FAST FACTS

ALLIANCE A171901 - 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

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 are post-organ transplantation, or are receiving ongoing immunosuppression treatment. Patients will be ineligible if they have active autoimmune disease that has required systemic treatment in past 2 years (i.e., with use of disease modifying agents, corticosteroids or immunosuppressive drugs).

   Note: Replacement therapy (i.e., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency, etc.) is not considered a form of systemic treatment. Patients who require inhaled corticosteroids would not be excluded from the study. Patients with vitiligo or resolved childhood asthma/atopy would not be excluded from the study. Patients who require local steroid injections (for example, a steroid injection to a joint) would not be excluded from the study.

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 oral and IV corticosteroids for this condition and asymptomatic at registration.

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

8. Required Initial Laboratory Values:
Absolute neutrophil count (ANC) \( \geq 1500/\text{mm}^3 (1.5 \times 10^6/L) \)

Platelet count \( \geq 100,000/\text{mm}^3 (100 \times 10^6/L) \)

Calculated creatinine clearance \( \geq 30 \text{ ml/min}^* \) for patients enrolled to pembrolizumab alone and \( > 45 \text{ ml/min} \) for patients enrolled to chemotherapy + pembrolizumab

Total bilirubin \( \leq 1.5 \text{ ULN (}\leq 3 \text{ ULN if Gilbert’s disease)} \)

Total bilirubin \( \leq 3 \times \text{ ULN (}\leq 5 \times \text{ ULN if liver metastases present)} \)

Alkaline phosphatase \( \leq 2.5 \times \text{ ULN (}\leq 5 \times \text{ ULN if bone or liver metastases present)} \)

* 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)

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<th>REGISTER</th>
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<tbody>
<tr>
<td>Treating physician/patient’s choice of:</td>
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<tr>
<td>single agent MK-3475 (pembrolizumab)</td>
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<tr>
<td>OR</td>
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<tr>
<td>MK-3475 (pembrolizumab) + carboplatin + pemetrexed</td>
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