ALLIANCE FOUNDATION TRIALS, LLC

AFT-09: Randomized Phase II Trial Evaluating the Optimal Sequencing of PD-1 Inhibition with Pembrolizumab (MK-3475) and Standard Platinum-based Chemotherapy in Patients with Chemotherapy Naive Stage IV Non-small Cell Lung Cancer

Thomas Hensing, MD
NorthShore University HealthSystem

TAP TO RETURN TO KIOSK MENU

While a genotype-directed strategy has been established as effective in treatment selection for patients with advanced NSCLC, only a minority of patients at this time will have a readily identifiable actionable molecular target. Furthermore, genotype-directed therapy has not been validated for patients with squamous cell carcinoma of the lung. Therefore, the majority of patients with advanced NSCLC will continue to rely on standard platinum-based doublet chemotherapy. Given the plateau in effectiveness of this approach, novel treatment strategies are clearly warranted.

RATIONALE

Primary

- To compare the ORR per RECIST 1.1 of MK-3475 in patients with chemotherapy naive advanced NSCLC after treatment with first-line carboplatin-based chemotherapy to patients treated with pembrolizumab prior to first-line chemotherapy.

Secondary

- To compare the progression-free survival (PFS) per RECIST 1.1 in previously chemotherapy naive with advanced NSCLC treated with first line carboplatin-based chemotherapy followed by pembrolizumab to patients treated with pembrolizumab prior to first-line carboplatin-based chemotherapy.
- To characterize the adverse events related to pembrolizumab by frequency, type and grade in patients with chemotherapy naive advanced NSCLC based on the sequence of administration with first-line chemotherapy.
- To evaluate the ORR per irRC of pembrolizumab (MK-3475) administered prior to or after treatment with first-line carboplatin-based chemotherapy in patients with chemotherapy naive NSCLC.

OBJECTIVE

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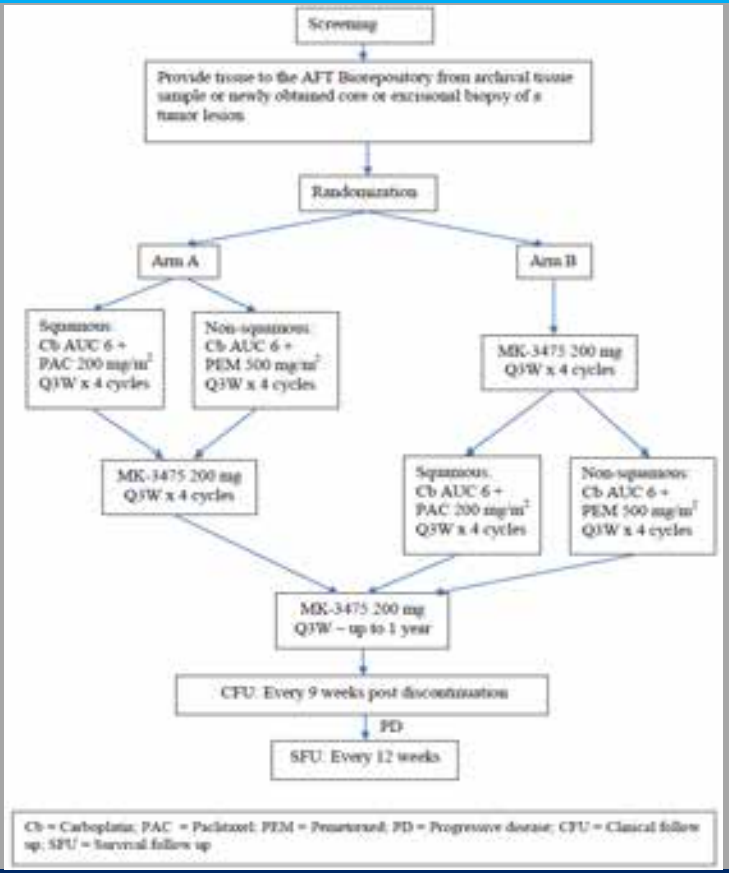
rationale/ objective
study schema
treatment plan/ intervention
key eligibility criteria
follow up



STUDY SCHEMA

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Arm A
Squamous Carcinoma: Carboplatin and Paclitaxel for up to 4 cycles
Non-squamous Carcinoma: Carboplatin and Pemetrexed for up to 4 cycles

Patients with progressive disease (PD) by RECIST 1.1 after cycle 2 or cycle 4 will be allowed to transition to pembrolizumab (MK-3475) every 21-days for up to 1 year, at the investigator's discretion.

Arm B
Pembrolizumab for up to 4 cycles. Patients with CR, PR, or SD by irRC will then be treated with:
Squamous Carcinoma: Carboplatin and Paclitaxel for up to 4 cycles
Non-squamous Carcinoma: Carboplatin and Pemetrexed for up to 4 cycles

Patients with PD by RECIST 1.1 after cycle 6 or cycle 8 will be allowed to transition back to pembrolizumab every 21-days for up to 1 year, at the investigator's discretion.
Patients with complete response (CR), partial response (PR) or stable disease (SD) by RECIST 1.1 criteria after cycle 8 will then be treated with pembrolizumab every 21-days for up to 1 year.

TREATMENT PLAN / INTERVENTION

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- Signed informed consent obtained prior to any study specific assessments and procedures.
- Age ≥18 years (or per national guidelines).
- Histologically or cytologically documented non-small cell lung cancer
- Have a life expectancy of at least 3 months.
- Have measurable disease based on RECIST 1.1. The target lesion(s) should also have bi-dimensional measurability for irRC evaluation on study.
- In patients with non-squamous non-small cell lung cancer, Investigators must be able to produce source documentation of the EGFR mutation status or ALK translocation status.
  - If a patient is known to have one molecular alteration (EGFR mutation or ALK translocation), then testing for the other alteration is not required.
  - If a patient is known to have a mutation in KRAS, then testing for an EGFR mutation or ALK translocation will not be required

KEY ELIGIBILITY CRITERIA

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