



Argos Therapeutics Study Confirms Optimal Quality Control Methods for Production of its RNA-Based Immunotherapies

RNA Analysis Data Published in *Journal of Pharmaceutical and Biomedical Analysis*

DURHAM, N.C., November 15, 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 publication of key findings that confirms the Company's current methods of analyzing RNA are robust and optimal for the assessment of RNA quality needed to develop the Company's novel immunotherapies. The study, which was published in the November issue of the *Journal of Pharmaceutical and Biomedical Analysis*, the journal of the American Association of Pharmaceutical Scientists, compared traditional slab electrophoresis currently in use at Argos to a newer microfluidics-based platform¹ for performing various RNA analyses.

"As we move ahead with our pivotal study of our novel immunotherapy for metastatic renal cell carcinoma, AGS-003, it is essential that we continue to employ the highest quality and most reliable manufacturing controls," said Jeff Abbey, Chief Executive Officer of Argos Therapeutics. "Despite the availability of newer technologies, we are pleased to report that our current methods of quality control for the RNA component of Arcelis immunotherapies produced highly reproducible results with superior accuracy and precision and lower error. This is significant, particularly for our AGS-003 program, because it confirms that our manufacturing and quality control systems are optimal as we move closer to FDA review and potential commercialization."

The published results demonstrated that the traditional method of denaturing gel (slab) electrophoresis was superior to the microfluidics-based Bioanalyzer for sizing multiple RNA samples at once, as error-producing "well effect" is significant for the Bioanalyzer. Both slab electrophoresis and the Bioanalyzer platform enabled operator-independent evaluation of RNA integrity. For quantification of RNA, the Bioanalyzer was compared to ultraviolet (UV) spectroscopy-based methods. The results showed that the Bioanalyzer, in contrast to UV-based techniques was fraught with high standard deviation and percent errors. Based on these observations, Argos' method of quality control combines slab electrophoresis to determine RNA size and integrity and UV-based techniques to derive the concentration of the RNA component of its immunotherapies. Although these analyses were demonstrated with HIV antigen RNA components that comprise our autologous HIV immunotherapy, AGS-004, the results are applicable to the RNA components of all Argos' Arcelis products, including AGS-003.

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.

¹Bioanalyzer 2100, Agilent Technologies, Santa Clara, CA

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