



Asuragen Signs Development and Worldwide Distribution Agreement with Life Technologies

Life Technologies to distribute Asuragen's BCR/ABL1 leukemia assay for use on Applied Biosystems real-time PCR instrument

Austin, Texas – November 18, 2009– Asuragen, Inc. announced today that it has entered into an exclusive agreement with Life Technologies Corporation to develop and distribute worldwide an in-vitro diagnostic test intended to aid clinicians in the monitoring and treatment of individuals afflicted with chronic myeloid leukemia (CML). As part of the agreement, Asuragen will pursue CE marked-IVD registration in Europe and regulatory clearance in the U.S. The diagnostic test will then be distributed by Life Technologies and run exclusively on the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument, which originally received 510(k) clearance from the FDA in late 2008 in conjunction with the Center for Disease Controls H5N1 assay. Applied Biosystems is part of Life Technologies.

Asuragen's in-vitro diagnostic test, a BCR/ ABL1 assay, will simultaneously detect and quantify BCR/ABL1 fusion transcripts (b2a2, b3a2, and e1a2) in a single reaction. The BCR-ABL1 fusion gene arises from a specific chromosome translocation, known as the Philadelphia chromosome or t(9:22). The resulting BCR/ABL1 fusion transcripts are present in approximately 95% of CML and 25-30% of acute lymphoblastic leukemia cases. If present, the expression level of the fusion transcript or its ratio to a reference transcript may be used to monitor disease progress. Monitoring the level of BCR/ABL1 may be helpful for both prognosis and management of Gleevec®, Sutent® and Sprycell® kinase therapies in patients with leukemia disease.

"Our development of a BCR/ABL1 test leverages both our expertise in molecular diagnostics development and our proprietary Armored RNA® technology. With streamlined multiplex workflow and inclusion of Armored RNA controls in the kit, the assay will have both broad target coverage and dynamic range, while offering unmatched standardization for both internal and external assay calibration" said Rollie Carlson, Ph.D., President of Asuragen. "We are pleased to partner with Life Technologies, and believe their strong molecular instrumentation offerings and broad commercialization capabilities will lead to adoption of this test throughout the world."

About the BCR/ABL1 assay

Asuragen's BCR/ABL1 assay will have the advantage of both detecting and quantifying e1a2, b2a2 and b3a2 fusion transcripts in a single reaction. Streamlined reagent formulation, multiplex assay format and inclusion of Armored RNA Quant® external calibrators improve the workflow and increase the number of specimens that can be tested per run. Co-detection of ABL1 and inclusion of an exogenous Armored RNA Quant® process control enable reporting of BCR/ABL1 to ABL1 ratio for standardization to the International Scale as well as reporting of absolute BCR/ABL1 copy number.

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® 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.

Armored RNA Quant® is a registered trademark of Asuragen, Inc.

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