



## **Argos Therapeutics' Arcelis™ Immunotherapy for the Treatment of Renal Cell Carcinoma (RCC) in Combination with Sunitinib Demonstrates Strong Immunologic Response That Correlates to Improved Clinical Outcomes**

**-Phase 2 Combination Study Demonstrates Decreases in T Regulatory Cells and Expansion of CD28<sup>+</sup> Memory Cytotoxic T Lymphocytes (CTLs)-**

**--Data Presented at 2011 ASCO Annual Meeting--**

**DURHAM, N.C. – June 1, 2011 –** [Argos Therapeutics](#) announced today that its [Arcelis™ immunotherapy](#) for the treatment of renal cell carcinoma (RCC), AGS-003, in combination with sunitinib demonstrated a strong immunologic response that correlated to improved clinical outcomes. The Phase 2 combination study in newly diagnosed, metastatic RCC patients with unfavorable prognosis demonstrated decreases in T regulatory cells, along with a concurrent expansion of CD28<sup>+</sup> memory cytotoxic T lymphocytes (CTL). Results will be presented by Dr. Robert Figlin, director of the Division of Hematology/Oncology at the Cedars-Sinai Samuel Oschin Comprehensive Cancer Institute, in a poster and a discussion session at 8 a.m. CDT, and noon CDT, respectively, Saturday, June 4, 2011, at the 2011 Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago.

The study is the first to demonstrate the combined immunologic and clinical effects of AGS-003, or any active immunotherapy, with sunitinib. Most patients experienced reversal of baseline tumor-induced immunosuppression and showed improved progression-free survival (PFS) compared to the expected PFS with sunitinib alone in an unfavorable risk, metastatic RCC patient population. Assessment of immunodynamics using multiparametric flow cytometry was performed on peripheral blood mononuclear cells isolated from blood draws collected prior to treatment and after treatment with AGS-003 during combination administration with sunitinib. Nine of 11 patients with PFS of >10 months demonstrated CTL population increases whereas two of four patients with PFS <10 months showed increases in this specific CTL population. Updates on the correlation between prolonged PFS and CTL expansion will be presented during ASCO.

"The study provides initial evidence that AGS-003 works as designed to address the underlying immune suppression observed in metastatic RCC patients, while also generating a highly specific and durable T-cell response that appears to improve clinical outcomes in terms of PFS, when combined with sunitinib," said Charles Nicolette, Ph.D., chief scientific officer and vice president of research and development of Argos. "This is the first prospective analysis of immunodynamics in RCC patients receiving sunitinib in combination with an immunotherapy, and we plan to confirm these positive results in a randomized setting in a Phase 3 clinical trial."

**About the [Arcelis™ Technology](#)**

Arcelis is Argos' proprietary technology for personalizing RNA-loaded dendritic cell immunotherapies for cancer, HIV and other infectious diseases. 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 customized to the patient's specific disease.

#### **About Argos Therapeutics, Inc.**

Argos is an immunotherapy company developing new treatments for cancer, infectious and autoimmune diseases and transplantation rejection. The Company has generated multiple platform technologies and a diverse pipeline of products based on its expertise in the biology of dendritic cells — the master switch that turns the immune system on or off. [www.argostherapeutics.com](http://www.argostherapeutics.com)

#### Contacts:

David Schull or Andreas Marathovouniotis  
Russo Partners LLC  
(212) 845-4271 or (212) 845-4235  
[david.schull@russopartnersllc.com](mailto:david.schull@russopartnersllc.com) or [andreas.marathis@russopartnersllc.com](mailto:andreas.marathis@russopartnersllc.com)

Jeff Abbey  
Argos Therapeutics  
(919) 287-6308  
[jabbey@argostherapeutics.com](mailto:jabbey@argostherapeutics.com)

# # #