



FOR IMMEDIATE RELEASE

**Argos Therapeutics Earns Global Regulatory Approval with Eurofins  
Lancaster Laboratories' Rapid Mycoplasma MilliPROBE® Assay**

DURHAM, NC, and LANCASTER, PA, September 23, 2013 — Argos Therapeutics, 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, and Eurofins Lancaster Laboratories, a global bio/pharmaceutical GMP product testing laboratory, today announced regulatory approval from authorities in the US, UK, Canada, Czech Republic and Israel for rapid mycoplasma testing of an autologous cell-based therapy produced by Argos Therapeutics.

Eurofins Lancaster Laboratories validated the use of the MilliPROBE® system, marketed by EMD Millipore, to test samples of the autologous immunotherapy currently in clinical trials for renal cell carcinoma. The assay can deliver same-day preliminary results compared to 28 days required for the standard compendial method, thereby eliminating the need to conditionally release cell-based products that require rapid turnaround time.

"Mycoplasma contamination of cell lines used to produce biopharmaceutical products can disrupt cellular growth and metabolism and alter gene expression, leading to decreased product quantity and quality," says Jeri Ann Boose, Ph.D., Director of Biopharmaceutical Services at Eurofins Lancaster Laboratories.

"World-wide regulatory agencies require that products produced in cell substrates be tested to ensure the absence of mycoplasma contamination. The compendial

method requires 28 days and is therefore not suitable for obtaining the rapid lot release testing results needed for biopharmaceutical products that have short half-lives or for which there is high market demand.”

For the FDA submission, Argos Therapeutics described how the test would be used, listed the validation standards for the test (USP <1223> and USP<1127>, EP 2.6.7, EP 2.6.21 and EP 5.1.6), summarized the Eurofins Lancaster Laboratories validation results for the MilliPROBE® system as well as the matrix interference testing performed at Eurofins Lancaster Laboratories for the Argos product. A summary of work performed was submitted to regulatory authorities in Canada, Israel, Spain, Czech Republic, Italy and the UK, along with the Eurofins Lancaster Laboratories interference testing summary.

The MilliPROBE® system uses Real-Time Transcription-Mediated Amplification (TMA) technology to detect targeted microbial contamination within hours compared to the weeks usually required to generate results using traditional culture-based technology. Faster detection allows biopharmaceutical manufacturers to take corrective action earlier in the production process, which reduces downstream processing risks, optimizes product yields and improves final product quality. The MilliPROBE® assay probe system was designed by sequence analysis to detect Mycoplasma, Spiroplasma and Acholeplasma using a multiplex of conserved rRNA sequences in non-clinical applications. EMD Millipore has validated the non-clinical specificity and sensitivity of the system using 13 key mycoplasma species, which include the eight species specified in EP 2.6.7.

“In addition to accelerating time to results, the MilliPROBE® system validated by Eurofins Lancaster Laboratories offers other important benefits,” described Fran Hutson, head of BioMonitoring North America sales and marketing, EMD Millipore. “The system can process up to 20 mL of a sample, making it preferable to PCR and RT-PCR methods typically limited to testing sample

volumes that are 1-2 mL. The membrane-based sample preparation device effectively removes inhibitory substances that can interfere with nucleic acid amplification technologies.”

### **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 pivotal 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 first half of 2014. For more information about Argos Therapeutics, visit [www.argostherapeutics.com](http://www.argostherapeutics.com).

### **About Eurofins Lancaster Laboratories**

A member of Eurofins Scientific’s BioPharma Product Testing Group—the largest network of harmonized bio/pharmaceutical GMP product testing laboratories worldwide—Eurofins Lancaster Laboratories provides comprehensive laboratory services for the world's largest pharmaceutical and biopharmaceutical companies. Founded in 1961, Eurofins Lancaster Laboratories has a global capacity of 330,000 square feet and 1,500 employees.

Eurofins Scientific is the world leader in laboratory testing for food, environment and bio/pharmaceutical products, employing over 14,000 staff in more than 180 laboratories across 35 countries. The shares of Eurofins Scientific are listed on the NYSE Euronext Paris Stock Exchange (ISIN FR0000038259, Reuters EUFI.PA, Bloomberg ERF FP).

For more information visit: [www.LancasterLabsPharm.com](http://www.LancasterLabsPharm.com)

Argos Media Contact:  
The Ruth Group  
Aaron Estrada (media)  
[aestrada@theruthgroup.com](mailto:aestrada@theruthgroup.com)  
(646) 536-7028

Eurofins Lancaster Laboratories Media Contact:  
Lisa Bamford  
[lbamford@lancasterlabs.com](mailto:lbamford@lancasterlabs.com)  
717.656.2300 X1368

