Protocol LUNG037 M7824 versus Pembroluzumab

A Phase II, Multicenter, Randomized, Open-Label, Controlled Study of M7824 versus Pembrolizumab as a First-line Treatment in Patients with PD-L1 Expressing Advanced Non-small Cell Lung Cancer.

This is the trial summary as assessed on clinicaltrials.gov on 24/01/2019.

Minor changes in the protocol may occur. You can check this on this direct link:

https://clinicaltrials.gov/ct2/show/NCT03631706?cond=M7824&rank=1

Trial Design :

The study will evaluate M7824 monotherapy versus pembrolizumab as 1L treatment for participants with advanced NSCLC with high PD-L1-tumor expression.

Inclusion Criteria:

Histologically confirmed diagnosis of advanced NSCLC

Have not received prior systemic therapy treatment for their advanced/Stage four NSCLC. Completion of treatment with cytotoxic chemotherapy, biological therapy, and/or radiation as part of neoadjuvant/adjuvant therapy is allowed as long as therapy was completed at least 6 months prior to the diagnosis of metastatic disease. Confirmation of resolution of toxic effects of previous neoadjuvant/adjuvant chemotherapy therapy to Grade less than or equal to 1. For radiation toxicity or prior major surgeries, participants should have recovered from side effects and/or complications.

Have measurable disease based on RECIST 1.1

Have a life expectancy of at least 3 months

Availability of either tumor archival material (less than 6 months old) or fresh biopsies collected within 28 days (excluding bone biopsies) before the first dose is mandatory to determine PD-L1 expression level prior to enrollment

PD-L1 high status as determined by central PD-L1 test or by prior testing using PD-L1 immunohistochemistry 22C3 pharmDx assay

Other protocol defined inclusion criteria could apply

Exclusion Criteria:

The participant's tumor harbors an epidermal growth factor receptor (EGFR) sensitizing (activating) mutation, anaplastic lymphoma kinase (ALK) translocation, ROS1 rearrangement, or BRAF V600E mutation, if targeted therapy is locally approved

Has received major surgery within 4 weeks prior to the first dose of study intervention; received thoracic radiation therapy of greater than 30 units of gray (Gy) within 6 months prior to the first dose of study

Known severe hypersensitivity to investigational products (M7824 or pembrolizumab), or any components in their formulations

Previous malignant disease (other than the target malignancy to be investigated in this study) within the last 3 years

Other protocol defined exclusion criteria could apply