LICENSING OPPORTUNITY

A Rapid and Non-invasive Lung Cancer Diagnostic to Predict PD-L1 Status Using Deep Learning Radiomics

Two major treatment strategies employed in non-small cell lung cancer (NSCLC) are tyrosine kinase inhibitors (TKIs) and immune checkpoint inhibitors (ICIs). The choice of strategy is based on heterogeneous biomarkers expressed by the lung tumor tissue. There is an unmet need to identify comprehensive biomarkers to help guide therapy choice. Additionally, there are several challenges with regards to the feasibility of obtaining tissue from lung, the turn around time for pathology tests and false negative results of blood biopsies. Moffitt's diagnostic technology with deep learning radiomics of PET/CT images provides a rapid and non-invasive method for precise quantification of EGFR mutation and PD-L1 status in NSCLC patients and predicts appropriate treatment regimens.

COMMERCIAL OPPORTUNITY

- Primary lung cancer is the most common malignancy worldwide, accounting for 11.6% of all cancers and 18.4% of all cancer-related deaths. Non-small cell lung cancer (NSCLC) accounts for 80–90% of all primary lung cancers, mostly with advanced stage unresectable disease and dismal prognosis.
- ^{18}F-FDG PET/CT is the current standard of care (SOC) for lung cancer for baseline tumor measurements in the management of NSCLC and is essential for staging and detection of remote metastases. In addition, the current NCCN Guidelines specifies PD-L1 and EGFR mutation statuses as two important biomarkers in NSCLC treatment planning.
- A major challenge for molecular testing of these biomarkers is the insufficiency of biopsy specimens from patients with advanced NSCLC. As such, the fine-needle aspirate (FNA) is routinely utilized for biopsy and the amount of tumor material obtained from the FNAs can be sparse, thus limiting the correct classification of NSCLC histology. While tissue sampling remains the gold standard, additional liquid lung biopsies are also gaining traction and require standardizations. Furthermore, the highest sensitivity of commercially available testing platforms is about 85%, posing a risk for false negative results, especially in those treatment-naïve patients.
- **Moffitt's technology is a rapid and non-invasive method to determine PD-L1 as well as EGFR mutation statuses using ^{18}F-FDG PET/CT in NSCLC patients. Additionally, this clinical decision support tool will be able to predict NSCLC patients who will be sensitive to EGFR-Tyrosine kinase inhibitor (TKI) therapy (with high DLS) and others who will benefit from FDA approved immune check-point inhibitor treatments such as Nivolumab and Pembrolizumab (with low DLS).**

TECHNOLOGY

This technology uses ^{18}F-FDG PET/CT images and Kulbek Leibler Divergence (KLD) statistics to generate a radiomic signature with a **Deep Learning Score (DLS)** that is predictive of PD-L1 (High or Low) and EGFR statuses (Wildtype or Mutant) along with TKI and immunotherapy responsiveness. The DLS predicted EGFR mutation status with AUC of 0.83 and predicted PD-L1 status with AUC of 0.84 in independent test cohort. Further, a high DLS was significantly associated with improved objective response ($p=0.023$) and longer PFS ($p<0.001$) in patients treated with EGFR-TKIs. The DLS was inversely correlated with PD-L1 status ($p=0.012$), and a low DLS was significantly associated with higher durable clinical benefit and longer PFS ($p<0.001$) among patients treated with immune checkpoint inhibitors (ICIs).

PUBLICATION/PATENT

PCT application was filed for Drs. Matthew Schabath and Robert Gillies.

CONTACT

Praba Soundararajan, PhD
Intellectual Property Manager
praba.soundararajan@moffitt.org
813.745.6776

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