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## **Asuragen Initiates Launch of CE-Marked Molecular Diagnostic Products with the Release of the Signature® LTx v2.0 Leukemia Translocation Panel Assay in Europe**

**Austin, Texas – December 5th, 2008** – Asuragen, Inc. announced today that the Signature® LTx v2.0 Leukemia Translocation Panel was released as a “Conformité Européenne” or “European Conformity” CE IVD product under the European Directive on In Vitro Diagnostic Medical Devices. The CE-marked Signature® LTx v2.0 is a qualitative in vitro diagnostic device for use in a clinical laboratory to identify specific fusion transcripts in total RNA from whole blood or bone marrow to aid in the clinical diagnosis of translocation positive leukemias. Clinical validation studies showed 100% diagnostic accuracy (95% confidence interval 93.8 to 100%) in comparison to standard cytogenetic methods. This represents the world’s first Luminex-based molecular oncology IVD product.

The assay is a multiplex reverse transcription PCR (RT-PCR) amplification, followed by multiplex amplicon detection on the Luminex® 100™ IS or 200™ system. The liquid bead array assay format provides comprehensive information on 12 different fusion transcripts associated with ALL, AML, APL or CML and an internal control in a single test. “Standard cytogenetic analysis by karyotyping or fluorescence in situ hybridization can be laborious or require multiple successive hybridizations to detect a given chromosomal translocation. Asuragen’s expertise in multiplex RNA-based assays enables the rapid molecular diagnosis of leukemia fusion transcripts and therefore improves workflow and efficiency in the clinical laboratory while nicely complementing standard diagnostic hematopathology testing”, according to Rollie Carlson, Ph.D., President, Asuragen Inc.

The Signature® LTx platform was initially launched in early 2005 as a research use only (RUO) product in order to assess its potential utility in the clinical diagnostic environment. After extensive clinical evaluation at major academic medical institutions, Signature® LTx v2.0 CE IVD is now available immediately to clinical laboratories throughout the European Union. “This launch signifies the transformation of an established research product into a clinical assay that provides fast and accurate results needed to aid in leukemia diagnosis and subsequent therapeutic decision making. It illustrates the potential of Asuragen’s broad menu of leukemia research tools and represents another step towards Asuragen’s goal of providing cutting edge clinical products to the global market”, said Matt Winkler, Ph.D., Chief Scientific Officer and Chief Executive Officer, Asuragen, Inc.

The Signature® LTx v2.0 CE IVD assay follows the European launch of RNARetain™, Asuragen’s clinically validated and cGMP manufactured sample collection and RNA stabilization in vitro diagnostic device.

### **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, cGLP 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](http://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](http://www.mirnatherapeutics.com)

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