

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 INDICATIVE OF IRINOTECAN EFFICACY

Pittsfield, Massachusetts.....September 8, 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 indicative of irinotecan efficacy.

BACKGROUND

Patients diagnosed with cancer are faced with costly and often painful treatment options. These treatments may be ineffective in a subpopulation of patients, and as a result, these patients endure these treatments without little or no therapeutic benefit. Some patients may react adversely to certain agents causing additional suffering and possibly death. Ineffective treatment also is problematic because time is a key variable when treating cancer. A treatment provider has a far greater chance of containing and managing the disease if the cancer is diagnosed at an early stage and treated with a therapeutically effective agent. An agent may provide great therapeutic benefits if administered at an early stage of the disease; however, with the passage of time, the same agent may cease to be effective.

Colorectal cancer is an example of a condition where early diagnosis is key for effective treatment. Colorectal cancer is cancer that develops in the colon or the rectum. The walls of the colon and rectum have several layers of tissue. Colorectal cancer often starts in the innermost layer and can grow through some or all of the other layers; the stage (extent of spread) of a colorectal cancer depends to a great degree on how deeply it has grown into these layers.

Chemotherapy is often used for treating colorectal cancer. Irinotecan hydrochloride (CAMPTOSAR®) is a chemotherapeutic agent indicated for first-line therapy of colorectal cancers. As with many chemotherapeutic agents, administration of irinotecan hydrochloride ("irinotecan") often causes deleterious side effects for the patient, and some patients do not respond well to the treatment. Some patients thus undergo treatment with irinotecan and suffer the painful side effects only to later realize that the agent has not been therapeutically beneficial to their condition. In addition to the unnecessary suffering, critical time is lost in determining an alternative treatment.

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 respond to treatment with irinotecan (these patients are referred to as “responders”), as well as those patients who are not likely to benefit from such treatment (these patients are referred to as “non-responders”). The GPEPs allow a treatment provider to identify those patients who are responders to irinotecan treatment, and those who are not non-responders to such treatment, prior to administration of the agent.

The GPEPs can be utilized in an assay to determine if a patient is a responder or non-responder to treatment with irinotecan. 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 selected from the Irinotecan Responder Genes, or at least one protein selected from the Irinotecan Responder Proteins, is over- or under-expressed in the sample. From this information, the treatment provider can ascertain whether the patient is likely to benefit from irinotecan therapy.

Nuclea has taken the GPEPs to the next step and has developed an immunohistochemistry (IHC) methodology which can quickly and accurately determine if a patient is a responder or non-responder to treatment with irinotecan. 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 responsiveness to irinotecan 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. Preliminary tests on archival samples from patients who were responders to irinotecan therapy indicate that the test detects about 92% of irinotecan responders/non-responders, has a sensitivity of about 96% and a specificity of about 98%.

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