

FAST FACTS

ALLIANCE A171901 - OLDER NON-SMALL CELL LUNG CANCER PATIENTS (\geq 70 YEARS OF AGE) TREATED WITH FIRST-LINE MK-3475 (PEMBROLIZUMAB) +/- CHEMOTHERAPY (ONCOLOGIST'S/PATIENT'S CHOICE)

Eligibility Criteria

1. Documentation of Disease: Histologic or cytologic diagnosis of non-small cell lung cancer (adenocarcinoma). Stage IV or recurrent metastatic non-small cell lung cancer. No planned initiation of definitive (potentially curative) concurrent chemo-radiation
2. Planning to begin MK-3475 (pembrolizumab) treatment within 14 days of registration, with or without combination chemotherapy.
Treating physician considers pembrolizumab as appropriate and plans to proceed with one of the following treatment schedules:
(a) MK-3475 (pembrolizumab) 200 mg IV flat dose every 21 days.

(b) MK-3475 (pembrolizumab) 200 mg IV + carboplatin AUC=5 + pemetrexed 500 mg/m² (20% chemotherapy dose reduction is permitted per the discretion of the treating physician).
3. Patients will be ineligible if they have an autoimmune disorder, are post-organ transplantation, or are receiving ongoing immunosuppression treatment.
4. Prior adjuvant therapy is allowed and must have been completed at least 6 months prior to registration.
5. No planned radiation or other cancer treatment in the 3 months following registration.
6. No untreated brain metastases. Patients must be off corticosteroids and asymptomatic at registration.
7. Age \geq 70 years of age. (See next page, for additional eligibility criteria.)
8. Required Initial Laboratory Values:

Absolute neutrophil count \geq 1500/mm³ (1.5×10^9 /L)
(ANC)

Platelet count: \geq 100,000/mm³ (100×10^9 /L)

Creatinine: \geq 30 ml/min* for patients enrolled to pembrolizumab alone and $>$ 45 ml/min for patients enrolled to chemotherapy + pembrolizumab

Total serum bilirubin \leq 1.5 ULN (\leq 3 ULN if Gilbert's disease)
AST and/or ALT \leq 3 x ULN (\leq 5.0 x ULN if liver metastases present)

Alkaline phosphatase \leq 2.5 x ULN (\leq 5 x ULN if bone or liver metastases present)

* Calculated using the Cockcroft-Gault formula

9. Language: Patients must be able to speak and comprehend English in order to complete the mandatory patient-completed measures.

Schema

1 cycle = 21 days or 42 days (for patients who are on every 6 week cycle)

