Gene Signature to Predict Distant Metastasis in Stage I Lung Cancer Patients Treated with Surgery

Our technology is a 35-gene signature statistically significantly (p=0.044) associated with distant metastasis in stage I non-small cell lung adenocarcinoma patients treated with surgery and considered "cured." Even though 14-23% of those patients will ultimately develop distant metastases, adjuvant chemotherapy is not given because there is no method to predict which patients will develop metastases and it is assumed few would benefit. Our technology can however identify those patients at the highest risk for distant metastasis who are likely to benefit from adjuvant chemotherapy.

COMMERCIAL OPPORTUNITY

- Of 200,000 new non-small cell lung cancer (NSCLC) cases that occur yearly in the US, approximately 12,000 are stage I adenocarcinomas. Even though successfully resected patients are deemed "cured" of cancer, 14-23% will ultimately develop distant metastasis.
- A 35-gene signature predicts distant metastasis in stage I non-small cell lung adenocarcinoma patients treated with surgery. It uses a small slice of post-operative tumor and standard gene expression techniques and is thus robust, inexpensive and easy to use. This test is expected to accurately identify patients that may benefit from adjuvant chemotherapy.
- The attractiveness of this market is evidenced by recently introduced tests by Life Technologies (Pervenio) and Myriad Genetics (MyPlan) that predict overall survival in surgically resected lung cancer patients. In fact, Myriad markets MyPlan as a test that accurately identifies which patients may need post-surgical chemotherapy.
- However, our diagnostic is different from these competitors because it predicts metastasis itself rather than using survival as a surrogate for metastasis.
- Conceptually, the test is similar to Oncotype Dx that can determine whether a node-negative breast cancer patient should receive adjuvant chemotherapy. The OncotypeDx test has been embraced by doctors and is currently reimbursed at approximately $4000.

TECHNOLOGY

A 35-gene signature was developed that is statistically significantly (p=0.044) associated with the risk of distant metastasis in a retrospective cohort of stage I non-small cell lung adenocarcinoma patients diagnosed and treated with surgery at Moffitt (56 control vs. 53 with metastasis). Moffitt Cancer Center's biorepository currently has samples with tumor microarray data linked to longitudinal clinical data. A retrospective chart review of pathologic T1-T2N0 NSCLC patients was conducted, where patients were classified according to their recurrence pattern, and then their gene expression profiles were analyzed. A cohort of patients treated with surgical resection was identified, in which 56 patients were without evidence of disease at least 3 years following surgery (Control cohort), and 53 patients developed distant metastasis (distant failure cohort).

PUBLICATION/PATENT

- Dr. Sungjune Kim will present data at ASCO 2014.

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LICENSING OPPORTUNITY

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