Technology Offer

Ref.-No. M07/22

Predictive level of PD-L1 on microvesicles in the evaluation whether being a responder to a treatment of NSCLC

Introduction

Lung cancer is still the leading cause of cancer-related death worldwide. For patients with advanced stage non-small cell lung cancer (NSCLC), immune checkpoint inhibitors (ICI) such as antibodies against programmed cell death protein 1 (PD-1) and programmed cell death ligand 1 (PD-L1) have significantly improved state-of-the-art lung cancer treatment.

NSCLC patients with high PD-L1 expression on tumor cells (tumor proportion score, TPS) or on tumor-infiltrating immune cells (combined positive score, CPS) benefit from a single-agent immunotherapy compared to standard platinum-based chemotherapy. However, so far there is no biomarker to predict response to immunotherapy.

Invention

The present invention relates to a novel method of evaluating whether a subject already suffering from NSCLC will respond to a treatment of NSCLC comprising immunotherapy. The current algorithm for therapeutic decisions in stage IV NSCLC patients without driver mutations is based on PD-L1 expression in the tumor tissue (TPS, CPS). According to that, patients with high PD-L1 expression (TPS > 50%) can either receive single-agent immunotherapy or combined chemoimmunotherapy, whereas patients with low (1-49%) or negative (<1%) PD-L1 expression are usually treated with combined chemoimmunotherapy. Our novel approach aims to measure PD-L1 expression on large extracellular vesicles (lEV) in a peripheral blood (PB) sample obtained from a subject suffering from NSCLC who has not yet been treated. For those patients with negative (<1%) or low (1-49%) tissue PD-L1 expression, the lEV PD-L1 level is a novel predictive biomarker for response to immunotherapy. If said level of PD-L1-positive lEVs is increased relative to corresponding levels of PD-L1-positive lEVs in control PB samples, the said subject will be evaluated as a responder to immunotherapy. Therefore, this method allows the predictive evaluation of NSCLC patients with low or negative tissue PD-L1 expression, whether they will benefit from immunotherapy or not, implementing the need for a closer monitoring of those patients.

Advantages of the invention

For stage IV NSCLC patients with low (1-49%) or negative (<1%) tissue PD-L1 expression, a single liquid biopsy prior to therapy and determination of lEV PD-L1 expression can act as a predictive biomarker to the response of immunotherapy. There is no need for evaluation of further samples during the treatment. The invention allows the selection of patients that will benefit from immunotherapy and a closer monitoring of those patients.

Areas of application

oncology, biomarker

Keywords

NSCLC, immunotherapy, biomarker

Development Status

proof of concept

Commercial Opportunity

The technology is offered for in-licensing and co-development

Patent Status

patent application filed in Europe

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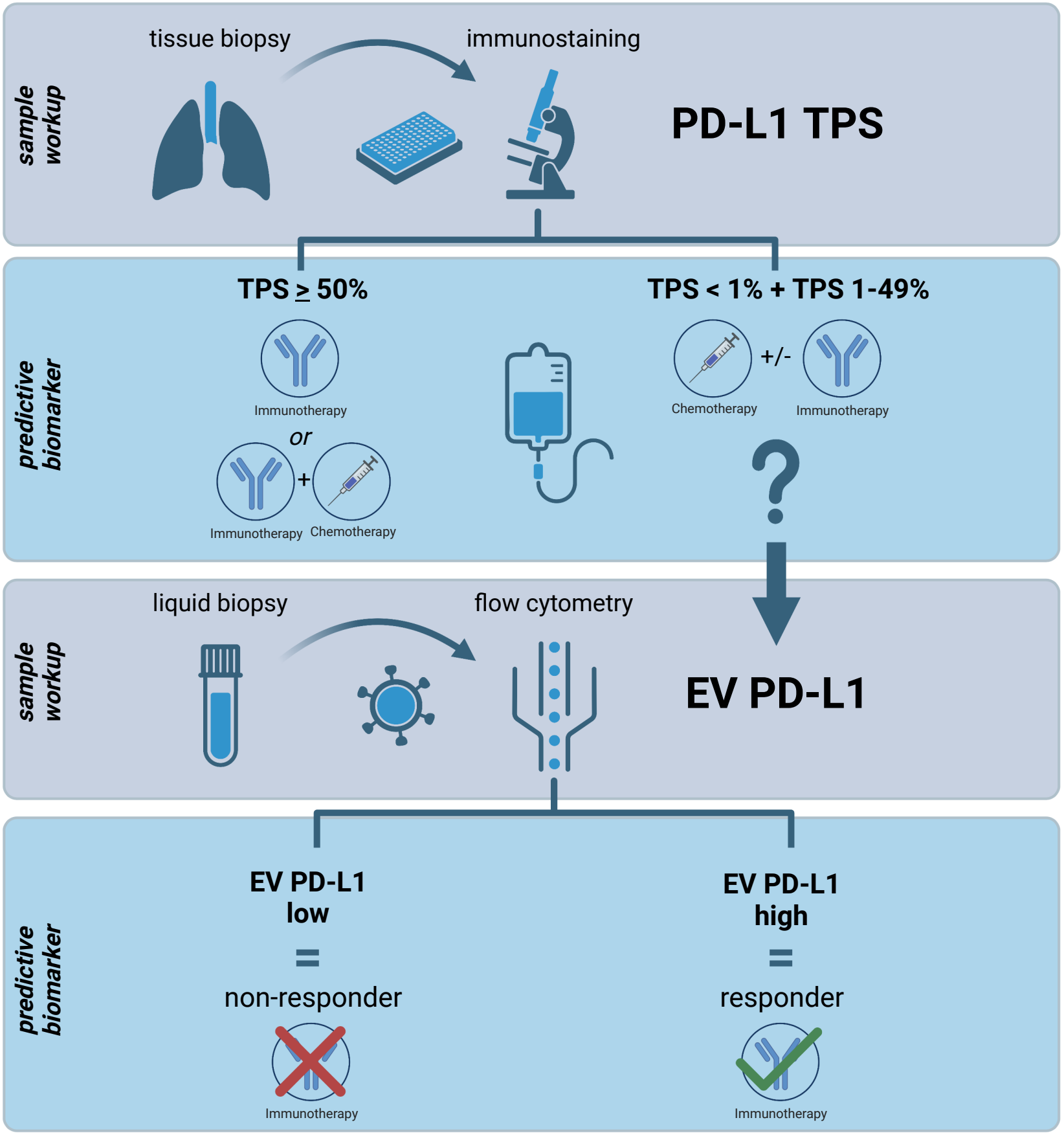
sample workup
tissue biopsy
immunostaining
PD-L1 TPS
predictive biomarker
TPS ≥ 50%
Immunotherapy
or
Immunotherapy
Chemotherapy
TPS < 1% + TPS 1-49%
Chemotherapy
+/-
Immunotherapy
?
sample workup
liquid biopsy
flow cytometry
EV PD-L1
predictive biomarker
EV PD-L1 low
=
non-responder
Immunotherapy
EV PD-L1 high
=
responder
Immunotherapy