



## Asuragen to present at Association for Molecular Pathology 15<sup>th</sup> Annual Meeting

**Austin, Texas – Date: November 19, 2009** – Asuragen, Inc., a leader in molecular diagnostic development, announced today that it will present at the Association for Molecular Pathology (AMP) 15th Annual Meeting, November 19-22, 2009 in Kissimmee, FL. Eight posters and a podium talk will be presented highlighting Asuragen's development efforts in the areas of oncology, genetic testing, microRNA and laboratory standards.

Elizabeth Mambo, Ph.D., of Asuragen will deliver a platform presentation titled, "MicroRNA Biomarkers for Colorectal Cancer Diagnosis and Recurrence" on Friday, November 20<sup>th</sup>. Reliable prediction of recurrence in colorectal cancer (CRC) patients is a major unresolved clinical need, as recurrence is often the ultimate cause of death in CRC patients. Dr. Mambo will present data describing microRNAs (miRNA) expression signatures that are associated with early stage CRC tumors as well as miRNAs that may be relevant in determining risk of recurrence.

In addition, the following poster presentations will be made during the conference by Asuragen and its collaborators:

- "Signature® KRAS Mutations: A Single-Tube Assay for the Rapid Multiplex Detection of KRAS Mutations in Codons 12 and 13." (Abstract No. TT15) – KRAS is an oncogene involved in the epidermal growth factor receptor (EGFR) signaling pathway that controls cell proliferation, differentiation and apoptosis. Mutated KRAS is permanently activated and hinders anti-EGFR therapies based on monoclonal antibodies (cetuximab and panitumumab) or tyrosine kinase inhibitors (erlotinib and gefitinib). As KRAS mutations are found in 20-30% of non-small cell lung cancers (NSCLC) and about 40% of colorectal cancers (CRC), molecular screening of KRAS mutations is important to identify patients who may or may not respond to anti-EGFR therapies. Asuragen will present data on the development and evaluation of a novel RUO method to simultaneously detect the seven key KRAS mutations in a rapid, single-tube assay.
- "Evaluation of BCR/ABL1 Quant Assay (RUO) for the Quantitative Detection of e1a2, b2a2 and b3a2 Fusion Transcripts." (Abstract No. H21) – BCR/ABL1 b2a2 or b3a2 fusion transcripts corresponding to the translocation (9;22) are present in >95% of chronic myeloid leukemia patients. The e1a2 variant is found in about 5% of children with acute lymphoblastic leukemia (ALL) and 20-35% of adult ALL. In collaboration with Bio-Reference Laboratories, Inc., Elmwood, New Jersey, Asuragen evaluated the use of a single multiplex assay for the quantitative detection of e1a2, b2a2 and b3a2 fusion transcripts.
- "Development of Armored RNA Quant® Reference Materials for the Standardization of Quantitative BCR/ABL1 Testing." (Abstract No. H12) – Currently there are no certified BCR/ABL1 reference materials for monitoring of inter-run and inter-laboratory assay performance. Armored RNA Quant (ARQ) is a well established technology in quantitative molecular infectious disease testing that could fulfill the role of a stable, nuclease-resistant and consistently manufactured reference material. Asuragen will present data regarding the development of a set of ARQ research reagents designed to improve the standardization of quantitative BCR/ABL1 testing.
- "Evaluation of MicroRNA Signatures for Identification of Pancreatic Ductal Adenocarcinoma in FFPE specimens and Fine Needle Aspirates of Pancreas." (Abstract No. ST25) – Differential diagnosis between pancreatic ductal adenocarcinoma and chronic pancreatitis can be challenging and errors can occur in up to 25% of cases. Previously, a two miRNA qRT-PCR assay based on de-regulated expression of miR-196a and miR-217 was developed and validated as a lab developed test using formalin fixed paraffin embedded specimens. In this study, the assay performance was evaluated in fine needle aspirates of pancreatic tissue collected under the guidance of endoscopic ultrasonography.
- "Two Novel PCR Strategies that Resolve the Clinical Spectrum of Fragile X Mutations." (Abstract No. G10) – Fragile X syndrome, fragile X-associated premature ovarian insufficiency and fragile X-associated tremor ataxia syndrome are linked to the expansion of CGG repeats in the fragile X mental retardation (FMR1) gene. In collaboration with University of California, School of Medicine, Davis, California, Asuragen will present the application of two novel PCR strategies for detection of full mutations and resolution of female homozygous samples in whole blood and blood spot card samples.



- “A Rapid PCR Method for the Determination of FMR1 Methylation Status in Both Males and Females” (Abstract No. G11) - Methylation of the FMR1 gene is associated with fragile X syndrome and may impact other FMR1 disorders. Asuragen, in collaboration with University of California, School of Medicine, Davis, California, will present results from the evaluation of a rapid PCR RUO assay for the determination of FMR1 methylation status.
- “Development of a cGMP-manufactured, streamlined RNA amplification, labeling and purification kit for microarray expression analysis optimized for the workflow of the clinical molecular laboratory” (Abstract No. TT40) – Microarrays have found use in medicine as tools for evaluating gene expression for the characterization of molecular signatures of disease. Asuragen will present data regarding the development of standardized RUO reagents for microarray expression analysis compatible with the diagnostic laboratory workflow.

### **About Asuragen**

Asuragen is a fully integrated diagnostic development company and pharmaceutical services provider. The Company’s diagnostic product portfolio consists of the first-ever validated microRNA diagnostic assay for pancreatic cancer, quantitative RNA tests for leukemia gene translocations, and the Signature<sup>®</sup> Oncology and Genetic Testing products. Asuragen is empowered with a high level of scientific expertise and assay development capabilities, CLIA and GLP testing services, and an established cGMP manufacturing facility, which allow it to span the spectrum of discovery, testing, production and commercialization. For more information, visit [www.asuragen.com](http://www.asuragen.com).

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