

## Argos Therapeutics Announces US and Global Expansion for Ongoing Pivotal Phase 3 ADAPT Study for Personalized Immunotherapy

Studies Presented During 2013 ASCO Meeting Further Validate ADAPT Study Design

**DURHAM, N.C. – June 10, 2013 –** 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 it has expanded its ADAPT Phase 3 clinical study for AGS-003 to additional top cancer centers in the United States, Canada and will soon be expanding into Europe and Israel.

To date, more than 50 sites have been activated and more than 30 subjects have been enrolled in North America. The study is expected to expand to more than 120 global sites by early Fall 2013. The Phase 3 ADAPT clinical study is evaluating AGS-003, an investigational, fully personalized immunotherapy designed to stimulate a tumor-specific T-cell response. AGS-003 is being evaluated in combination with standard surgery followed by targeted drug therapy in this study to determine its potential to extend overall survival in newly-diagnosed, unfavorable risk metastatic renal cell carcinoma (mRCC) patients. Secondary endpoints in this study include progression-free survival, safety, overall response and immune response.

Additionally, studies highlighted during this year's American Society for Clinical Oncology (ASCO) Annual Meeting, held May 31-June 4 in Chicago, offered data which further validates the ADAPT study design and the continued unmet need in newly diagnosed, unfavorable risk mRCC patients. The data were published in two poster presentations and one published abstract, consisting of Abstract 4579 entitled "Impact of cytoreductive nephrectomy on disease-specific survival (DSS) in the cytokine and targeted therapy eras: Age- and TNM-stage matched analysis of SEER data"; Abstract 4586 entitled "First-, second-, third-line therapy for metastatic renal cell carcinoma (mRCC): Benchmarks for trials design from the International mRCC Database Consortium (IMDC)"; and Abstract e15525 entitled "MSKCC and Heng prognostic risk assessment for synchronous metastatic renal cell carcinoma (syncmRCC) and the tumor in place treated in the targeted therapy era."

"Data presented at ASCO supports the continued role of cytoreductive nephrectomy in newly diagnosed, metastatic RCC patients," said Christopher G. Wood, M.D., F.A.C.S., Professor, Department of Urology, Division of Surgery, The University of Texas MD Anderson Cancer Center and Co-Global PI for the ADAPT Study. "Despite the belief that targeted drug therapies alone are sufficient, cytoreductive nephrectomy continues to play a vital role in the management of properly selected, metastatic RCC patients based upon its significant impact on overall survival."

"This year's ASCO meeting highlighted the exciting advances and progress being made in the rapidly evolving field of cancer immunotherapy," said Robert Figlin, M.D., F.A.C.P., Professor of Medicine and Biomedical Sciences, Director of the Division of Hematology Oncology and Deputy Director at Cedars-Sinai's Samuel Oschin Comprehensive Cancer Institute and Co-Global PI for the ADAPT Study. "The progress and broad availability of the ADAPT study will contribute to these advances and the growing body of evidence demonstrating the power of the human immune system

and the potential for a fully personalized immunotherapy to extend survival in a poor prognoses group of RCC patients."

"Activating the ADAPT study across several top cancer centers in the U.S. and expanding to key centers in Europe, Canada and Israel in the coming months, provides us with great confidence we are now on track to fully enroll the trial by mid-2014," said Doug Plessinger, VP of Clinical and Medical Affairs of Argos Therapeutics. "Further, data presented during ASCO confirms the reduced survival expectation with targeted therapy of less than 15 months in our target population and highlights the importance of the ongoing ADAPT trial, as we seek to extend survival and realize the potential of a fully personalized, active immunotherapy."

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. Argos Therapeutics expects to initiate the majority of all trial sites, including approximately 90 in the United States and 30-40 globally by September of 2013.

The ADAPT study will enroll synchronous, mRCC patients who present with 1-4 baseline Heng risk factors who are good candidates for surgery followed by standard targeted drug therapy. The validated Heng risk model utilizes six risk factors which predict survival for mRCC patients treated with standard targeted therapy. The study will exclude patients with five or more Heng risk factors because these poor risk patients are not expected to respond well to standard treatments and may progress too quickly to benefit from a novel immunotherapy like AGS-003.

For more information about AGS-003 and the ADAPT study, visit <a href="www.ADAPTkidneycancer.com">www.ADAPTkidneycancer.com</a>, or follow us on Twitter <a href="www.ADAPTkdnycancer">@ADAPTkdnycancer</a>.

## 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 late 2013. For more information about Argos Therapeutics, visit <a href="https://www.argostherapeutics.com">www.argostherapeutics.com</a>.

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