

## Epigenomics' biomarker shows promising results in clinical study, 1/14

January 2014—Epigenomics announced the results from a clinical study that showed methylated SHOX2 to be a sensitive and specific biomarker for therapy monitoring and early detection of tumor response in lung cancer patients.

In a blinded study conducted between December 2012 and June 2013, blood samples from 32 advanced stage lung cancer patients were taken prior to and during therapy every seven to 10 days for approximately three months. Restaging after that period was confirmed by a local tumor board, based on clinical and imaging results. Epigenomics' proprietary biomarker mSHOX2 was detected using a modified Epi proLung BL assay.

At restaging, 14 of the 32 patients with progressive disease showed no change or an increase in the amount of methylated SHOX2. Thirteen patients with treatment response showed a decrease of methylated SHOX2 under therapy. In the majority of patients this response to therapy was seen at the time of second blood draw. By the time of blood draw four, four weeks after start of therapy, a decrease of methylated SHOX2 was observed in all patients. Five patients, who had received a therapy before enrollment in the study, were negative for methylated SHOX2 from the beginning. The results of this study were presented at the CNAPS VIII meeting in November.

"The results reported in this study demonstrate further potential of our proprietary SHOX2 DNA methylation biomarker," Uwe Staub, PhD, chief operating officer of Epigenomics, said in a statement. "Cell-free mSHOX2 DNA isolated from plasma and bronchial lavage has already proven to be a sensitive and specific marker for the detection of lung cancer. It is exciting to see that the biomarker additionally enables rapid and sensitive determination of tumor response and therapy monitoring."

An additional multicentric study with a larger patient population is planned to verify the initial results.

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