



Asuragen's Clinical Laboratory launches KRAS and BRAF mutation testing

Austin, Texas – September 1, 2010. Asuragen, Inc., a leader in molecular diagnostics and nucleic acid-based pharmacogenomics services, announced today that it has launched KRAS and BRAF mutational testing services in its CAP-accredited CLIA laboratory. Asuragen's KRAS and BRAF laboratory developed tests (LDTs) were designed in response to newly modified guidelines from the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN). Asuragen's KRAS and BRAF tests are intended to be used and interpreted in conjunction with all other available clinical and diagnostic information when evaluating anti-EGFR treatment options for colorectal cancer (CRC) patients. The tests are available in various configurations based on the patient's need or the clinical trial objective. The KRAS 7 Mutation testing service allows for detection of the seven clinically relevant KRAS mutations in codons 12 and 13 and the KRAS 12 Mutation test configuration expands the KRAS 7 test to detect an additional five KRAS mutations in codon 13.

"Adding KRAS and BRAF mutational testing to our CLIA laboratory menu further expands our mission in bringing personalized medicine solutions to our partners and patients," said Carol Berry, Vice President and General Manager of Asuragen's Pharmacogenomics Services. "In addition, our CLIA laboratory provides our pharmaceutical and biotech partners with the full complement of assay development services and regulated testing facilities."

About KRAS and BRAF Mutation Testing

RAS genes are the most common targets for somatic gain-of-function mutations in human cancers. Activating RAS mutations occur in approximately 30% of human cancers and specific RAS genes are mutated in different cancers, including colorectal cancer (CRC), non-small cell lung cancer, pancreatic cancer and others. Some mutations in the KRAS gene (about 40% of colorectal cancer patients) are associated with poor prognosis and lack of response to anti-EGFR therapy. In July 2009, the FDA approved labeling changes to cetuximab and panitumumab stating that these agents are not recommended for the treatment of colorectal cancer (CRC) harboring KRAS mutations. Thus, determination of KRAS mutation status in these tumors is critical when evaluating a patient for anti-epidermal growth factor receptor therapy. ASCO has further recommended that all patients with metastatic colorectal cancer for whom EGFR antagonists are being considered should be specifically tested for KRAS mutational status at codons 12 and 13.

BRAF is a downstream molecule from KRAS in a signaling pathway involved in cell cycling, and like KRAS, mutations in BRAF are observed in CRC. Data from the CRYSTAL trial suggests that BRAF mutations are also indicative of poor prognosis and the NCCN Colon Cancer Guideline Update 2010 states that testing for mutations in BRAF (identified in 3% to 12% of CRC patients) should occur when KRAS testing indicates KRAS wild type.

About Asuragen, Inc.

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 testing service 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.

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