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

Eligibility Criteria (see Section 3.2)

- Histologic or cytologic diagnosis of non-small cell lung cancer (adenocarcinoma). Stage IV or recurrent metastatic non-small cell lung cancer. (See §3.2.1.)
- Planning to begin MK-3475 (pembrolizumab) treatment within 14 days of registration, with or without combination chemotherapy. (See §3.2.2) Patients with autoimmune disorder, post-organ transplantation, or are receiving ongoing immunosuppression treatment are ineligible (See §3.2.3) .
- Prior adjuvant therapy is allowed and must have been completed at least 6 months prior to registration. (See §3.2.4)
- No planned radiation or other cancer treatment in the 3 months following registration (See §3.2.5)
- No untreated brain metastases. Patients must be off corticosteroids and asymptomatic at registration. (See §3.2.6)
- Age ≥70 years of age. (See §3.2.7)
- Language: Patients must be able to read and comprehend English (See §3.2.9)

Required Initial Laboratory Values (See § 3.2.8)

ANC	≥ 1500/mm^3 (1.5 x 10^9/L
Platelet count:	≥ 100,000/mm^3 (100x 10^9/L)
Creatinine:	≥ 30 ml/min* for patients enrolled to pembrolizumab alone and > 45 ml/min for patients enrolled to chemotherapy + pembrolizumab
Total serum bilirubin	≤ 1.5 ULN (< 3 ULN if Gilbert's disease)
AST and/or ALT	≤ 3 x ULN (≤ 5.0 x ULN if liver metastases present)
Alkaline phosphatase	≤ 2.5 x ULN (≤5 x ULN if bone or liver metastases present)

*Calculated using the Cockcroft-Gault formula

Schema

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

REGISTER → **Treating physician/patient's choice of:**
single agent MK-3475 (pembrolizumab)

OR

MK-3475 (pembrolizumab) +
carboplatin + pemetrexed

Pembrolizumab treatment is to continue until disease progression (treating physician's discretion) or unacceptable adverse event. Patients will be followed for survival for 5 years after registration or until death, whichever comes first.

Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.

Site staff who intend to administer the comprehensive geriatric assessment must complete the geriatric assessment training. (See Section 15.0)

If the Group credited for enrollment is a non-Alliance Group, then other requirements from the credited Group may apply.

3.2 Eligibility Criteria

Use the spaces provided to confirm a patient's eligibility by indicating Yes or No as appropriate. It is not required to complete or submit the following pages.

When calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test were done on a Monday, the Monday one week later would be considered Day 7.

___ **3.2.1 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.

___ **3.2.2 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/m^2 (20% chemotherapy dose reduction is permitted per the discretion of the treating physician).

___ **3.2.3 Patients will be ineligible if they have an autoimmune disorder, are post-organ transplantation, or are receiving ongoing immunosuppression treatment.**

___ **3.2.4 Prior adjuvant therapy is allowed and must have been completed at least 6 months prior to registration.**

___ **3.2.5 No planned radiation or other cancer treatment in the 3 months following registration.**

___ **3.2.6 No untreated brain metastases. Patients must be off corticosteroids and asymptomatic at registration.**

___ **3.2.7 Age ≥ 70 years of age. (See next page, for additional eligibility criteria.)**

___ **3.2.8 Required Initial Laboratory Values:**

Absolute neutrophil count (ANC)	≥ 1500/mm^3 (1.5 x 10^9/L)
Platelet count:	≥ 100,000/mm^3 (100x 10^9/L)
Creatinine:	≥ 30 ml/min* for patients enrolled to pembrolizumab alone and > 45 ml/min for patients enrolled to chemotherapy + pembrolizumab
Total serum bilirubin	≤ 1.5 ULN (< 3 ULN if Gilbert's disease)
AST and/or ALT	≤ 3 x ULN (≤ 5.0 x ULN if liver metastases present)
Alkaline phosphatase	≤ 2.5 x ULN (≤5 x ULN if bone or liver metastases present)

* Calculated using the Cockcroft-Gault formula

___ **3.2.9 Language: Patients must be able to speak and comprehend English** in order to complete the mandatory patient-completed measures.