



Results of a Multi-center Study Show microRNA-based Pancreatic Cancer Assay Improves the Diagnostic Accuracy of FNA Cytology

Austin, Texas – November 3, 2011. Asuragen, Inc. announced today that data from a multi-center study evaluating its microRNA-based test, [miRInform™ Pancreas](#), for the diagnosis of pancreatic ductal adenocarcinoma (PDAC) in fine needle aspirates, was presented as a Poster of Distinction at the American Pancreatic Association (APA) Annual Meeting being held November 2-5, 2011 in Chicago.

Currently, gastroenterologists use endoscopic ultrasound guided fine needle aspiration (EUS-FNA) to obtain tissue for diagnosis of pancreas carcinoma. While EUS-guided FNA has a high sensitivity and specificity for the diagnosis of cancer in a pancreatic mass, there are a number of aspirated cytology specimens that are either indeterminate or suspicious for cancer. The definitive diagnosis of pancreas cancer in these instances impacts the mode of therapeutic intervention. In addition, mass-forming benign pancreatic lesions, such as chronic pancreatitis or autoimmune pancreatitis, need to be distinguished from pancreatic carcinomas because each type of lesion may result in different surgical or non-surgical interventions.

The data presented by Asuragen at the APA meeting demonstrates that the addition of a miRNA-based molecular test may enhance the diagnostic accuracy of FNA cytology on indeterminate and suspicious specimens. Asuragen developed and validated miRInform™ Pancreas, which interrogates expression of seven proprietary miRNAs, in a large multi-center collaboration involving seven sites and 186 subjects. When used in conjunction with conventional FNA cytology, miRInform™ Pancreas allows diagnosis of PDAC with 92.5% accuracy, as compared to 80.2% for FNA cytology alone. Furthermore, a primary benefit of the miRNA panel is its ability to characterize samples with indeterminate or suspicious FNA cytology with an overall accuracy of approximately 77%. One of the multicenter study participants, Dr. Darwin Conwell of Brigham and Women's Hospital, stated, "The introduction of a molecular test to aid in resolving indeterminate FNA cytology and to help identify false negative cytology is an important step forward in improving the diagnostic care available for pancreatic cancer patients. To date, molecular analysis has not been considered a routine component of the diagnostic evaluation for pancreatic masses, but this landmark study has clearly shown how molecular analysis can have a central role in the evaluation of indeterminate cytology specimens in pancreas mass lesions. The future is now and the medical community is going to see a major shift in diagnostic testing with the aid of molecular analysis of human tissue specimens." The miRInform™ Pancreas test will be available in Asuragen's CAP accredited CLIA Laboratory starting December 1, 2011.

Mature microRNAs (miRNA) are small 19-23 nt regulatory RNAs that control gene expression at the post-transcriptional level and whose mis-regulation has been linked to many human cancers, including pancreatic carcinomas. Asuragen previously identified a miRNA signature consisting of miR-196a and miR-217 that distinguishes PDAC from chronic pancreatitis using frozen tissue and FNA specimens. Asuragen further established the excellent clinical performance of this classifier with the sensitivity and specificity of approximately 95%. Performance evaluation of this laboratory developed test (LDT) in resected pancreatic specimens was a key step to ensure success of the development and validation of a less invasive miRNA test in pancreatic FNAs for which final pathology is not always available and/or more difficult to obtain.

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, innovative genetic testing solutions for the fragile X mental retardation (FMR1) gene, Signature® Oncology products for the qualitative detection of gene translocations and mutations in a variety of hematological and solid tumors, RNA stabilization technologies, and industry-leading controls and standards engineered using its



patented Armored RNA[®] technology. 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.

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