therapeutics, visit www.argostherapeutics.com.

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