



Insight Genetics Receives Contract from National Cancer Institute

Diagnostics company will develop new test to identify resistance mutations in lung cancer patients undergoing anaplastic lymphoma kinase-inhibitor therapy

Nashville, Tenn. (October 5, 2011) – Cancer diagnostics firm [Insight Genetics](#) today announced that it has received a \$193,000 Small Business Innovation Research contract from the [National Cancer Institute](#) (NCI) to develop a companion diagnostic test for drugs targeting mutations and fusions of anaplastic lymphoma kinase (ALK). The test, Insight ALK Resistance™, is being developed to meet a growing challenge within personalized cancer care: the development of tumor resistance to a prescribed drug. It will meet a significant unmet medical need by helping physicians monitor and make more effective treatment selection decisions for patients being treated for non-small cell lung cancer and other ALK-driven malignancies.

"Diagnostic tests are critical not only in helping doctors decipher which cancer therapies are most appropriate for a patient, but also in monitoring if a treatment is effective for that patient," said Eric Dahlhauser, Chairman and CEO of Insight Genetics. "It is common for cancer patients to develop resistance to their treatments. Our Insight ALK Resistance assay will help improve patient care by providing patients and healthcare providers with valuable, real-time information about the mutation status of ALK in cancers to help guide the prescription of alternate treatments. Insight Genetics is excited to be part of the national effort to improve care available to cancer patients."

ALK has been identified as the cause of a number of cancers, leading to the development of many ALK-inhibiting therapies. Several ALK inhibitors are in clinical trials, and Xalkori (crizotinib) was recently approved by the US Food and Drug Administration. Some patients develop ALK resistance mutations while under treatment with an ALK inhibitor, making the therapy ineffective, while other patients have existing ALK resistance mutations that render ALK inhibitor therapy ineffective from the start.

A genetic test to identify inhibitor-resistance mutations is needed to guide the development and use of next-generation ALK inhibitors. Under the terms of the NCI contract, Insight Genetics will further the development of Insight ALK Resistance, a clinical diagnostic assay for ALK inhibitor-resistance mutations. The assay is being developed to detect all known ALK inhibitor-resistance mutations using an allele-specific PCR platform.

ALK was discovered by physician-scientist Dr. Stephan W. Morris of [St. Jude Children's Research Hospital](#), who is a collaborator of Insight Genetics. The Morris lab has identified in preclinical assays a large number of ALK kinase mutations that confer high-level Xalkori resistance, a subset of which have already been reported in patients who exhibited resistance to Xalkori therapy. The challenge of treatment resistance is leading oncologists to the belief that a

combination of therapies will probably be needed in most instances to optimally fight off various cancers. Insight ALK Resistance will be able to identify inhibitor-resistance mutations and help guide the development and use of next-generation ALK inhibitors for patients resistant to first-generation therapy.

"The initial determination of the ALK status of the patient's cancer should be followed with the resistance assay to ensure that the patient will respond to an ALK inhibitor at the start, allowing the physician to determine if another therapeutic approach is needed," said Morris. "In addition, the test should be used to monitor the tumor while the patient is receiving ALK inhibitor therapy to determine when resistance mutations begin to compromise the treatment, rather than continuing to treat with an ineffective inhibitor until the tumor has regrown."

The NCI contract was awarded as a solicitation titled, "Companion Diagnostics: Predictive and Prognostic Tests Enabling Personalized Medicine in Cancer Therapy." The goal of the solicitation is to stimulate research, development and commercialization of innovative tests and technology platforms in companion diagnostics, a field that holds the promise of safer, more effective patient care and reduced healthcare costs. Companion diagnostic tests screen patients for a particular biomarker, such as a genetic mutation or gene expression marker, which can indicate if a medication is likely to work for the patient or what dose will be most effective. Companion diagnostic assays can prevent the administration of ineffective therapies or medications that might cause an adverse reaction in a certain patient. Such tests also can gauge the ongoing effectiveness of some medications and help physicians determine when a new treatment might be necessary.

Insight Genetics was one of only four companies in the nation to be selected for the Companion Diagnostics program. The key success metric for the program is the demonstration and validation of the ability of the test to identify ALK mutations from both cell lines with ALK inhibitor resistance and re-biopsied lung cancer specimens from patients who develop Xalkori resistance. If successful in carrying out the objectives of the Phase I contract, the company would be eligible to apply for Phase II funding of \$1.5 million to complete the commercialization of the assay.

Insight Genetics is developing additional diagnostic tests for ALK and other cancer biomarkers. For more information about Insight Genetics and Insight ALK Resistance, please visit www.insightgeneticsinc.com.

About Insight Genetics

Insight Genetics provides molecular diagnostic solutions that enable personalized cancer care and improve patient outcomes. Insight's portfolio of companion diagnostic products detects specific cancer biomarkers for which a therapeutic is either in development or currently on the market. The company partners with leading academic researchers, pharmaceutical and biotechnology companies, clinical reference laboratories, and IVD kit manufacturers to provide new standards of care for cancer patients. www.insightgeneticsinc.com

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