

PRESS RELEASE



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FOR IMMEDIATE RELEASE

NUCLEA BIOTECHNOLOGIES, LLC WILL OFFER A NEW LABORATORY ASSAY DESIGNED TO DETECT THE GENE/PROTEIN EXPRESSION PROFILE FOR PREDICTING RECURRENT COLON CANCER

Pittsfield, Massachusetts.....November 12, 2008.....Nuclea biotechnologies, LLC released today that the company will be ready to offer a new laboratory assay designed to detect the gene/protein expression profile for predicting recurrent colon cancer

BACKGROUND

Recurrence of colon cancer often occurs at sites and in tissues other than the site of the primary tumor (referred to as metastasis). Treatment of recurrent colon cancer depends on the sites of recurrent disease demonstrable by physical examination and/or radiographic studies. In addition to standard radiographic procedures, radioimmunoscinotography may add clinical information which may affect management. However, such approaches have not led to improvements in long-term outcome measures such as survival.

In stage IV and recurrent colon cancer, chemotherapy has been used for palliation, with fluorouracil (5-FU)-based treatment considered to be standard. Combination chemotherapy has not been shown to be more effective than 5-FU alone. 5-FU has been shown to be more cytotoxic, with increased response rates but with variable effects on survival, when modulated by leucovorin, methotrexate, or other agents. Interferon alfa appears to add toxic effects but no clinical benefit to 5-FU therapy. The choice of a 5-FU-based chemotherapy regimen for an individual patient should be based on known response rates and the toxic effects profile of the chosen regimen, as well as cost and quality-of-life issues.

Another therapeutic agent, irinotecan has only a 10% to 20% partial response rate in patients with metastatic colon cancer, in patients who have received no prior chemotherapy, and in patients progressing on 5-FU therapy. It is now considered standard therapy for patients with stage IV disease who do not respond to or progress on 5-FU. Tomudex, a specific thymidylate synthase inhibitor, has demonstrated activity similar to that of bolus 5-FU and leucovorin. Oxaliplatin plus 5-FU and leucovorin has also shown activity in 5-FU refractory patients.

Patients with advanced colon cancer who have relapsed after either adjuvant therapy or treatment for advanced disease with 5-FU and leucovorin may be considered for additional therapy. A number of approaches have been used in the treatment of such patients, including retreatment with 5-FU and treatment with irinotecan. Patients retreated with bolus or infusional 5-FU following adjuvant 5-FU therapy or discontinuation of 5-FU in responding patients with metastatic disease have response rates and response durations similar to previously untreated patients. Irinotecan has been compared to either retreatment with 5-FU or best supportive care in a pair of randomized European trials of patients with colorectal cancer refractory to 5-FU. In both trials, there was a survival and quality of life advantage for patients treated with irinotecan over 5-FU or supportive care.

NUCLEA ASSAY AND CLINICAL DATA

Nuclea has identified gene and/protein expression profiles (GPEPs) and methods for using them to identify those patients who are likely to experience a recurrence and/or metastasis of their colon cancer after treatment of the primary tumor, as well as those patients that are not likely to experience a recurrence of their cancer. The test allows a treatment provider to identify those patients who are most likely to experience recurrence, and to adjust treatment options for such patients accordingly.

The GPEPs can be utilized in an assay to determine the likelihood that a patient's colon cancer will recur/metastasize after treatment of the primary tumor. In one aspect, the method comprises obtaining a sample from the patient, determining the gene and/or protein expression profile of the sample, and determining from the gene or protein expression profile whether at least one gene, or at least one protein, in the GPEP is over-expressed in the sample. From this information, the treatment provider can ascertain the best course of therapy.

Nuclea has taken the GPEPs to the next step and has developed an immunohistochemistry (IHC) methodology which can quickly and accurately determine the likelihood that a patient's colon cancer will recur/metastasize after treatment of the primary tumor. Nuclea has acquired from commercial sources, or developed internally, antibodies specific for each of the proteins in the GPEP. These antibodies are labeled with detectable labels, and embodied in a kit which can be used with an automated IHC instrument. The kit can be used with tissue microarrays containing patient tumor samples to efficiently determine the likelihood of recurrence of the colon cancer of several hundred patients simultaneously. This method is less cumbersome and time consuming than methods that rely on detection of nucleic acid expression and that require amplification (such as RT-PCR), and provides a high degree of predictive accuracy. The predictive accuracy has been validated using archival samples from patients whose colon cancer had metastasized as well as those whose cancer had not recurred; these tests indicate that Nuclea's assay has a sensitivity and specificity greater than 90%.

Nuclea Biotechnologies, LLC - Nuclea Biotechnologies, LLC is a biotechnology services company that has developed a novel technology platform to improve greatly the efficiency of diagnostics and drug discovery research. Using the Company's extensive libraries of genetic, molecular, and outcomes data and data-mining services, research professionals in pharmaceutical and life sciences companies are able to focus time and money on the most promising paths for diagnosing and treating a broad range of diseases