



## Johns Hopkins Researchers Publish Results of Study Evaluating Multiplex Assay for Detection of Common *NPM1* Mutations

**Austin, Texas – September 23, 2010** – Asuragen, Inc. announced today the results of a collaborative study with scientists at Johns Hopkins University School of Medicine evaluating a RNA-based assay for the rapid, sensitive and multiplex detection of common *NPM1* mutations. The study results were published in the September issue of the *Journal of Molecular Diagnostics*.

Determination of *NPM1* mutation status has become essential for the molecular classification of acute myeloid leukemias (AML). The nucleophosmin gene (*NPM1*) is thought to be the most frequently mutated gene in de novo acute myeloid leukemias, particularly those with normal karyotype. The *NPM1* mutation has important prognostic implications for patients with AML. Patients with *NPM1* mutations typically do not carry cytogenetic abnormalities and generally respond better to induction chemotherapy than those without mutations. The published study reports the evaluation of the rapid detection of common *NPM1* mutations using total RNA purified from cultured cells, bone marrow or peripheral blood using a laboratory-developed test based on Asuragen's Signature<sup>®</sup> *NPM1* Mutations Research Use Only reagents\*. The assay uses multiplex RT-PCR in combination with fluorescent bead-based detection to simultaneously identify transcripts for *NPM1* mutations A, B, D and J and wild-type targets.

Evaluation of 69 clinical specimens at initial diagnosis resulted in 100% agreement with reference methods. Of the AML patients with normal karyotype, 53% carried one of four different mutations detected by the assay. The results of this study demonstrate that the Asuragen *NPM1* reagents are a versatile and specific tool for the screening of *NPM1* mutations in patients with AML. The high preliminary analytical sensitivity further suggests potential utility for the monitoring of residual disease in AML with a normal karyotype.

"As a co-exclusive licensee of the Trovogene *NPM1* technology, we are enabled to provide a commercial solution for *NPM1* testing," said Rollie Carlson, President of Asuragen. "Our Signature<sup>®</sup> *NPM1* Mutations RUO kit\* complements our growing menu of cutting edge molecular diagnostic products for leukemia."

### About Asuragen

Asuragen is a fully integrated molecular diagnostic company and pharmaceutical services provider. The Company's diagnostic product portfolio consists of the first-ever validated microRNA diagnostic assay for pancreatic cancer, quantitative assays for the monitoring of leukemia fusion transcripts expression, innovative genetic testing solutions for the fragile X mental retardation (FMR1) gene, and the Signature<sup>®</sup> Oncology products for the qualitative detection of gene translocations and mutations in a variety of hematological and solid tumors. 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).

\*For Research Use Only. Not For Use in Diagnostic Procedures.

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