



## **Argos Therapeutics Secures \$25 million Series D Financing to Commence Phase 3 ADAPT Study in Patients with Metastatic Renal Cell Carcinoma (mRCC) in Mid-2012**

**-Arcelis™ Immunotherapy AGS-003 Granted U.S. FDA Fast Track Designation for Treatment of mRCC-**

**DURHAM, N.C. – April 24, 2012** –[Argos Therapeutics Inc.](http://www.argos-therapeutics.com) today announced that it has secured a \$25 million Series D financing to support the commencement of its Phase 3 ADAPT study in patients with newly diagnosed, metastatic renal cell carcinoma (mRCC) in mid-2012. The financing was led by Forbion Capital and included other existing investors, including TVM Capital, Lumira Capital, Intersouth Partners, Caisse de dépôt et placement du Québec, Morningside Group, and Aurora Funds. Argos's Arcelis™ immunotherapy, AGS-003, has also been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with mRCC. The international Phase 3 ADAPT study is expected to commence in mid-2012 under a revised Special Protocol Assessment (SPA) agreement with the FDA. This pivotal study will evaluate the addition of AGS-003 to standard therapy versus standard therapy alone.

“With this latest round of financing Argos is well positioned to execute its business strategy and move forward with the planned Phase 3 ADAPT study of its lead product candidate, AGS-003,” said Jeff Abbey, president and chief executive officer of Argos. “We recently presented updated results at the 2012 ASCO Genitourinary Cancers Symposium from a Phase 2 study of AGS-003 demonstrating prolonged survival in newly diagnosed, metastatic RCC patients. Importantly, we also demonstrated that our intended mechanism of action, the induction of memory T cells, significantly correlated with improved overall survival. The Phase 3 ADAPT study is designed to confirm these positive results and demonstrate that AGS-003 may be an effective, safe and readily combinable therapeutic option for patients with metastatic RCC.”

Charles Nicolette, Ph.D., chief scientific officer and vice president of research and development of Argos, said, “The Fast Track designation by the FDA recognizes the need for more effective treatments in metastatic RCC.”

The FDA's Fast Track program is designed to facilitate the development and expedite the review of new drugs for the treatment of serious or life-threatening diseases with the potential to address unmet medical needs. Fast Track designation allows for the review timeline to be truncated to six months compared to the traditional 12 months.

The Phase 3 ADAPT study is a randomized, multicenter, open-label study of AGS-003 in combination with sunitinib compared to sunitinib plus placebo. Argos plans to enroll approximately 450 mRCC

patients at approximately 100 clinical sites in North America and Europe. The primary endpoint for the ADAPT study is overall survival. Additional endpoints include overall response, immune response, progression-free survival and safety.

Regarding the Phase 2 clinical study, 21 patients with newly diagnosed metastatic clear cell RCC were enrolled. Treatment consisted of six-week cycles of sunitinib, four weeks on and two weeks off, plus AGS-003, which was administered as an intradermal injection every three weeks for five doses, and then every 12 weeks until progression in combination with sunitinib. Results presented during the 2012 ASCO Genitourinary Cancers Symposium indicated that the median progression-free survival in patients with newly diagnosed, unfavorable risk mRCC was 11.2 months and estimated Kaplan-Meier median overall survival was 29.3 months in this study, based upon follow-up through January 2012. In addition, AGS-003 was well tolerated in combination with sunitinib, with no immunotherapy related serious adverse events observed.

#### **About the Arcelis™ Technology**

Arcelis is Argos's proprietary technology for personalizing RNA-loaded dendritic cell immunotherapies. 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 fully personalized for each patient's disease.

#### **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 based on its Arcelis™ technology platform. Using biological components from each patient, Arcelis-based immunotherapies employ the patient's dendritic cells to activate an immune response specific to the patient's disease. Argos' most advanced product candidates include AGS-003 for the treatment of metastatic renal cell carcinoma, or mRCC, and AGS-004 for the treatment of HIV.

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