SUMMARY: The invention is a gene signature as well as individual markers that can be used to identify which NSCLC patients are more likely to respond to erlotinib. This signature may also be useful for predicting response to other EGFR inhibitors in NSCLC as well as other tumor types. This invention could help select patients that will experience greater benefit from a specific treatment regimen for NSCLC and other cancers and potentially spare patients who are less likely to benefit from receiving toxic therapy. Currently, EGFR mutation is the only validated marker; notably this marker predicts erlotinib benefit in patients with wild type EGFR, and therefore could be used in conjunction with (1) EMT signature and (2) to identify patients at greater risk for relapse or metastatic spread after definitive (e.g. surgery, radiation) therapy. The EMT signature was developed using non-small cell lung cancer (NSCLC) cell lines. Results of the signature were validated using independent gene expression platforms, for NSCLC lines and head and neck cell lines. Clinical validation has been done using several clinical datasets including the BATTLE study, which confirmed it is a marker of erlotinib resistance, and a set of head and neck patients who received PORT (post-operative radiotherapy). This confirmed that the signature was associated with shorter progression-free and overall survival. The signature or markers could be useful for the purpose of better selecting patients likely to respond to a given treatment, particularly for NSCLC patients treated with erlotinib or other EGFR inhibitors. The signature also may be used for selecting patients to receive cisplatin-based chemotherapy.

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