Asuragen Launches The First Validated microRNA Diagnostic Assay

Austin, Texas – April 23, 2008 – Asuragen, Inc. announced today the launch of the first microRNA (miRNA) test for clinical diagnosis and disease management. The assay utilizes qRT-PCR technology* and differentiates between chronic pancreatitis and pancreatic cancer (pancreatic ductal adenocarcinoma). Pancreatic cancer is the 4th leading cause of cancer related deaths in the United States. Chronic pancreatitis and pancreatic cancer present similar symptoms and can be mis-diagnosed in up to 25% of patients.

The test was developed following the discovery of novel microRNAs associated with pancreatic cancer in collaboration between Asuragen scientists and Dr. Stephan Hahn and colleagues at Ruhr University, Bochum, Germany as reported in the journal Oncogene in 2007. According to Dr. Hahn, "The identification of a microRNA, which as far as we know is specific for pancreatic cancer cells, represents a major step forward in supporting new diagnostic strategies for pancreatic diseases."

"The definitive diagnosis of pancreatic cancer can be quite challenging, particularly in patients displaying chronic pancreatitis. There is a tremendous need for improved diagnostics in pancreatic cancer, and this microRNA test could become a valuable asset in patient management and diagnosis of pancreatic cancer," said Dr. Gregory Tsongalis, Director of Molecular Pathology, Dartmouth Hitchcock Medical Center, Lebanon, New Hampshire.

In a blinded validation study utilizing 60 clinical samples, the assay achieved a sensitivity of 95.2% and a specificity of 94.9%. The test can be performed on frozen or formalin-fixed paraffin embedded (FFPE) tissues, and will initially be made available in Asuragen's CLIA laboratory in Austin, Texas. Validation is ongoing for use with fine-needle aspiration (FNA) specimens preserved with RNARetain™, Asuragen's clinically validated sample collection and RNA stabilization solution.

"miRNAs are an emerging category of biomarkers. There were three publications on miRNAs in the year 2000 and over 900 in 2007. The introduction of this first microRNA test ushers in a new era of clinically relevant molecular diagnostic assays utilizing this exciting new class of RNA biomarkers," said Matt Winkler, CEO/CSO, Asuragen, Inc.

"The fact that miRNAs are relatively stable in clinical specimens, such as FNA and FFPE, makes these small RNA molecules compelling biomarkers for diagnostic applications," added Dr. Hahn.

The test will be available to order on May 2, 2008.

About Asuragen, Inc.

Asuragen is a fully integrated diagnostic reagent company and molecular biology service provider, focused on molecular oncology and genetic diseases, with emphasis on microRNA (miRNA). Asuragen's current diagnostic product portfolio consists of Signature® Genetic Testing and Oncology Testing products as well as 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 along with a well developed business infrastructure, GLP testing services and an established cGMP manufacturing facility that allows it to span the spectrum of discovery, testing, production and commercialization. Asuragen is dedicated to developing new technologies that will become cutting edge clinical products. More information is available at the Company's website: www.asuragen.com.

In addition, Asuragen has a miRNA therapeutics program which was recently spun off into a separate entity called Mirna Therapeutics. More information on Mirna Therapeutics is available at www.mirnatherapeutics.com.

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*This test is performed pursuant to license arrangements with Roche Molecular Systems, Inc. and Applera Corporation.

Szafranska, A.E., Davison, T.S., John, J., Cannon, T., Sipos, B., Maghnouj, A., Labourier, E., Hahn, S.A. MicroRNA expression alterations are linked to tumorigenesis and non-neoplastic processes in pancreatic ductal adenocarcinoma. Oncogene. 2007. Jun28; 26(30):4442-52.