



7:00AM 2006.03.10 (GMT) Ad hoc: EPIGENOMICS CONFIRMS LEAD MARKER FOR PREDICTION OF BREAST CANCER RELAPSE

Berlin, Germany and Seattle, WA, USA - March 10, 2006 - Epigenomics AG (Frankfurt, Prime Standard: ECX), a molecular diagnostics company developing tests based on DNA methylation today announced positive results of a study investigating the prognostic power of its proprietary prognostic PITX2 DNA methylation biomarker in early stage breast cancer. In addition, the study validated one other prognostic biomarker.

The study again confirmed that the marker is of prognostic value for making treatment decisions in cancer. Previously, Epigenomics has demonstrated a correlation between the presence of low levels of PITX2 gene methylation and low risk of metastasis development and vice versa in prostate cancer patients and in patients with node-negative, hormone-receptor positive breast cancer, a less aggressive form of the cancer. The present study investigated 395 breast cancer patients suffering from lymph node positive cancers, a more aggressive form.

End of Ad-hoc

"At present, a lot of breast cancer patients are treated with chemotherapy although they have a low risk of developing metastases," Alexander Olek, CEO of Epigenomics said. "However, this group is difficult to identify, so many are treated just for precautionary reasons. Our ultimate goal is to develop a test to find these patients and to provide doctors and patients with the necessary confidence that they don't need to administer chemotherapy."

He added, the data corroborate PITX2 as lead marker in Epigenomics' panel of markers for the prediction of breast cancer treatment response and relapse. "The benefit of combining PITX2 with other methylation markers to improve prognosis even further will undergo further analysis," Olek said. "Our preliminary results show an even better separation of good versus poor prognosis patient groups when a panel of several markers is used."

Study details

The study was conducted in 395 patients with lymph node positive cancers. All patients were treated with an adjuvant anthracycline-based chemotherapy regimen. Study endpoint was metastasis-free survival. The grouping of patients in a "good" or a "poor" prognosis group was based on a methylation classification function defined in a previous study.

Results: As a single marker, PITX2 methylation identified two-thirds of the patients as belonging to the "good prognosis" group. In this group, the likelihood of remaining metastasis-free for at least ten years was 62%. In contrast, patients in the "poor prognosis" group had only a 43% chance of remaining metastasis-free for ten years (Kaplan Meier analysis; median follow-up time of 83 months, $p < 0.001$).

About Breast Cancer Treatment

In breast cancer, post-surgery treatment decisions are currently made by an individualized assessment based on specific risk classes. Most patients receive some form of adjuvant treatment after tumor removal to prevent a relapse of the disease. The decision about an adjuvant treatment is based on nodal status (spread to the axillary lymph glands) and hormone receptor status (response to endocrine therapy). Of all breast cancer patients (annual incidence: 213,000 women in the US and 251,000 women in Europe), about half are lymphnode-negative and hormone receptor positive. In the majority of patients in this group the cancer is effectively treated with surgery and endocrine therapy, without additional cytotoxic chemotherapy. However unfortunately this low-risk patient population is difficult to identify at present. Therefore, most patients will receive additional chemotherapy, even though only a small proportion really requires it.

DNA Methylation

Methylation is a natural epigenetic process in which a methyl group binds to cytosine, one of DNA's four bases. Methylation is a control mechanism by which cells can switch off genes if their activity is not needed. By measuring the differences in the methylation patterns of healthy and diseased tissue, it is possible to detect changes in gene activity that may trigger diseases such as cancer. Epigenomics has developed an industrial process to read and interpret these methylation patterns.

About Epigenomics

Epigenomics is a molecular diagnostic company with a focus on the development of novel products for cancer. By detecting and interpreting DNA methylation patterns, Epigenomics' tests can potentially diagnose disease at an early stage and help guide physicians to select an appropriate therapy.

Epigenomics collaborates with Roche Diagnostics on the development of several diagnostic products in cancer. The company has its headquarters in Berlin, Germany, and a wholly owned subsidiary in Seattle, USA. For more information, please visit our website at www.epigenomics.com.

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